UNIVERSITY OF BIRMINGHAM | INSTITUTE OF APPLIED HEALTH RESEARCH

CONNECT

STUDY PROTOCOL

The CONNECT Study:

Understanding the Impact of Remote Consultations in Sexual and Reproductive Health Services on Health Inequalities

Version Number: 1.0

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Full title of the study

The CONNECT Study: Understanding the Impact of Remote Consultations in Sexual and Reproductive Health Services on Health Inequalities

Short study title

The CONNECT Study

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Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to adhere to the signed University of Birmingham's Sponsorship CI declaration.

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

I 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; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:  Date: 29/09/2023

Name: (please print): *Dr Louise Jackson*

Sponsor statement:

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

Funder statement:

This study/project is funded by the NIHR Health and Social Care Delivery Research (HSDR) Programme NIHR153151. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Table of Contents

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Study Summary

Study Title	The CONNECT Study: Understanding the Impact of Remote Consultations in Sexual and Reproductive Health Services on Health Inequalities (NIHR153151)
Short Title	The CONNECT study
Study Design	Qualitative and quantitative research study
Study Participants	Qualitative: Approximately 45 healthcare professionals or other stakeholders across the three case study areas (approximately 10-15 per case study area). Approximately 60 service users/ potential service users in case study areas (approximately 15-20 per case study area). Quantitative: Service users of sexual and reproductive health services in case study areas
Case Study Areas	Hywel Dda University Health Board Umbrella Health Partners, University Hospitals Birmingham NHS Foundation Trust Central and North West London NHS Foundation Trust (CNWL)
Planned Size of Sample (if applicable)	Qualitative: approximately 105 participants Quantitative: >5,000 service users
Follow up duration (if applicable)	N/A
Planned Study Period	February 2023 to January 2025
Research Question/Aim(s)	RQ1. What is the existing published evidence on equity, effectiveness, safety and cost -effectiveness for remote consultations in sexual and reproductive health services (SRHS)? RQ2a) What is the impact of remote consultations on health inequalities in relation to access to care and clinical outcomes, as well as timeliness of treatment, access to contraception, cost -effectiveness, the identification of domestic violence/sexual violence and safeguarding concerns? RQ2b) What factors do service users and clinicians consider important in making remote consultations equitable, acceptable and appropriate? RQ3. How can remote consultations best be utilised as part of equitable, effective, safe and sustainable SRHS?

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Role of Study Sponsor and Funder

Neither the study funder (NIHR) nor the sponsor (University of Birmingham) has played a role in determining the study design of this research. Nor will they play a role in carrying out the research, data analysis and interpretation, manuscript writing or dissemination of results. Neither the funder nor sponsor will have a say in the final decision regarding any of these aspects of the study.

Roles and Responsibilities of Study Management Committees/Groups and Individuals

Study Steering Committee

Rebecca French (Chair)	Associate Professor of Sexual and Reproductive Health Research, London School of Hygiene and Tropical Medicine	Expertise in public health, sexual and reproductive health, policy related research and evaluation.
Andrew Winter	Consultant in Sexual Health & HIV Medicine, Joint Clinical Lead for e-Health, NHS Glasgow & Clyde	Clinical expertise and service provision, with a background in digital health.
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Patient and Public Involvement and Engagement (PPIE)

Ms Jo Josh	PPIE Coordinator
Dr Melvina Woode Owusu	Inclusion Lead

Study protocol

1. Background

Sexually Transmitted Infections (STIs) remain a major public health challenge, with 311,604 new diagnoses in 2021 in England (1), at a cost of around £620 million annually (2). Those most at risk are young people, men who have sex with men (MSM), ethnic minorities, and those from lower socio-economic groups (3). Access and uptake of contraception is also a problem, with England's teenage birth rate almost twice as high as comparable western European countries, and rates are particularly high in more deprived communities (4). There are a range of factors which make sexual and reproductive health services (SRHS) unique. The stigma which surround STIs and contraception results in specific and significant barriers to accessing services and, in contrast to many other services, direct patient self-referral accounts for the overwhelming majority of attendees (5). Sexual health screening and contraception are available in a range of settings, including GP surgeries, Accident and Emergency Departments (A&E), and pharmacies, but specialist SRHS are the largest service provider in England accounting for 3,482,700 consultations in 2020 (1). Timely attendance is important to rapidly identify and treat STIs and prevent unplanned pregnancies (6). Furthermore, in England, compared to other healthcare services, there has been a substantial reduction in SRHS budgets since 2015, which means that there is a heightened pressure to reduce costs (7). In Wales, a recent review found that SRHS were not meeting existing demand (8).

A key response to the COVID pandemic was a rapid reduction in face-to-face consultations and dramatic expansion in the volume and scope of 'remote' consultations, which involve the use of telecommunications/ digital technology to substitute for in-person contact between clinicians and service users (9). For SRHS such consultations can be used to diagnose, treat and manage infection, and provide user dependent contraceptive methods. While these remote consultations by telephone, video, online or text allowed continued access to services, provisional analysis by Public Health England (PHE, now the UK Health Security Agency, UKHSA) suggests that some population groups were underrepresented which emphasises "a critical need to evaluate the impact of these changes on health inequalities" (10).

SRHS and other NHS services are still evolving following the COVID-19 pandemic, and new care pathways incorporating remote consultations have been implemented, although optimal service configurations for the future remain unclear. As well as refining new models of care, there is a need to tackle the impact of the pandemic in terms of unmet need and resultant impact on SRHS (11, 12). There are several potential benefits associated with remote consultations in SRHS. The increased convenience of remote services can improve uptake by groups who are less likely to access face-to-face services or who face barriers in accessing such services (13) and remote consultations have the potential to reduce costs (14).

The distinctive features of SRHS mean that they face specific challenges (15). Those from lower socio-demographic groups, ethnic minorities, and people with mental health problems experience poorer SRH and have worse access to care, and there is a concern that remote consultations can widen these disparities by creating barriers and reducing choice (16). Evidence suggests that although many people accessed SRHS during COVID associated lockdowns, difficulties in accessing services were reported particularly for young people and those reporting sexual risk behaviours (11). There is a strong association between digital exclusion and lower education attainment and social disadvantage, with a potentially greater risk of poorer outcomes for those individuals who are already at increased risk of poor SRH (17). Also, SRHS play a key role in the identification and engagement of those who experience sexual violence and domestic violence, which increased in COVID lockdowns (18), and it is not known how remote access to services might affect this. Finally, it is generally assumed that providing services remotely will decrease costs. However, the evidence on cost-effectiveness remains limited (14, 19).

A scoping search revealed that there is currently a paucity of evidence relating to remote consultations in SRHS, and in particular their impact on health inequalities in relation to access to care and clinical outcomes, as well as timeliness of treatment, access to contracption, cost-effectiveness, the identification of domestic violence and safeguarding concerns. Remote technologies have the potential to reach new patient groups but might also reinforce existing inequalities in access to SRHS, for example, lower socio-economic groups have less access to digital health information and may prefer face-to-face services (20). Video consultations can also raise additional barriers in disadvantaged groups related to access to technology and digital literacy (21), and limited availability of private space in the home to access remote services (22), which could potentially exacerbate existing inequalities in access to SRHS (23). In particular, there is a lack of evidence around which populations and conditions are most appropriate to manage remotely (24).

2. Rationale

There is a pressing need to evaluate the impact of remote SRHS consultations on health inequalities in terms of impacts on access to care and clinical outcomes, as well as other aspects of care. Services continue to be reshaped following the disruption associated with the COVID pandemic. This gives a valuable opportunity to analyse the impact of remote consultations and how services can be improved moving forwards. Importantly, the COVID pandemic has highlighted the deep-rooted nature of health inequalities and tacking these has been highlighted as a key priority (25, 26). This evaluation seeks to inform the future design of services and ensure these are focussed on delivering high quality care for all patient groups (27). Moreover, this research will help to improve patient safety through improved identification of domestic abuse and sexual violence which are areas of priority within the Domestic Abuse Act and the Violence Against Women and Girls Strategy 2021-24 in England, the Women's Health Strategy in England and the Violence Against Women and Girls, Domestic Abuse and Sexual Violence (Wales) Act 2015 and Violence Against Women and Girls, Domestic Abuse and Sexual Violence (Wales) Strategy 2022-2026.

The study's focus on inequality will complement existing and recent evaluations, for example the British Association for Sexual Health & HIV (BASHH) Clinical Thermometer Surveys which focus on service capacity and delivery; Faculty of Sexual and Reproductive Health (FSRH) member surveys which focus on monitoring, understanding and addressing service issues; local and national survey work on changing sexual behaviours and service use (e.g. Britain's National Survey of Sexual Attitudes and Lifestyles– 'Natsal'-COVID surveys (28); RiiSH-COVID surveys (12)); PHE/ UKHSA surveillance data on STI testing activity; Public Health Wales surveillance data; Sexual and Reproductive Health Activity Data Set (SRHAD); and the ASSIST study evaluating online postal self-sampling for STIs (29). In addition, it will expand the evidence base from existing small local service evaluations focussed on particular patient groups. This project will provide evidence to inform new guidance and update existing guidelines (e.g. BASHH guidance on the Principles for Recovery, BASHH guidance on Contingency Planning, and Triage Integration Considerations & Methods to prioritise Vulnerable Groups; FSRH guidance on provision of Sexual and Reproductive Healthcare (SRH) services during the third COVID-19 lockdown and beyond in the UK). The study will thus improve equitable delivery of SRHS for service users, guide clinicians in developing optimal models of care, and inform commissioning arrangements in relation to equity, safety and cost-effectiveness.

3. Theoretical Framework

The study involves a theoretically informed, mixed methods analysis of the impact of remote consultations in SRHS on health inequalities using three case study areas (CSAs). Health inequalities are analysed in terms of access to care, clinical outcomes, the identification of domestic violence/sexual violence and safeguarding concerns, and patient experiences. We adopt a health equity approach, which views health as determined by complex and integrated factors, such as physical environments, education, healthcare services, housing, job opportunities, income and discrimination (30, 31). This approach highlights the mechanisms underlying health disparities. This means that inequalities in population health status are linked to broader social differences such as in socioeconomic status, ethnic background, and other factors (32). This research will particularly draw on the Health Equity Framework (HEF) to structure our analysis of the factors influencing usage and impact of remote consultations (33). The HEF was developed by drawing on aspects of several previous health equity models (33, 34) and aims to provide a comprehensive framework for analysing social determinants of health. The framework combines approaches from public health, education, and social science and focuses on the complex interactions between people and their broader environment.

4. Research Question/Aims

The overall aim of the project is to evaluate the impact of remote SRHS consultations on health inequalities. The research questions are:

RQ1. What is the existing published evidence on equity, effectiveness, safety and cost -effectiveness for remote consultations in SRHS?

RQ2a) What is the impact of remote consultations on health inequalities in relation to access to care and clinical outcomes, as well as timeliness of treatment, access to contraception, cost -effectiveness, the identification of domestic violence/sexual violence and safeguarding concerns?

RQ2b) What factors do service users/ potential service users and clinicians consider important in making remote consultations equitable, acceptable and appropriate?

RQ3. How can remote consultations best be utilised as part of equitable, effective, safe and sustainable SRHS?

4.1 Outcomes

- Publication of a range of research papers and policy briefings related to the specified research objectives.
- Development of evidence-based and theoretically informed recommendations on the design and delivery of inclusive consultations in SRHS, and optimising consultations to meet diverse patient needs.
- Dissemination and engagement outputs which will influence policies and lead to improvements in patient care and a reduction in health inequality.

5. Study Design and Methods of Data Collection and Data Analysis

The research involves three distinct but interconnecting work packages (WPs) involving both qualitative and quantitative elements, with patient and public involvement and engagement (PPIE) at all stages. WPs are set out in detail below but in summary will encompass:

WP1: Synthesis of current published evidence on remote consultations for SRHS – including guidelines, policy documents and research findings;

WP2: In depth analysis of the impact of remote consultations on health equity in terms of access to care, clinical outcomes and signposting to external services;

WP3: Development of recommendations on reducing inequality, identifying at risk individuals, improving clinical practice, and adoption into national guidelines and standards.

5.1 Work Package 1: Evidence Synthesis

5.1.1 WP1 summary

This WP addresses RQ1 and will systematically identify and analyse the published evidence on remote consultations for SRHS. It will synthesise evidence on the factors influencing how remote consultations are implemented, and the impact of such consultations on outcomes, especially equity.

The synthesis will address RQ1 through considering the following questions in relation to remote consultations:

- What is the existing published evidence relating to remote consultations in SRHS?
- How have remote consultations been integrated within broader care pathways in SRHS?
- What are the findings in relation to effectiveness and cost-effectiveness, in particular in terms of access to care and clinical outcomes, as well as timeliness of treatment, access to contraception, cost-effectiveness, the identification of domestic violence/sexual violence and safeguarding concerns? What has been found in terms of the factors that service users/ potential service users and clinicians consider important in making remote consultations equitable, acceptable and appropriate?
- To what extent has intersectionality between groups which are at risk of inequality been evaluated?
- What guidelines/recommendations are available which might inform practice and reduce inequality?
- What is the methodological quality of the existing evidence?
- What are the key knowledge gaps in terms of evidence and practice relating to health inequalities in remote delivery of SRHS?

The review will be conducted according to the guidelines of the UK's Centre for Review and Dissemination (CRD) (35) and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (36). The review has been registered on PROSPERO, the international prospective register of systematic reviews (ref no. 397288). The overall search strategy has been formulated using the population, intervention, comparator and outcomes (PICO) framework.

5.1.2 Inclusion and exclusion criteria

We will include a range of conditions/services relating to SRHS including contraception, abortion, STI screening and management, psychosexual medicine, and HIV screening. This will include evidence from other similar healthcare systems (in Organisation for Economic Cooperation and Development (OECD) countries) and will focus on the years from 2011 (when mobile phone became more common than landline use) (37).

Population/problem:

The review will include evidence on remote consultations relating to sexual health/reproductive health, abortion care, and HIV testing from published/publicly available and anonymised data research.

Interest/ intervention:

For the purpose of the review, we will adopt a broad definition of remote consultations including telephone, video, text or web-based consultations, which could be synchronous or asynchronous (38, 39). Such consultations could be considered individually, as part of a whole system, or as part of digital interventions more broadly. We will include evidence concerned with 'hybrid' or flexible approaches, as well as those focussed on one modality. Although the particular focus of the review is on health inequalities, we will not restrict our review to evidence that just considers health inequalities, as part of our aim is to assess to what extent health inequalities are considered in the existing evidence on effective and safe delivery of services.

Context/comparator:

We will include evidence that compares remote consultations to other types of consultation, such as face-to-face consultations and any other approaches. We will also synthesise evidence on the contextual factors reported as influencing implementation and what outcomes are observed, including using the categories of our theoretical framework (33).

Evidence type:

We will be broad in terms of the types of evidence considered. This will include qualitative, quantitative and mixed-methods studies, previous literature reviews, grey literature including guidance, policy documentation, evaluation reports and recommendations for technology/practice.

5.1.3 Search strategy

After consultation with our PPIE panel (CONNECT Voices), PPIE and Inclusion Leads and our expert advisory groups, the review protocol will be finalised. Relevant evidence will be identified through a combination of approaches including using a range of bibliographic databases (e.g. Web of Science, Health Management Information Consortium), searching using online sources including Google, searching relevant websites (such as BASHH, BHIVA, NICE, WHO), contacting experts (including members of our proposed Expert Advisory Group, many of whom are involved in policy and guideline development), citation checking, and specialist databases. Authors of reports and studies will be contacted for further information where items are not sufficiently well reported to allow effective synthesis (40). Hand-searching will be undertaken to identify additional studies, as well as manual checks of the reference lists of included studies and known relevant reviews.

5.1.4 Screening

A two-stage process will be used to identify studies for inclusion: i. review of abstracts and titles; ii. relevant papers read in full and further assessed against detailed criteria (41). Screening (initially by title and abstracts, and then full text) and data extraction (including quality assessment) will be carried out by 2 independent reviewers (RF, IW). Any disagreement will be refereed by other members of WP1 (LJ, JR). We will record reasons for exclusions.

5.1.5 Data extraction

For included studies, a standardised, pre-piloted form will be used to extract data. This form will include:

- Evidence characteristics: aims and objectives, study design, country, healthcare system context, source of funding
- Problem/population: condition/disease area, demographic considerations such as age, gender, ethnicity, etc.
- Interest/intervention details: type of remote consultation considered, role in patient pathways, wider healthcare system, aims of consultation, technology used, etc.
- Context/comparators considered
- Study design
- Data on resource use/costs and benefits
- Contextual factors: e.g. 'individual factors'; 'relationships and networks'; 'physiological pathways', 'systems of power'

5.1.6 Quality assessment

An established tool will be used to appraise the quality of the evidence, (e.g. Mixed Methods Evaluation Tool (42)) or other standard tools as appropriate. Quality assessment will be used to inform the analysis rather than to exclude studies.

5.1.7 Synthesis

The synthesis will involve three components:

i. We will produce a map of the evidence on remote consultations for SRHS, exploring the relationships between different types of evidence in different disease areas. The map will provide an overview of guidance, policy documentation, recommendations and research findings directly concerned with SRHS. As part of this step, we will describe the evidence available which focuses on health inequalities in the context of remote consultations. Stakeholders in the Expert Advisory Group and the CONNECT Voices Panel will provide input to this mapping process to ensure a comprehensive approach, drawing links between different areas.

ii. Information and data will be tabulated and the findings of individual studies will be collated and subject to comparative thematic analysis using a narrative approach which is recommended for synthesising studies with heterogenous methods and conceptual approaches (35). This step will also involve analysis to assess what evidence exists on the impact of remote consultations on health inequalities, and the models and practices which have been proposed to tackle health inequalities in this context. We will develop a schema to show (a) groups considered in the existing evidence, and (b) models/practices/technologies proposed to address health inequalities in the existing evidence.

iii. As the final step we will produce a framework showing the existing evidence both directly related to SRHS, and the gaps in terms of particular dimensions of equity, and implications for practice and policy.

5.1.8 Outputs

Overall, the evidence synthesis will enable us to identify theoretical propositions about the relationships between modes of remote consultation, contextual determinants of health inequality, and outcomes in terms of effectiveness and cost-effectiveness. These will inform conduct and focus of subsequent work packages through the identification of a) key questions and b) gaps in knowledge.

5.2 Work Package 2: Case Study Analysis

This WP will analyse the impact of introducing/expanding remote consultations on health inequalities in relation to access to care and clinical outcomes. We will employ a broad definition of 'remote consultations' to include consultations by telephone, video, online, email and by text messaging (9, 43), and as part of the whole patient pathway/system. This work package will use qualitative and quantitative data from the three case study areas (CSAs). The three case study areas are Hywel Dda University Health Board, Umbrella Health Partners in Birmingham (University Hospitals Birmingham NHS Foundation Trust [UHB]), and Central and North West London NHS Foundation Trust (CNWL). The case study areas are described in more detail in section 6. Study Setting.

5.2.1 WP2.1 Quantitative analysis of the impact of remote consultations on health inequalities in terms of access and clinical outcomes

Design and Methods

This WP will focus on the impacts of the expansion of remote consultations provision on health inequalities by examining effects on service access, activities and outcomes for different population groups. We will compare anonymised data on access to remote consultations and clinical outcomes for service users between a 12-month period of predominantly face-to-face consultations (January- December 2019 before the first pandemic lockdown), and a more recent 12-month period where consultations were mixed between face-to-face and remote (from January -December 2022). Data on access and outcomes for the COVID period (January 2020-December 2021) will be accessed, processed and analysed to provide additional context, where possible.

We will (i) assess change in access and outcomes between these time periods overall and also by population subgroup, so as to address change in inequality, and (ii) compare outcomes within the more recent time period between service users who received a face-to-face consultation and those who received a remote consultation, again overall and by population subgroup to address current patterns of inequality. The key population subgroups will be defined by age, gender, ethnicity, socio-economic status, sexual orientation, and geography.

Outcome measures

The primary outcome measures will be: i) the proportion of cases of chlamydia treated within three weeks (in line with national recommendations); and ii) uptake of long-acting reversible contraception (LARC). These have been selected because they relate to key policy priorities (44), encompass both sexual and reproductive health, and they are routinely collected. We will also analyse a number of secondary clinical outcomes. These will include: service access, repeat termination of pregnancy, proportion of cases of gonorrhoea treated, time to treatment for STIs, rates of partner notification following an STI diagnosis, and identification of vulnerable individuals or those at risk of sexual/domestic violence. Service access and other outcomes are likely to have been impacted by behavioural change at the time of the peak COVID restrictions, but this period is not included in our primary analyses.

Our analyses focus on the time periods before the pandemic (January- December 2019) and the 'recovery period' (after January 2022) when services had stabilised and access had largely been restored, as indicated by Natsal-COVID (45), RiiSH-COVID and BASHH surveys, and feedback from SRHS in our CSAs. Local and national surveys which measured changes in sexual behaviour over the relevant time periods will be used to help contextualise our findings. We will adjust for demographic factors associated with our outcomes to minimise confounding.

Our analyses will be conducted for patient cohorts within each site and the variation between the three case study sites will help us to assess the impact of different policies permitting or directing certain individuals to face-to-face consultations when remote consultations are also available.

Sample size considerations

The case study areas are each large enough to provide good power to detect moderate interactions between time periods and population subgroups (change in inequality) for the primary outcomes. Taking chlamydia treatment as an example, based on preliminary data we estimate 4000+ chlamydia cases in the face-to-face period, and 2000+ in the recent mixed mode period, and that around 60% of cases were treated from clinic prescriptions in the first period and 50% in the recent period. For illustration we consider subgroups to be unassociated with treatment in the first period, and equally prevalent in the two time periods. The sample size provides good power for subgroups as small as 20% of chlamydia cases, which may be compared to either all other cases (80%), or to another subgroup representing half of all cases, or a different 20%. For these comparisons the sample size provides 80% power to detect an interaction odds ratio of 1.48, 1.51, and 1.64 respectively, corresponding to differences between subgroups in treatment rate of 10%, 10% and 12% respectively (46).

Data collection

We will use routinely collected data which is captured by clinics in the CSAs to meet the requirements of a range of surveillance systems in England (e.g. Chlamydia Testing Activity Dataset, GUMCAD STI surveillance) and Wales (Public Health Wales Surveillance Data). We will also obtain data on clinical outcomes which is held by clinics as part of their electronic patient record system. We will work with each CSA to specify the fields required for data extraction from existing databases. This will include demographic information, details of consultations, follow-up and clinical outcomes. We will request abortion data for England and Wales from the Department of Health, using the established process for researchers to be granted access to data relating to the notification of an abortion (form HSA04). We will also use local and national survey data to contextualise our analysis and help with interpretation of findings. This will include data from the latest decennial Natsal study (funded as part of Wellcome Trust's Longitudinal Population Studies Strategy with contributions from NIHR), fieldwork for which is planned to start in September 2022; as well as Natsal-COVID (45).

Statistical analysis

For each CSA we will first compare data on outcomes for service users in the 'mainly face-to-face' period with the recent 'mixed consultation model' period as defined above to assess overall changes in the outcome measures and differential change between population sub-groups associated with the consultation policy change, using multivariable regression models suited to each outcome. Specifically, our analysis will be based on fitting regression models for each outcome that include time period, confounders, indicators corresponding to our key population subgroups, and interactions between these and time period/consultation model. These interaction terms reflect differences in the magnitude of change in inequality.

For the analysis of service access we will use estimates of the size of population subgroups in the catchment area to act as 'exposure' variables and permit Poisson regression models of the rate of access. Confounders in the regression models will include behavioural and lifestyle factors so as to limit confounding due to changes following the pandemic. Secondly we will fit regression models restricted to the recent period so as to directly compare outcomes between those who received face-to-face and remote consultation. Interaction terms between consultation mode and population subgroup will address unequal impacts of consultation mode. We will also investigate associations between population subgroups and consultation mode to understand patterns of access by consultation mode. The results from the three CSAs will be compared qualitatively and differences will be interpreted relative to differences between CSAs including the extent of remote provision and local policies to direct certain individuals towards a remote or face-to-face consultation.

5.2.2 WP2.2 Qualitative analysis of service user and healthcare professional views and experiences on the impact of remote consultations on health inequalities

Design and Methods

For each CSA, a series of qualitative semi-structured interviews will be undertaken with service users and potential service users from a variety of backgrounds, and staff in a range of roles (47). These will explore perceptions of the impact of remote consultations on health inequalities and address: views on optimising delivery; local guidance and practice; implementation of local patient pathways; and approaches to integrate remote and face-to-face consultations. The qualitative interviews will allow us to explore a wider range of impacts on health inequalities and capture aspects that might not be captured in routine data (for example, in relation to homelessness, disability or mental health).

i. ***Interviews with service users and potential service users****:* It is anticipated that approximately 15 – 20 one-to-one interviews per CSA will be undertaken, as this is likely to be the point at which saturation is approached (when additional emerging data is not shedding additional useful light on the emerging themes) (48). The interviews with service users will allow us to explore their experience of the whole consultation journey, what influenced their decisions to access consultations remotely or face to face, whether their needs were addressed, and if/how they could be improved. We will also include interviews with potential service users (e.g. those who tried to access services but have not been able to). Costs have been included for tokens of appreciation for participants (£20 per participant).

ii. ***Interviews with health service providers***: For each CSA, qualitative semi-structured interviews (47) will be performed with service providers across a range of roles. It is anticipated that 10-15 interviews will be required per CSA to approach saturation (49). These will explore local experiences and views on remote consultations and will allow a detailed understanding of the ways in which remote consultations have been conducted in each CSA and the perceptions of staff on the impacts for different population groups. This will take into account changes over time (i.e. in the pre-Covid 'mainly face-to-face' period and the more recent 'mixed consultation model' period).

Sampling, inclusion criteria and recruitment

We will follow best practice and work with our CONNECT Voices panel (PPIE group), PPIE Lead and Inclusion Lead to adopt a maximum variation approach to ensure that service users and potential service users are included from diverse populations and that marginalised groups are included (50). This will include differences in terms of age, gender, ethnicity, sexual orientation, socio-economic status, educational attainment, housing (including homelessness), disabilities and geography/rurality. We will also ensure diversity in experience of service pathway (51). This will include service users who have used only remote services, service users who have accessed face-to-face services, service users who have used both remote and face to face consultations, and those who are potential services users (e.g. they have tried to access services but have not been able to).

A multimodal approach will be employed for recruitment of participants including the use of advertisements in local communities and SRHS, purposive criterion-based sampling, and the use of social media. Members of the target audiences will be involved in co-producing the advertisements so that they resonate with the intended target audience. Participant recruitment and information materials will be provided for service users and potential service users in both paper format and electronically, explaining the purpose and nature of the interviews. Information will be made available in Welsh. Additional information/support in relation to the research will be available for participants by phone or email. Purposive sampling will also be undertaken to include service providers (staff) from a variety of roles including clinicians, managers, members of health boards/commissioners, and administrative staff (51).

Data collection

Interviews with service users and potential service users

The in-depth interviews will adopt a semi-structured format using a topic guide [63]. The topic guide will be used to stimulate discussion about the views and experiences of service users and potential service users from different population groups and their opinions on different consultation methods with a focus on inequality. The content of the topic guides has been developed with PPIE involvement, to ensure they are accessible and culturally appropriate for a broad group of service users/ potential service users and staff. The interviews will be informed by the evidence synthesis conducted in WP1, and the theoretical framework used in the study. Preliminary topics for the guide include: 1) knowledge about the different types of consultations available; 2) experience of different methods of consultations; 3) factors that influence preferences for different types of consultation; 4) factors that would influence access to services; 5) views on the advantages and disadvantages of different types of consultations; 6) factors that would help to increase acceptability of different types of consultation. For service users who have used both face to face and remote consultations, we will ask them to compare their experiences and to reflect on the factors influencing patient choice.

Interviews with staff

These will be semi-structured interviews, as described above. The topic guide will include themes relating to perceived impacts of remote consultations on health inequalities; local guidance and practice; patient pathways and incorporation of remote and face-to-face consultations; and views on optimising delivery.

Data analysis

Interviews will be transcribed verbatim and analysed using thematic analysis [64]. Following full familiarisation with the transcripts, open codes will be applied to four transcripts to identify emerging themes of relevance by two researchers. This will be undertaken digitally using a Computer Assisted Qualitative Data Analysis (CAQDAS) package (NVivo 12 for Windows). Researchers will then meet and agree a set of codes which can be used with the rest of the transcripts. At this stage, codes will be grouped together to create and define categories, and this will form a working coding framework which can be used with the rest of the data [64]. The researchers will use the framework to code the remaining transcripts, amending the coding framework as necessary. The coding framework will then be applied to all transcripts to index each code. A Framework Method matrix will be used to summarise and manage the data [65]. The matrix will involve cases (rows), codes (columns) and cells of summarised data. The matrix will be used by the researchers to compare and contrast data across and within cases. Connections and differences between codes will be analysed to identify the factors that are meaningful and relevant to stakeholders [65]. Stakeholders, our CONNECT Voices Panel and our PPIE/ Inclusion Leads will be involved in the interpretation of findings.

5.2.3 WP2.3 Economic evaluation

Design and Methods

The aim of WP2.3 is to analyse the costs and outcomes for remote consultations and face to face consultations, taking into account distributional impacts in terms of age, gender, ethnicity, sexual orientation and socio-economic status, using a distributional cost-effectiveness analysis method (52). Consultations will be analysed as part of the whole patient pathway and not simply a 'bolt on' or standalone element. The primary base case analysis will adopt a healthcare perspective, in keeping with NICE guidance and to reflect the focus of the study on different models of care delivery (53). This work package will involve an analysis of routinely collected data from the CSAs as described for WP2.1.

Data collection

Resource use and cost data will be collected from each CSA to estimate the overall costs associated with remote compared to face-to-face consultation care pathways. The cost data to be collected will include: (1) cost of the consultations and follow up activities; (2) costs associated with testing and screening for STIs; (3) laboratory costs; (4) costs associated with result notification and partner notification; (5) treatment costs; (6) costs associated with reproductive health interventions; (7) other resource use. Information on unit costs or prices will be sourced to attach to each resource use item using published information (e.g. (54)). Where necessary, local cost information for CSAs 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 WP2.1. The patient outcomes considered will include uptake of LARC, treatment rates for chlamydia, and the secondary outcomes considered in WP2.1.

Economic analysis

This component will assess the costs and benefits of different modes of consultation, using the outcome data from the CSAs (as described in WP2.1) and cost data, for the 'mixed consultation model' period. A distributional cost-effectiveness analysis will also be undertaken to compare the economic and distributional impacts associated with different types of consultation (55). The economic analyses will be conducted and reported in accordance with relevant guidance (56). Initially a cost-consequence analysis will be presented which involves reporting all costs and outcomes in a disaggregated manner. An incremental cost-effectiveness analysis will be undertaken using the primary outcomes included in WP2.1 (cost per case of chlamydia treated and uptake of LARC) and secondary outcomes (57). 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. Deterministic and probabilistic sensitivity analyses (PSA) will be conducted to explore the effects of the uncertainty in the parameter estimates on the results (58). Deterministic sensitivity analysis involves varying one or more parameters while keeping the others at their baseline value. A PSA involves varying all parameters simultaneously, and multiple sets of parameter values are sampled from defined probability distributions (57).

Currently the methods for incorporating equity considerations within economic evaluations are being refined and a range of possible methods will need to be considered (55). 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) (59). Variations of multicriteria decision analysis (MCDA) have also been proposed as possible methods (60). As such methods have not previously been used in a sexual health context, we will assess the most appropriate approach and be informed by emerging practice (59).

Outputs

Overall, the mixed methods in-depth analysis of the CSAs will allow a theoretically informed understanding of the relationships between remote consultation and impacts on health inequalities, in terms of clinical outcomes, access, safeguarding and cost-effectiveness. The findings will be integrated as part of WP3 to develop recommendations and inform policy.

5.3 Work Package 3: Synthesis and Recommendations

5.3.1 Design and Methods

This WP will synthesise the findings from WP1-2, and will use a modified Delphi technique exercise (61) and triangulation methods (62) to identify individuals at risk of poor outcomes, and develop recommendations for reducing inequality, improving clinical practice and facilitating adoption into national guidelines and standards. This will include recommendations on consultation and treatment pathways to ensure the inclusion of disadvantaged groups. Following the Delphi exercise, we will hold three consensus workshops with 10-12 SRHS stakeholders drawn from professional organisations, public health professionals, commissioners and public representatives.

The WP will work in partnership with key stakeholders to co-produce recommendations for sexual and reproductive health services on the delivery of inclusive remote SRH consultations and co-produce the means to rapidly translate research findings and recommendations into practice.

5.3.2 Synthesis of findings from WP1-2

Triangulation methods will be used to synthesise the quantitative and qualitative data collected in WP1-2 (62). For the integration of study findings we will draw upon the work of Sandelowski (48), and integrate quantitative and qualitative data in relation to discussion of results (i.e. parallel-results convergent synthesis design). Our synthesis will utilise questions as anchors and compasses to articulate the aspects of remote consultations to be explored (63). We will use the Health Equity Framework to help focus the synthesis of research findings and to explore and explain the impacts of remote consultations on health inequalities. This framework allows exploration of how health outcomes are influenced by complex interactions between people and their environments, and thus will allow understanding of how access to and engagement with remote consultations varies across social groups, and the impact on health outcomes. The framework will be used to identify factors that contribute to lower levels of use and engagement and worse health outcomes, in order to inform inclusive service provision and patient-led approaches. We will involve our CONNECT Voices Panel, PPIE and Inclusion Leads and other stakeholders in the interpretation of findings from WP1 and 2, to ensure an Equality, Diversity and Inclusion (EDI) lens and provide constructive critique of matters which may have inadvertently been overlooked/misappropriated and to support establishing ownership of the resulting project recommendations.

5.3.3 Modified Delphi exercise

The Delphi method is recommended for use in healthcare settings to reach consensus on clinical or service issues (64). The Delphi method uses an iterative process of repeated rounds of voting and is an effective process for building expert group consensus where definitive evidence is lacking and where stakeholder opinion is important (65). A Delphi panel will therefore be convened to reach consensus on recommendations for reducing inequality and improving clinical practice, with an option for additional separate panels if the data synthesis suggests that different recommendations are required for separate key groups.

Sampling

For the Delphi process, our whole systems co-production approach will facilitate representation and participation from marginalised groups (people from gender minorities, ethnic minorities, different religious affiliations), to address power imbalances and to optimise purposive recruitment. Participants will include those who are clinicians, public health professionals, commissioners, managers, government officers, technology specialists and public representatives. Recruitment of participants will use the wider team's existing extensive professional networks with government, public health, professional and community organisations (see expertise of the applicants), directed by our PPIE and Inclusion leads. The recruitment process will be based on a methodology previously used by Bunch et al. (66), and adapted from Okoli and Pawlowski (67).

Data collection

A modified Delphi approach will be used with two rounds of online questionnaires and a final face to face meeting to achieve consensus on how the study findings should be translated to guidance for service providers, commissioners and other stakeholders (63). By working in a collaborative manner from the outset of the project and with a diverse group, including people who share characteristics with intended participants and stakeholders, we aim to reduce the risks of inadvertently stereotyping participants and/or excluding stakeholders from decision-making. A series of potential items for inclusion in guidance will be developed based on the findings of WP1-2. A Delphi questionnaire will be developed to assess these items and reach consensus on the most important elements to include. For the first round the Delphi participants will be asked to rate the items using Likert scale with an opportunity to make additional free-text comments (68). For the second round of the exercise, a summary of the results from the first round will be included using bar charts. Participants will be asked to rate each item using the same rating scale, and it will be explained that they will be able to change their ratings from the first round. In the final step, a face to face consensus workshop will be held to discuss and confirm findings. Consensus will be defined as >70% of respondents rating the item as being of high importance and < 15% rating it as low importance. Advice and support for participants who are unfamiliar with the Delphi process will be provided.

Data analysis & recommendations

The results of the modified Delphi process will be used to finalise the recommendations developed from WP1-2. With the engagement with stakeholders in WP3, we will collectively generate a plan to disseminate and implement the key findings and recommendations from the research. We will co-produce a plan for translation of recommendations into policy and practice, and for the adoption of recommendations. Three consensus workshops will be held to facilitate this following the Delphi process. The workshops will involve stakeholders drawn from patient and public representatives, professional organisations, public health professionals, and commissioners, and they will focus on knowledge exchange and rapidly translating the research findings into practice. Although we will explore context of delivery of services in WP2, the work in WP3 also offers an opportunity to ask stakeholders to share any new/ recent changes and emerging issues relevant to the recommendations.

Stakeholder workshops

Following the Delphi exercise a series of three stakeholder workshops will be undertaken. We will aim to include 10-12 SRHS stakeholders in each consensus workshop and participants will be drawn from a range of stakeholder organisations such as the UKHSA, NIHR-funded Health Protection Research Units (HPRUs), BASHH, English Sexual Health Commissioners Forum, FSRH, Public Health Wales, NHS England, NHS Wales, TEC Cymru, Public Health Scotland, Sexual Assault Referral Centres, NHS Digital, British Society of Abortion Care Providers, and patient representative groups (e.g. NAZ, BHA, THT, Women's Aid). The workshops will discuss the findings from all the WPs and will have a focus on knowledge exchange and translation of the research findings and recommendations into practice.

Outputs

In consultation with the Expert Advisory Group and CONNECT Voices Panel we will co-produce accessible online documents summarising the synthesised evidence and good practice recommendations. We will use existing networks to disseminate findings and ensure impact.

6. Study Setting

Our case study areas (WP2) have been selected to ensure diversity in terms of geographical area, rural/urban nature, different models of the use of remote consultations, and other issues that the equity literature suggests are important such as commissioning structures, legislation, finance and funding, and policy priorities.

i. **The city of Birmingham** has a relatively young population with high levels of ethnic diversity (69). A citywide sexual health system has been commissioned for Birmingham since 2015, with services being provided by 'Umbrella', a partnership led by University Hospitals Birmingham NHS Trust involving a number of community-based organisations, charities and health service providers. There has been a fundamental change in the delivery of care over recent years with a move away from centralised clinics to greater use of Family Doctors (GPs) and community-based pharmacies, and internet provision (70). In Birmingham, remote consultations have mainly involved telephone appointments with minimal use of video appointments.

ii. **Hywel Dda University Health Board** provides healthcare services to a total population of around 384,000 throughout Carmarthenshire, Ceredigion and Pembrokeshire. The Board covers one of Wales's most rural areas and involves a quarter of the landmass of Wales. The National Health Service (NHS) in Wales is the responsibility of the devolved Welsh Government. For Hywel Dda, there has been a higher use of video consultations compared to other areas. The NHS Wales Video Consulting Service is delivered by the platform 'Attend Anywhere' and was rolled out as a response to the COVID pandemic.

iii. **Central and North West London NHS Foundation Trust (CNWL)** provides a range of services across the London boroughs of Barnet, Camden, Islington, and Haringey. Services are provided in four clinic hubs and two community locations. Online self-sampling is available via the Sexual Health London Programme. For CNWL, since the beginning of the pandemic, a mixed model for consultations has been adopted, with some telephone appointments, but face to face appointments including walk-in appointments have also continued.

7. Participant Recruitment

The quantitative component will involve routinely collected data and hence no participant recruitment is required. Data will be anonymised for the purpose of analysis. The sections below relate to WP2.2 Qualitative Interviews and WP3 Delphi component.

7.1 Qualitative Interviews (WP2.2)

7.1.1 Eligibility Criteria

Inclusion criteria

Service users and potential services users:

People aged 16 years and older who are users or potential users of reproductive and sexual health services who have accessed (or had tried to access) these services (online and/or clinic-based) within the past 12 months in any of the three case study areas and who are willing to provide informed consent and to undertake the protocol activities.

Health professionals, commissioners and other stakeholders:

People aged 18 years and older currently working as a consultant, nurse, health adviser, GP, other type of physician or clinician, counsellor, manager, commissioner or otherwise connected to the delivery of reproductive and sexual health services in the three case study areas, and who are willing to provide informed consent and to undertake the protocol activities.

Exclusion criteria

Service users and potential service users:

- Individuals aged under 16 years.
- Individuals unable/unwilling to provide informed consent (e.g. lacks capacity to consent to research due to a significant learning disability)
- Although translated documents (for participant information leaflet and website information) will be also available in Welsh, participation will depend on the ability to understand English sufficiently to be able to provide informed consent and answer the questions in the semi-structured interviews. Due to the sensitive nature of the topic and stigma associated with accessing sexual and reproductive health services, it is not appropriate for a translator to be present with the interviewer 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.

Health professionals and other stakeholders:

- Health professionals whose role is not connected with the delivery of reproductive and sexual health services e.g. Dentist, physiotherapists, dieticians.

7.1.2 Size of recruitment target

It is anticipated that approximately 15-20 service users/potential service users and approximately 10-15 healthcare professionals/stakeholders will be interviewed in each case study area to allow for data saturation to be approached (49). It is therefore anticipated that a total of approximately 60 service users/potential service users and 45 healthcare professionals are recruited.

7.1.3 Screening and recruitment technique

Service users and potential service users

- *Screening*

It is important to ensure a diverse study population to maximise the study results and identify health inequalities. The researchers will therefore monitor the demographics of participants and advise the clinical care team of any particular characteristics that may be underrepresented in the study and should therefore be approached about participation.

The clinical care team (who may also be research staff) will screen the clinical notes of patients in clinic to identify suitable candidates. Notes will also be screened of patients that have accessed online services.

- *Informing service users/potential service users about the study:*

We have multiple ways of informing potential participants about the study to make it as accessible and inclusive as possible. Service users will be informed about the study in the following ways:

- Approached by clinical care team during clinic visits. This could be face-to-face, by telephone or video
- Approached by clinical care team outside of clinic visits e.g. by telephone, email or post. This may be more relevant to patients who have recently accessed online services
- Using posters in the health clinic and in the community (e.g. community centre)
- Social media, including NHS social accounts e.g. Facebook, Twitter, Instagram
- Study website
- Community group leaders and key stakeholders will also increase awareness of the study and support recruitment

Printed Participant Information Leaflets (PILs) will be available and given to potential participants in the health clinic with electronic copies also available online via the study website. PILs will include the aims and purposes of the research, what participation entails and how the participants data will be used. These will be made available in Welsh.

- *Expressing an interest in study participation:*

Service users/potential service users can express their interest in taking part by:

- *Completing an Expression of Interest Form in clinic* and posting it in the designated secure locked box (in the clinic): This form will collect the patient's name, telephone and/or email address and completion of this form provides the service users consent to be contacted by the researcher.
- *Registering their interest with the clinical or research staff in clinic:* In doing so, service users/potential service users are asked to give their consent to be contacted by the researcher. This verbal consent will be documented in the medical notes, and the patients contact details (name, telephone and/or email address) will be securely transferred by the clinical care team to the researcher at the University by email.
- *Contacting the researcher directly by email or phone:* The researcher's contact details are featured on all study material (posters, information leaflets, website, social media) and the patient may choose to contact them directly.

If the researcher is present in clinic on the day of their clinic appointment, they may have a face-to-face discussion about the study with the patient following an introduction by a member of the clinical care team.

- *Contacting the potential participant and obtaining informed consent:*

Minimal personal information (name, telephone number and/or email address) will be collected to enable the researcher to contact the potential participant once they have given verbal consent to their details being passed on and this is documented in the medical notes. Service users will be contacted by the researcher by telephone or email (or discussed in person if present in clinic) to discuss the study further and go through any questions they may have. A copy of the information leaflet will also be provided by the researcher at their first point of contact (in person in clinic, by email or post depending on the service user's preference).

Participants will be given ample time to read and consider the study information, however the length of time is undefined due to the low-risk nature of this non-interventional study, and will be guided by both the participant's and researcher's judgement that they are fully informed and happy to take part. Researchers are trained to assess participant's 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. If they had all of their questions answered satisfactorily and wish to take part, the researcher will take the patients consent to study participation. The patient will be asked to confirm that they understand the purpose and nature of the research, what it involves, and the benefits and risks to themselves.

If the researcher is in clinic and speaking to the potential participant face-to-face, consent will be captured on the paper Informed Consent Form. A link to the online informed consent survey hosted by Redcap server can be texted or emailed to participants being recruited over the phone/remotely. Researchers will then verify their identity at interview by asking them to confirm details from the screening questionnaire, such as their name and age, and reconfirm their consent verbally. This would be recorded and the audio file retained and stored separately to the interview data. See section 12. Data Protection and Patient Confidentiality for details of storage of audio recordings.

If the participant is unable to consent by either of these methods (written or online), verbal consent would be obtained over the telephone. This would involve the researcher going through the contents of the Informed Consent Form and asking the participant to indicate their consent to each statement. A record of the statements used, participant's details and the date and time of consent would be taken, and the transcript would be retained with the study paperwork, separately to the interview data. The details of where the audio recording can be accessed would be documented and filed with the study documents. At the end of study, the recording and written confirmation of the consent recording would be verified by a member of the study team who did not take consent, and the audio file would then be deleted.

- *Collecting screening data*

Once consent has been obtained, the researcher will arrange completion of a screening questionnaire before scheduling the interview.

We will follow best practice and work with our CONNECT Voices panel, PPIE Lead and Inclusion Lead to adopt a maximum variation approach to ensure that service users/ potential service users are included from diverse populations and that marginalised groups are included [61]. This will include differences in terms of age, gender, ethnicity, sexual orientation, socio-economic status, educational attainment, housing (including homelessness), disabilities and geography / rurality. We will also ensure diversity in experience of service pathway [62]. This will include service users who have used only remote services, service users who have accessed face-to-face services only, service users who have used both remote and face-to-face consultations, and potential service users (e.g. those who have tried to access services but have not been able to). We will use a chart to list and monitor the characteristics of each participant and keep track of which characteristics still need to be identified or whether there is an overinclusion of people with certain characteristics.

We anticipate that approximately 15-20 service users or potential service users in each case study area will take part in the interviews, based on purposive sampling (i.e. diverse sample based on age, gender, ethnicity, sexual identity and socio-economic status). A sample of 15-20 participants in each case study area should allow for data saturation to be reached.

In order to ensure maximum diversity of sample, the service user/potential service user will be asked to complete a screening questionnaire which collects demographic information and health background information (age, ethnicity, gender, sexual identity etc.). We will then contact them at a later date by telephone or email to let the know if they are eligible and have been selected for interview. If eligible, participation will be confirmed and the interview will be arranged.

The service user will have the choice of completing the screening questionnaire over the phone with the researcher, in person or via an online link to a secure Redcap survey. Some of the questions are of a personal and sensitive nature – including questions about abortion and sexually transmitted infections (STIs) – and participants are informed that all questions are optional and they may leave questions unanswered if they are not comfortable with answering them.

- *Arranging and conducting the interview:*

If the participant is selected for interview, the researcher will check they still wish to participate, go through any additional questions and to arrange the interview. The interview may be carried out on the same day if it is convenient to the participant. Participants will be offered a text or email reminder service for their interview appointment if this is conducted on a different day. Reminders will be discrete with minimal information about the study.

The interview will be conducted by a researcher who is part of the central research team at the University of Birmingham or University College London and can be held in the centre, on University premises, online (e.g. Microsoft Teams, Zoom), or over the telephone – to suit the participant.

By offering service users multiple ways of accessing study material, registering their interest in the study, completing the screening questionnaire and attending their interview, this allows potential participants to select the most convenient methods and those they are most comfortable with (given the sensitive study subject), and does not exclude those who do not have access to the internet.

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 questions 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 who wish to withdraw their consent to their interview data being used may do so within 7 days of the interview by contacting the researcher. After 7 days, the interview data will be used in the study analysis to ensure the integrity of the research.

Researchers will verify the participant's identity at interview by asking them to confirm details from the screening questionnaire, such as their name and age, and reconfirm their consent verbally. This would be recorded and the audio file retained and stored separately to the interview data.

- *Interviews and recognition for involvement:*

The in-depth interviews will adopt a semi-structured format using a topic guide and will be used to stimulate discussion about the experiences of patients from different population groups and their views on different consultation methods. The content of the topic guide and interviews will be informed by the evidence synthesis conducted in Work Package 1. Preliminary topics for the guide include: 1) knowledge about the different types of consultations available; 2) experience of different methods of consultations; 3) factors that influence preferences for different types of consultation; 4) factors that would influence access to services; 5) views on the advantages and disadvantages of different types of consultations; 6) factors that would help to increase the acceptability of different types of consultation. For service users who have used both face-to-face and remote consultations, we will ask them to compare their experiences and to reflect on the factors influencing patient choice. Interviews are expected to last up to 45 minutes.

Service user participants will be given a £20 gift card as a thank you for their time, even if their interview is stopped early. This is a modest amount in recognition of their time. Participants will be offered a paper voucher to spend on the high street, or an electronic voucher to spend online depending on their preference.

Healthcare staff and stakeholders:

- *Screening*

It is important to ensure a diverse study population to maximise the study results and identify health inequalities. The researchers will therefore monitor the demographics of participants and advise the research team of any particular characteristics that may be underrepresented in the study and should therefore be approached about participation.

- *Informing healthcare staff/stakeholders users about the study:*

Healthcare staff and stakeholders will also be made aware of the study via:

- Contact from the local research team
- Posters in staff areas
- The study website

Information leaflets will be made available online or printed/electronic copies will be shared via the local research team or any other staff at site who has received study training and has been delegated this responsibility by the PI. Information leaflets sent by post or email will be sent together with an invitation letter. A copy of the information leaflet will also be provided by the researcher at the first point of contact (in person in the workplace, by email or post depending on the healthcare professional's preference).

The researcher's contact details are featured on all study material (posters, information leaflets, website, social media). If the researcher is present in clinic during their working day, they may have a face-to-face discussion about the study. Minimal information (name, telephone number and/or email address) will be collected to enable the researcher to contact the potential participant.

- *Expressing an interest in study participation, contacting the potential participant and collecting screening data:*

Healthcare professionals can express an interest in taking part by:

- *Accessing the website and completing the online Screening Questionnaire:* The questionnaire collects the potential participants contact details to enable the researcher to contact them, and will collect their demographic information (more details about the questionnaire are below).
- *Registering their interest with the research staff in the workplace:* The staff member's contact details (name, telephone and/or email address) will be securely transferred by the site research team/individual delegated this responsibility by the PI to the researcher at the University by email
- *Contacting the researcher directly by email or phone:* The researcher's contact details are featured on all study material (posters, information leaflets, website, social media) and the staff member may choose to contact them directly.

Interested healthcare professionals will be contacted by the researcher by telephone or email (or in person if present in the workplace) to discuss the study further and go through any questions they may have. If they wish to take part, the researcher will arrange completion of a screening questionnaire over the phone, in person or via a secure online link. The screening questionnaire collects demographic information and work background to ensure a wide range of people are taking part in the research. Participants are informed that all questions are optional. Questionnaires completed online or on paper will capture the consent of the staff member for the collection of the demographic data, and to be contacted again by the researcher if they are selected for interview.

- *Arranging the interview and obtaining informed consent:*

After ample time to read and consider the study information and following questionnaire completion, the researcher will contact the potential participant to let them know if they are eligible and have been selected for interview. If eligible, the participant will be asked if they still wish to participate and the researcher will go through any additional questions before the interview is arranged. Participants will also be offered a discrete interview reminder service for their interview appointment if this is conducted on a different day.

The interview will be conducted by the researcher who is part of the central research team at the University of Birmingham or University College London and may also be held in the centre, on University premises, online (e.g. Microsoft Teams, Zoom), or over the telephone – to suit the participant. The flexible approaches described are designed to encourage recruitment and retention to the study.

In all study material and conversations with clinic research staff or the researcher, healthcare professionals will be informed that their participation is voluntary and they may change their mind at any time without giving a reason.

Informed consent for the interview will be captured prior to or at the interview by the researcher and prior to commencement of questions. Written informed consent will be captured at interview for those attending a face-to-face interview in the presence of the researcher. Participants being interviewed over the telephone or via online methods will be asked to complete an online informed consent survey via Redcap secure server. Researchers will then verify their identity at interview by asking them to confirm details from the screening questionnaire, such as their name and role and reconfirm their consent verbally. This would be recorded and the audio file retained and stored separately to the interview data.

If the participant is unable to consent by either of these methods (written or online), verbal consent would be obtained at interview immediately prior to the interview questions. This would involve the researcher going through the contents of the Informed Consent Form and asking the participant to indicate their consent to each statement. A record of the statements used, participant's details and date and time of consent would be taken, and the transcript would be retained with the study paperwork, separately to the interview data. The details of where the audio recording can be accessed would be documented and filed with the study documents. At the end of study, the recording and written confirmation of the consent recording would be verified by a member of the study team who did not take consent, and the audio file would then be deleted.

Participants will be informed that they are free to withdraw from the study, without giving a reason, and without affecting their employment. They will be asked to confirm that they understand the purpose and nature of the research, what it involves, and the benefits and risks to themselves. Before the interview, they will be informed that they have the option of not answering any questions they feel uncomfortable answering.

Participants who wish to withdraw their consent to the interview data being used may do so within 7 days of the interview by contacting the researcher. After 7 days, the interview data will be used in the study analysis to ensure the integrity of the research.

Figure 1: Service user's recruitment pathway

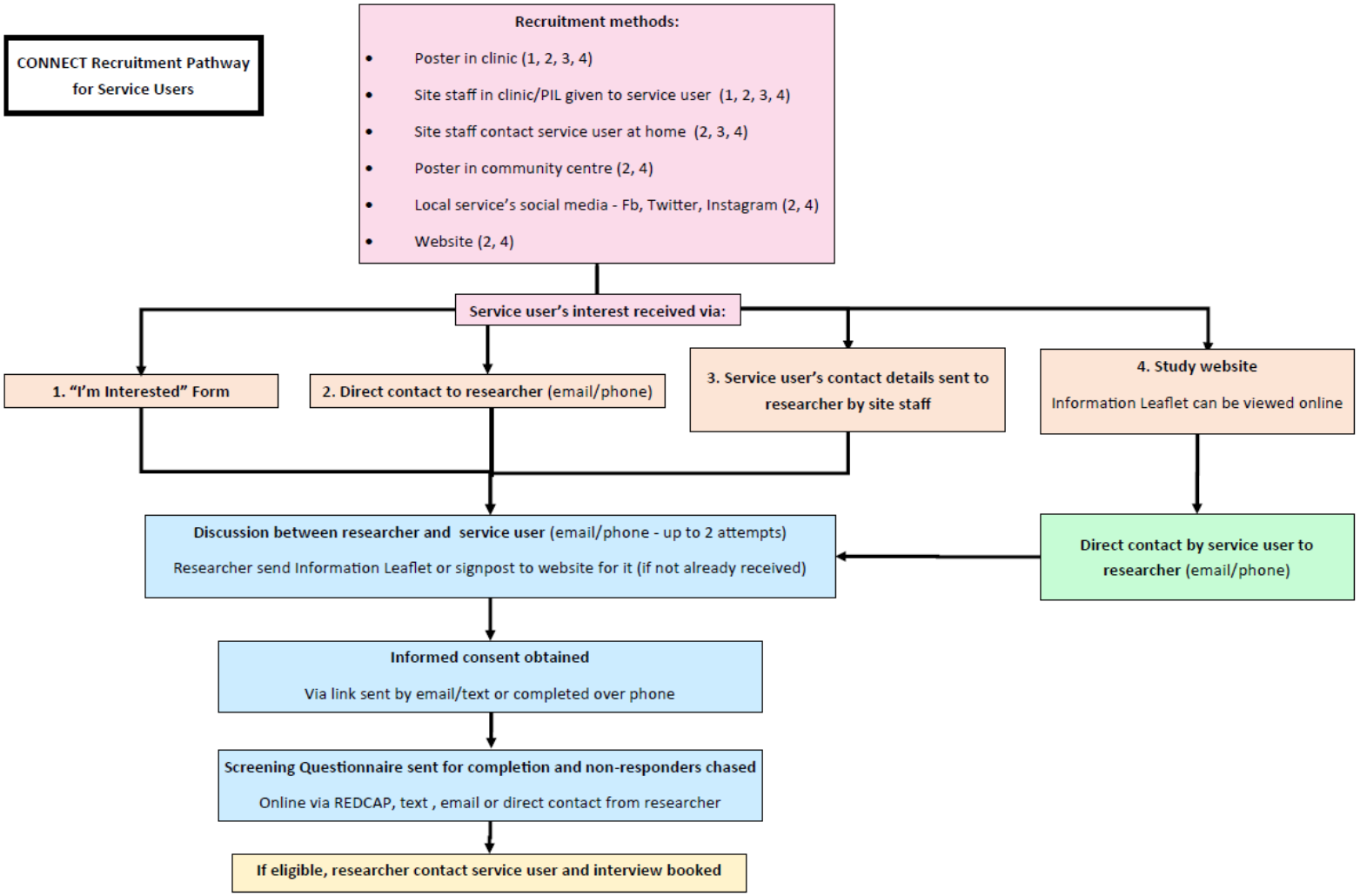
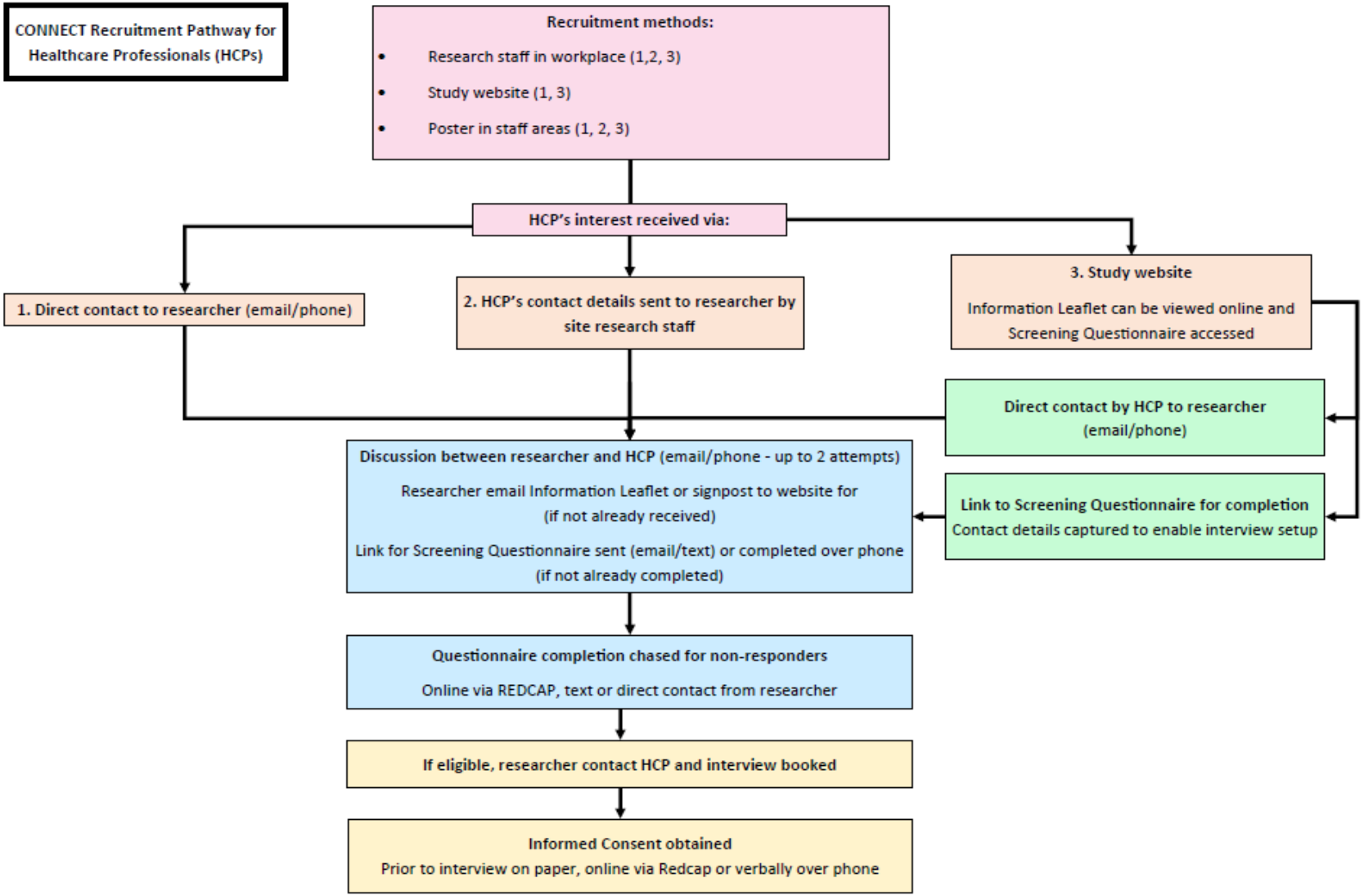


Figure 2: Healthcare Professional's recruitment pathway



7.2 Delphi exercise (WP3)

The Delphi exercise will involve a range of participants from a range of stakeholder organisations such as the UKHSA, NIHR-funded Health Protection Research Units (HPRUs), BASHH, English Sexual Health Commissioners Forum, FSRH, Public Health Wales, NHS England, NHS Wales, TEC Cymru, Public Health Scotland, Sexual Assault Referral Centres, NHS Digital, British Society of Abortion Care Providers, and patient representative groups (e.g. NAZ, BHA, THT, Women's Aid). Stakeholders will be invited to take part via email, telephone or face to face. If they are interested, a member of the research team will contact them about the study. Recruitment of participants will use the wider team's existing extensive professional networks with government, public health, professional and community organisations (see expertise of the applicants), directed by our PPIE and Inclusion leads. We will also adopt a "snowball sampling" approach, this will involve inviting potential panel members to forward information about the Delphi exercise to other relevant potential participants. **WP3 will be carried out following completion of WP2, therefore many of the documents are in development at the time of writing and will be submitted via an amendment prior to this work commencing.**

7.2.1 Eligibility Criteria

Inclusion criteria

People aged 18 years and older from a range of stakeholder organisations connected to the delivery of reproductive and sexual health services in the three case study areas. Patient or public representatives working nationally or regionally.

Exclusion criteria

- Although translated documents (for participant information leaflet and website information) will be also available in Welsh, participation will depend on the ability to understand English sufficiently to be able to provide informed consent and participate in the Delphi exercise and discussions. It is anticipated that only a very small proportion of those approached to participate in the research will be unable to understand English sufficiently.
- Health professionals and stakeholders whose role is not connected with the delivery of reproductive and sexual health services e.g. Dentist, physiotherapists, dieticians.

7.2.2 Size of recruitment target

There is no standard sample size for a Delphi panel, but it is generally recognised that more panel members will improve the reliability of judgements that are made by the panel (71). We will aim for a minimum sample size of 50 participants. We will aim for maximum diversity within the overall sample (e.g. age, gender, ethnicity, socio-economic status, healthcare professional occupational role and location, time since qualification) which will be monitored by keeping a chart listing each characteristic by each participant and keeping track of which characteristics each participant has to see what characteristics still need to be identified or whether there is an overinclusion of people with certain characteristics. We will invite approximately 70 people to be potential panel members, assuming a 25% rejection rate, yielding a final sample size of approximately 50 panel members (64).

7.2.3 Recruitment technique

Stakeholders from a range of relevant organisations will be invited to take part via email or telephone or social media. If they are interested, they will be asked to contact the research team via email or telephone, and a member of the research team will contact them about the study. We will also use a "snowball sampling" approach, and we will invite potential panel members to forward information about the Delphi exercise to other relevant potential participants.

Those interested in taking part will be asked to complete an expression of interest form via email. This form will collect some demographic and professional information about participants. This will enable us to recruit

up to 50 diverse stakeholders in terms of profession, age, years of experience, gender, ethnicity and geography (urban/rural, teaching/non-teaching etc) in each case study area.

7.2.4 Consent

For stakeholders, the invitation letter and information sheet will be sent out as an attachment to any email communications. The research team will then invite them to ask any questions they may have about the study.

All participants will provide informed consent. Written informed consent will be obtained from participants in the face-to-face interviews and audio informed consent will be sought from participants for video or phone interviews. With participant's consent, audio recordings will be made of all interviews. Verbal consent will be recorded and the audio file retained and stored separately to the interview data. Informed consent may also be documented via a remote survey using Redcap secure server.

7.3 Stakeholder Workshops (WP3)

Following the completion of the Delphi process, three consensus workshops will be held to develop recommendations. These will involve stakeholders drawn from patient and public representatives, professional organisations, public health professionals, and commissioners, and they will focus on knowledge exchange and rapidly translating the research findings into practice.

7.3.1 Eligibility Criteria

Inclusion criteria

People aged 18 years and older from a range of stakeholder organisations connected to the delivery of reproductive and sexual health services.

Exclusion criteria

- Although translated documents (for participant information leaflet and website information) will be also available in Welsh, participation will depend on the ability to understand English sufficiently to be able to provide informed consent and participate in the Delphi exercise and discussions. It is anticipated that only a very small proportion of those approached to participate in the research will be unable to understand English sufficiently.
- Health professionals and stakeholders whose role is not connected with the delivery of reproductive and sexual health services e.g. Dentist, physiotherapists, dieticians.

7.3.2 Size of recruitment target

There is no standard size for this type of workshop, but we will aim for 10-12 participants in each of the three workshops. We will aim for maximum diversity within the overall sample (e.g. age, gender, ethnicity, socio-economic status, healthcare professional occupational role and location, time since qualification) which will be monitored by keeping a chart listing each characteristic by each participant and keeping track of which characteristics each participant has to see what characteristics still need to be identified or whether there is an overinclusion of people with certain characteristics. We will invite approximately 50 people to be potential participants in the workshops, assuming a 25% rejection rate, yielding a final sample size of approximately 12 stakeholder members per workshop.

7.3.4 Recruitment technique

Stakeholders from a range of relevant organisations will be invited to take part via email or telephone or social media. If they are interested, they will be asked to contact the research team via email or telephone, and a member of the research team will contact them about the study. We will also use a "snowball sampling" approach, and we will invite potential panel members to forward information about the workshops to other relevant potential participants.

Those interested in taking part will be asked to complete an expression of interest form via email. This form will collect some demographic and professional information about participants. This will enable us to recruit up to 50 diverse stakeholders in terms of profession, age, years of experience, gender, ethnicity and geography (urban/rural, teaching/non-teaching etc) in each case study area.

7.3.5 Consent

For stakeholders, the invitation letter and information sheet will be sent out as an attachment to any email communications. The research team will invite them to ask any questions they may have about the study.

All participants will provide informed consent. Written informed consent will be obtained from participants in the face-to-face workshops and audio informed consent will be sought from participants attending workshops via video or phone. With participant's consent, audio recordings will be made of all workshops. Verbal consent will be recorded and the audio file retained and stored separately to the interview data. Informed consent may also be documented via a remote survey using Redcap secure server.

8. Ethical and Regulatory Considerations

8.1 Assessment and management of risk

Participants taking part in the qualitative interviews will be fully informed about what taking part involves before they provide consent to participate. Before taking part, the Participant Information Leaflet and Informed Consent Form will be given in person or sent by email, post or via a link to the study website (as preferred) to all service users, healthcare staff and stakeholders who express an interest. This will inform them about the interview topic and purpose of the research, and give them ample time to consider whether they would like to take part. The study information 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, 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.

Safeguarding of participants will be considered in accordance with local procedures.

8.2 Research Ethics Committee (REC) and other regulatory review & reports

8.2.1 Regulatory Review & Compliance

Ethical approval will be sought from NHS REC. The study application will include a copy of this protocol, completed IRAS form and all relevant documents including the drafted topic guides, consent forms, information sheets and invitation letters. Prior to applying for ethical approval from NHS REC, we will seek approval from the sponsor (University of Birmingham). Recruitment for the study will not commence until ethical approval has been provided by NHS REC and Health Research Authority and local R&D permissions including confirmation of capability and capacity have been obtained.

8.2.2 Amendments

The REC will be notified of any changes to the study dates or approved documents. We expect minimum, if any, changes to the methods outlined in this protocol and to the drafted documents. However, in the event of any changes made through discussion with the research team (and if necessary, the study steering group and PPIE group), the CI will be responsible for amending the protocol and deciding together with the University's Research Governance Team, whether an amendment is substantial or non-substantial. The key protocol contributor will communicate any agreed changes to the relevant stakeholders. We will keep a log of any protocol changes along with each protocol (the version labelled clearly) within our team's shared network.

9. Peer Review

The study was peer-reviewed and approved for funding by the National Institute of Health Research (NIHR) NIHR153151

10. Patient & Public Involvement

Members of the public and patients have been involved in helping to develop this research from its conception. We used individual interviews with users and potential users to discuss the proposed research and obtain views on remote consultations in sexual and reproductive health services. Two lay co-applicants have also advised us in the development of our research and grant proposal.

Our PPIE co-applicants helped us shape how PPIE will be structured and embedded into the research and they have/ will be specifically involved with the following activities:

- Helping to set up the PPIE advisory group (CONNECT Voices) to provide input to all aspects of delivery for the project
- Input to this protocol and ethics application including reviewing sections to ensure that they are suitable for a lay audience, that all aspects related to participation in the research were acceptable, and the public and patient input is appropriate
- Involved in monthly study management meetings
- Input to the selection of inclusion/exclusion criteria of participants
- Input to the locations and wording of advertisements to users or potential users asking them to take part in interviews
- Developing the topic guide for the interviews with users or potential users of services
- A Patient & Public Involvement and Engagement Group will be co-ordinated by a dedicated PPIE Lead

Our PPIE Lead and Inclusion Lead will be involved at all stages of the work, and will attend all major co-investigator research meetings. They will be involved in planning and delivery, particularly around the design and content of research materials, as well as with overall direction, collection of data, interpretation of findings and dissemination.

We will also actively involve a variety of patients and the public in all stages of our research via the 'CONNECT Voices' panel. We have already established the panel with support from our local NIHR RDS PPIE fund and it will be further expanded with support from Health and Care Research Wales. Our previous research has shown us that there are often sensitivities around talking about SRHS, and the involvement of panel members in developing the recruitment approaches and materials will help us to plan the research to ensure that it is inclusive and that we consider the best ways to ensure successful participant recruitment.

Panel members will also help us to think about interpretation of study findings and how the research study and our emerging results can be made accessible and shared with study participants and the wider public. Additional support for the PPIE work will be gained through consultation with the British Association for Sexual Health & HIV (BASHH) and Terrence Higgins Trust (https://www.tht.org.uk/) joint Lay Research Panel. This panel comprises a diverse range of lay reviewers who have received training in peer review. The BASHH/THT public panel will be consulted at an early stage of the project to help inform our PPIE strategy. We will provide regular updates to the group and seek advice on relevant issues. The panel will also help identify individuals to become members of the Expert Advisory Group and the Study Steering Committee (SSC) from communities with poor sexual and reproductive health, as a result of inequalities leading to reduced access to services.

Further, we will engage with the NIHR Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections, who are developing resources for PPIE in Sexual Health, in order to gain advice and input on our overall approach.

All 'CONNECT Voices' members will be reimbursed their expenses, paid for their time at INVOLVE rates and receive appropriate training for the tasks in which they are involved. We are aware that we are proposing research in an area of health that is often viewed as stigmatising, and in order to be inclusive, we will offer engagement via email as well as face-to-face, out-of-office hours activities, flexible levels of input and the option to contribute anonymously. PPIE training will be provided as needed through our links with local CRN PPIE teams and Patient Research Champions (PRCs).

11. Protocol Compliance

The study principal investigators along with the study coordinator will ensure protocol and GCP compliance by adhering to GCP standards and applicable regulations. Any accidental deviation will be documented according to guidelines from REC and sponsor (University of Birmingham).

Any deviation from the protocol or principles of GCP that is likely to affect the safety, rights of participants and/or data reliability and integrity will be deemed as serious and will be reportable to the REC and study sponsor in accordance with the sponsor's procedures for reporting serious breaches.

11.1 Qualitative interviews

Interviewers will be aware of the study methodology and relevant documents and are therefore informed of the protocol procedures. They will be reminded to review the procedures outlined in the protocol throughout the duration of the study to reduce the risk of accidental deviations.

12. Data Protection and Patient Confidentiality

All investigators and study site staff will comply with the requirements of the GDPR and the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Data will be stored and shared via Sharepoint at UoB and UCL. Screening data will be stored on Redcap.

12.1 Routine data -Case study quantitative analysis

This study will be registered with the University of Birmingham (UoB) and University College London (UCL) Data Protection Offices, as data will be stored in the UCL Data Safe Haven and UoB Secure Servers.

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 for the quantitative work; the UCL Data Protection Officer is data-protection@ucl.ac.uk. The data processors are UoB.

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 UoB Research Guidelines) 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 1):

- Depersonalised electronic routinely collected data from existing surveillance systems in England will be transferred from case study areas 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.
- Fully anonymous routine data will be transferred to restricted-access password-protected drives at UCL for analysis. The original data will be transferred by MFT to UoB for further analysis. The password will be provided by phone or encrypted online messaging service (e.g. WhatsApp) message.
- Access to pseudonymised abortion data for England and Wales will be requested from the Department of Health using the established process for researchers to access data relating to the notification of an abortion (form HSA04). Following NHS Ethical approval, this request will be subject to the Chief Medical Officer's(s) agreement and a confidentiality agreement. Once approval is received, pseudonymised data will be transferred the UCL Data Safe Haven via MFT.

12.2 Qualitative interviews

Personal information will be collected from patients and healthcare professionals that contact the research team with an interest in participating. Consent to be contacted will be recorded in the medical notes after the patient gives verbal consent to their details being passed on to the researcher, Following consent, contact information will be transferred to the Research Team based at UoB via NHS mail.net which is a secure email service. This information will be used to contact them and take informed consent. For those that are chosen to participate, we will keep their contact (name, number and email) and other personal data (age, gender, sexual identity, ethnicity and socio-economic status collected on the screening questionnaire) until the end of the study. Contact details will be deleted/destroyed for those who choose not to participate. Participant's contact details will in no way be linked to their interview data, and participants will be assigned a study ID code to ensure anonymity.

All files will be stored in password protected folders accessible only to the research team held securely on encrypted machines protected by passwords. All study data collected on paper will be held securely, in a locked room and within a locked cabinet that is accessible only to the research team and relevant regulatory authorities. Participants will be assigned a study ID code, which will be kept separate from any identifiable data (e.g. name, telephone number).

Audio files will be transcribed by a specialist external company subject to a contract and Confidentiality Agreements. Interview recordings will be stored on portable hand-held encrypted recorders in the first instance; they will subsequently be saved on the UoB secured network and deleted from the hand-held device at the earliest opportunity. Once interviews have been fully transcribed, original audio recordings will be deleted, however separate recordings of consent will be retained until the end of study. Interviews conducted remotely will be held via Zoom or Microsoft Teams on university approved accounts only and recordings will be saved on the University's secure servers.

All interview transcripts will be anonymised and saved securely on the UoB or UCL network. Only research team members responsible for analysing the data will have access to the full anonymised transcripts and only selected quotes from the anonymised transcripts will be included in the public domain (i.e. through peer-reviewed publications). PPIE representatives and members of the multi-disciplinary research team will have access to a selection of the anonymised transcripts to discuss and agree on emerging themes.

The text messaging service to send informed consent form surveys, screening questionnaire surveys and appointment reminders will be carried out using Firetext. The company is ISO27001 accredited for Information Security and are one of the very few SMS companies globally to have gained the Cyber Essentials + credential. They are also the main SMS provider for the UK Government via their GOV.UK Notify service and the NHS. A full list of their security badges can be found at: https://www.firetext.co.uk/about/our-badges.

13. Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage. This includes for harm to participants arising from the management, design or conduct of the research. No provision has been made for indemnity in the event of a claim for "non-negligent" harm.

This study requires no equipment and therefore no arrangements will be made for insurance and/or indemnity to meet the legal liability arising in relation to equipment.

14. End of Study and Archiving

For the participants, the end of study is defined as two weeks following their interview to allow for time for the participant to withdraw consent to using their data, and to allow the researcher time to send the participant's voucher as a thank you for their involvement (patients only).

The end of study is defined as six months after the date of the last data capture, and following resolution of all data queries. The CONNECT team will notify the main REC within 90 days of the end of study by completion of an end of study declaration form. If the study is terminated early, the REC will be informed within 15 days of the end of study. A final study report will be sent to the REC within 12 months of the end of study.

Data will be stored for 10 years after the end of the study at the University of Birmingham and UCL, then securely destroyed. The UoB is the data controller/data custodian for the study.

15. Access to the Final Study Dataset

Only the research team members that will be responsible for analysing the data will have access to the full (anonymised) transcripts. All other research team members including the PPIE representatives will have access to a selection of the transcripts for the purpose of discussing and agreeing on emerging themes. It is important to note that the transcripts will always be anonymised and in no way linked to participants' personal information or contact details.

Participants will be informed at the time of consent that the data we collect may be subject to future analysis to answer related research questions; though the data will always remain anonymised.

16. Dissemination Policy

16.1 Dissemination policy

The University of Birmingham will own the data arising from the study. The data will be kept securely on the University's servers for 10 years and then securely destroyed, as per the University's policy. Within one month following completion of the study, a final study report will be delivered to the funder (NIHR). The final study report will be peer-reviewed and circulated to relevant stakeholders within the Department of Health and Social Care and its partners. A summary of the final report will be made publicly available by the NIHR.

16.2 Authorship eligibility guidelines and any intended use of professional writers

We will follow the International Committee of Medical Journal Editors in determining authorship for any publication or materials presented at conferences. This will include members of the research team that contributed to the conception or design of the study or acquisition, analysis or interpretation of the data and drafted or revised the written content and approved the final version for publication and agreed to be accountable for all aspects of the work. Specific parts of the work that each author was responsible for will also be detailed in any peer-reviewed publication.

The final study report will include all named collaborators within our funding application along with additional members of the team that worked on the report and substantially contributed to the conception or design of the study or acquisition, analysis or interpretation of the data.

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18. Appendices

Appendix 1 – Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version:

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment