The East London Project

A participatory mixed-method evaluation on how removing enforcement could affect sex workers' safety, health and access to services, in East London

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Collaborators: Open Doors, Homerton Hospital, National Ugly Mugs, (SWISH)

Cohort Study Protocol, version 6

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Background and Overview

For a number of reasons, sex workers are sometimes more likely to experience violence[1], HIV and sexually transmitted infections (STIs)[2, 3] than people who do not sell sex, and some sex workers have higher levels of emotional health problems (e.g. stress, anxiety and depression) – disparities referred to as 'health inequalities'[4]. International research shows that sex workers who have experienced police enforcement (e.g. arrest, displacement via police raids), for example, are more vulnerable to these health problems than those who have not[5-7], for several reasons. Firstly, their work environments, safety strategies and access to health services may be disrupted: for example, they may move to more isolated places to avoid arrest, and where outreach services are less likely to reach them, or they may work alone to avoid being prosecuted for 'brothel keeping'[8-11]. Secondly, criminalisation can reinforce existing inequalities (e.g. housing and financial insecurity, stigma, insecure immigration status) – factors that, themselves, can have a negative effect on sex workers' safety, health and access to services[5, 7]. For example, a police record can make it difficult to access housing and, if desired, alternative employment; police fines can exacerbate financial insecurity; and stigma, coupled with fears of being arrested or deported, can discourage sex workers from reporting violence to the police[8, 12, 13]. Data from Sweden shows that criminalising sex workers' clients (similar to targeting 'kerb crawlers' in the UK) has similar effects[14]. Research also shows that decriminalising sex work (as in New Zealand) can improve sex workers' safety, health, and access to services[15]. There is a lack of quantitative evidence on this issue specific to the UK, where most aspects of sex work are criminalised (e.g. soliciting, kerb crawling, working with other sex workers or third parties) but where enforcement of these penalties differs by area. In East London, for example, the extent to which police arrest sex workers and their clients varies between the boroughs of Hackney, Newham and Tower Hamlets.

The project approach and components

We will use a participatory, mixed-methods research approach, with researchers, practitioners and sex workers working as partners, to design, conduct and make available the results of the research (see Project Team). The project has four key components (A-D). (A): a qualitative study; (B): a prospective cohort study, comprising two epidemiological surveys; (C) mathematical modelling; (D): collation of routine data.

This protocol relates to component (B) but will make reference to the other components, and the wider project, as appropriate.

We will carry out a qualitative study to understand *how* sex work-related laws and police enforcement affects sex workers' safety, health and access to care, in the three study boroughs (Hackney, Newham and Tower Hamlets). This will include interviewing sex workers, other people working in the sex industry and 'key stakeholders', and carrying out walks with sex workers and outreach workers, in the study boroughs. (B): We will also carry out two quantitative surveys, which will measure *how much* these laws and enforcement affects sex workers' safety, health and access to care, and how this changes over time. We will invite sex workers to fill in a questionnaire and, if they wish, to undergo screening for HIV, chlamydia and gonorrhoea, twice, about six months apart (when needed, we will facilitate access to treatment via Open Doors and Homerton Hospital). (C): Using the qualitative and survey results, we will develop a mathematical model – a simulation designed to

resemble the 'real world' - to predict how removing enforcement across all study boroughs could affect sex workers' safety, health and access to care. (D): Throughout the project, we will collect information on the number of arrests and other enforcement measures used against sex workers and their clients across the three boroughs, to help us develop the mathematical model.

Aims and Objectives

The overall aim of the project is to evaluate the impact of removing sex work-related police enforcement sanctions, on male, female and transgender sex workers' experiences of violence, HIV, STIs, emotional ill-health, and access to health and social care, in East London.

Our working definition of police enforcement sanctions includes the threat and enactment of: on-the-spot fines, warnings or arrests for soliciting, loitering, brothel keeping (sex workers) and kerb crawling (clients); raids on sex work venues (including anti-trafficking raids in conjunction with immigration teams); deportations (migrant sex workers); anti-social behaviour/dispersal orders for sex working; brothel-closure orders; confiscation of condoms as evidence of sex work, or of sex workers' funds under Proceeds of Crime Act (2002); and imprisonment for sex work-related offenses.

The working aim and specific objectives of the cohort study are outlined below. We will refine these in discussion with the project Advisory Group (AG) and through the qualitative study (component A)

The project has six linked objectives, **three of which (2, 4 and 5) relate specifically to the cohort study, component B:**

1. To estimate, with mathematical modelling, the effects of removing police enforcement sanctions on sex workers' experiences of violence, HIV, STIs, emotional ill-health and access to health and social care ('outcomes of interest'), in East London

2. To investigate the pathways through which police enforcement sanctions of sex work, and their removal, shape our outcomes of interest, including by interacting with other macro-structural, community and work-environment factors

3. To use formative qualitative data to further develop our working 'theory of change' model and define explanatory, mediating and outcome variables (OBJ 4)

4. To measure associations over time between (non-)exposure to police enforcement sanctions and outcomes of interest, including the mediating effect of other macro-structural, community and work-environment factors (based on our theory of change), to parameterise the mathematical model (OBJ 1)

5. To measure how the presence of a sex worker support service (e.g. Open Doors) changes police enforcement practices over time

6. To identify social, political, economic and operational factors that influence the acceptability, feasibility and implementation of non-enforcement, to inform any scale-up

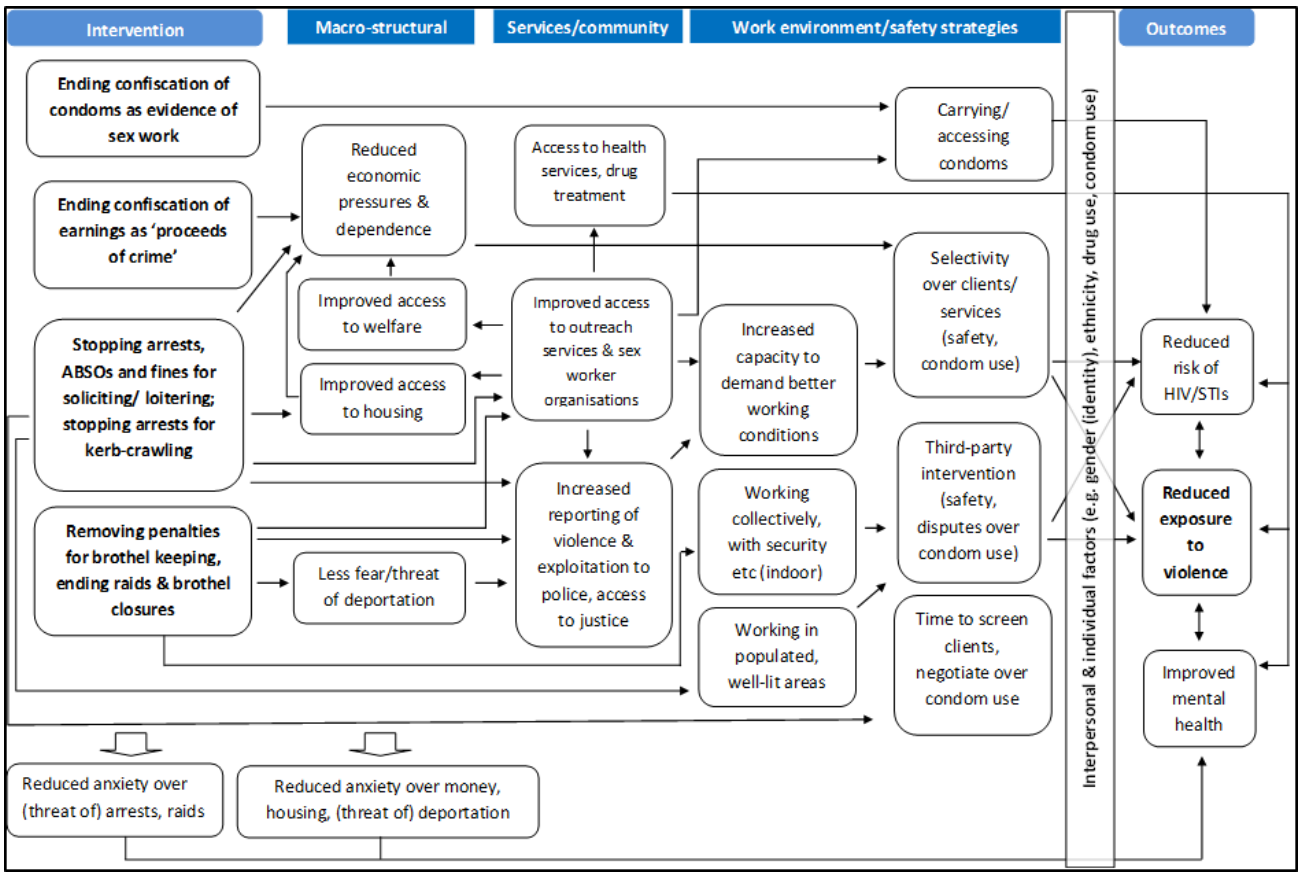
The project will address four research questions, **two of which relate specifically to the cohort study, component A (RQs 2 and 4):**

RQ1: What is the estimated impact of removing police enforcement sanctions on sex workers' health (violence, HIV, STIs, emotional ill-health) and access to health/social care?

RQ2-3: How (RQ2) and **to what extent (RQ3) do police enforcement sanctions and their removal affect sex workers' health and access to health/social care, including in interaction with other macro-structural, community and work-environment factors?**

RQ4: What are the social, political, economic and operational factors that influence the implementation of removed police enforcement sanctions of sex work?

Hypothesised mechanisms of the effect of removing police enforcement on sex workers' health, and their interplay with macro-structural, community and work environment factors, are depicted in our working theory of change (Fig. 1).



Research team (Component B)

Lucy Platt (Associate Professor in Public Health Epidemiology, LSHTM) is the Project PI, survey and mixed-methods lead. She will oversee the management of the project, and will lead components B and D, and the overall mixed-method study design. She has extensive expertise in the epidemiology of sex workers' health and safety.

Jocelyn Elmes (Research Fellow, Department of Social and Environmental Health Research (SEHR), LSHTM). Jocelyn will be responsible for the day-to-day management of the cohort study, including: setting up the system for follow-up of participants; recruitment methods; provision and feedback of HIV/STI testing; confidential storage of behavioural data; and supervision of eight co-researchers (see below). She will work under the guidance of Dr Lucy Platt and Co-I Dr Sarah Creighton. She will collaborate with Pippa Grenfell and Maggie O'Neil over participatory research methods and integrating findings from the qualitative study into the cohort study and she will work closely with Georgina Perry to design recruitment

Dr Sarah Creighton, GUM (genitourinary medicine) consultant at Homerton Hospital, will advise on providing testing and treatment to survey participants. She has extensive experience of providing healthcare services to sex workers in East London.

Co-researchers

Eight co-researchers, who have experience of sex work or working closely with sex workers (e.g. in sex worker support services), will be appointed on a freelance basis to: recruit around two thirds of participants into the cohort at baseline to complete questionnaires and offer testing for HIV, gonorrhoea and chlamydia; they will follow up participants 6 months later to repeat the study including the questionnaire and provision of HIV/STI testing.

Wider Project Team

Pippa Grenfell, Research Fellow, Department of Social and Environmental Health Research (SEHR), LSHTM - Co-PI, qualitative and participatory lead

Pippa is a sociologist with expertise in qualitative, mixed-methods and participatory research on the social and structural context of violence, HIV and other health risks that sex workers, and other marginalised and criminalised populations, may face. Pippa is responsible for day-to-day management of the qualitative study, including study design, conduct and reporting, and supervision of two co-researchers

Professor Maggie O'Neill**,** Chair in Sociology (Criminology), University of York - (co-I) Maggie is an applied sociologist/criminologist with over 25 years of experience of participatory research with sex workers. She will advise on qualitative methods (particularly the use of neighbourhood walks) and the wider participatory research approach, as well as on conceptualising and measuring sex work-related police enforcement.

Prof. Peter Vickerman (co-I), Chair in Infectious Disease Modelling at the University of Bristol, will lead the mathematical modelling (component C), in collaboration with Prof. Marie-Claude Boily (co-I), Chair in Mathematical Epidemiology at Imperial College. They both have expertise in developing mathematical models to understand how HIV and other health risks faced by sex workers are spread and can be reduced, including through public health interventions and law reforms (e.g. decriminalisation). Prof. James Hargreaves, professor in Epidemiology and Evaluation at LSHTM, will advise on the overall implementation of the project. He has expertise in evaluation methods, including in relation to sex work. Georgina Perry, Chair of the National Ugly Mugs Board (see Collaborators), will advise on meeting and keeping in contact with potential study participants (components A & B), as well as on study design, interpretation and community engagement. She managed sex worker support service Open Doors for 13 years (see collaborators, below).

Collaborators

Our key project partners are Open Doors, National Ugly Mugs, Homerton University Hospital and SWISH. Open Doors is a specialist health and social care service, providing outreach and clinical services, for sex workers in East London, affiliated with Homerton University Hospital NHS Trust. National Ugly Mugs is a pioneering, national organisation which provides greater access to justice and protection for sex workers who are often targeted by dangerous individuals but are frequently reluctant to report these incidents to the police. SWISH is a sexual health service working with transgender sex workers.

Advisory Group

This project is steered by an advisory group with representatives from local sex worker and resident communities, the English Collective of Prostitutes, National Ugly Mugs, City and Hackney Local Authority, Newham Metropolitan Police, Public Health England, Lancashire Police, Imperial College, University of Leicester and University College London. The group will meet 4 times, at LSHTM, during the course of the project and will provide advice on: research design; information for participants (information sheets, recruitment advertisements, referral/services information); development of study instruments; sampling and recruitment; interpretation of findings; formulation of recommendations; approaches to involving and engaging sex workers, residents and the public in the research; and strategies for feeding findings into advocacy and policy. Individual members are also being asked to comment on study documents – for example, participant information sheets, recruitment advertisements, interview topic guides.

The first advisory group meeting has already taken place and has fed into the development of this study protocol.

Community representatives (sex worker/resident members) receive compensation for their time spent preparing for and attending advisory group meetings, and commenting on study materials/strategies outside of these meetings, at a rate of £20/hour, in line with the National Institute for Health Research (NIHR)'s INVOLVE guidelines, to constitute reimbursement for involvement in research, not employment (http://www.invo.org.uk/posttypepublication/what-you-need-to-know-about-payment-2/). We also reimburse travel expenses and out-of-pocket expenses pre-agreed with the PI. We ask community representatives to consider the implications of these payments for any government benefits they are currently receiving.

Methods

Participatory research approach and public involvement/engagement

Using a participatory mixed-method evaluation design[17], academics, practitioners and sex workers will work as partners to make decisions over how the research is designed, conducted and used (see Project Team). Together, we will use the results to advocate for evidence-based policy and practice to improve the safety, health and well-being of sex workers in the UK and internationally.

In addition to working with community advisory group members, we will hire eight co-researchers to contribute to the quantitative study design, data collection, analysis and dissemination phases. Co-researchers will: have experience of sex work themselves, of working with sex worker support services, or be members of sex worker organisations.

Co-researchers will provide advice and input in relation to study processes outlined in this protocol and associated documents (e.g. questionnaire, participant information sheets).

Before data collection, we will provide co-researchers with a two day training course in relation to: recruitment methods; research ethics; the study protocol; the wider project; and specific ethical and safety considerations related to the project. Training will comprise interactive presentations, applied exercises and interview role-playing. After the training, co-researchers will each carry out a 'pilot' interview with another member of the research team and collaborator to practice the recruitment process, gaining informed consent, administering the questionnaire and voluntary HIV/STI testing and the process for follow-up and feeding back HIV/STI tests results. Once fieldwork begins, we will provide ongoing opportunities to further develop research skills during team meetings (see Analysis).

Throughout the project, we will support all interviewers through daily debriefings (see Analysis). All researchers will also have access to confidential counselling (see Researcher Safety and Well-being).

Preparation and consultations

All aspects of the study protocol will be informed by the qualitative study that will be completed prior to field work. This will involve: consultations with community organisations, service providers, academics and local residents; 30 in-depth interviews with sex workers (cis and transgender men and women); 30 in-depth interviews with key stakeholders (representatives from the police, clinical services; sex worker specialists services and activists); six neighbourhood walks with sex workers and outreach workers from collaborating partner organisations. This preparation will inform the working definition of enforcement and wider 'theory of change' (Figure 1); our research methods, tools and processes (e.g. mapping, sampling and recruitment, questionnaire, referral information/processes for participants); how best to involve and engage sex workers and others in the research; and dissemination plans.

Design

The cohort study (B) will comprise a baseline survey (wave 1) and then a follow-up survey 6 months later (wave 2) using structured questionnaires to collect behavioural

data on hand-held computers and offering testing for HIV, gonorrhoea and chlamydia using self-collected devices.

Sampling and recruitment

At wave 1 we will recruit 450 sex workers into the survey across London boroughs. We will recruit subsamples of cisgender men (80) and transgender women (80) across all sites to reflect the diversity of the sex work population. In order to ensure all diverse groups are included in the study, we will monitor the characteristics of sex workers recruited in terms of gender; immigration status; ethnicity, work sector (e.g. street, flat, sauna, agency, independent) duration and recency of sex work in the boroughs, membership of sex worker organisations, current/past substance use, and experience of sex work-related enforcement/criminal justice involvement (see 'Recruitment'). We will also refine our recruitment strategy should we find that certain groups are under-represented or based on emerging findings from the qualitative study (for example, if participants tell us that people who sell sex in certain areas of a study borough are more/less at risk of police contact, we would actively recruit participants working in these areas). We anticipate recruiting 90 participants per month for a period of seven months.

Inclusion criteria

All sex worker participants will currently exchange, or in the ***last three months*** have exchanged, direct sexual services for money, drugs or other material goods in London. They will be aged 18 or over and be capable of providing informed consent to participate in the research (survey questionnaire and voluntary HIV/STI testing).

Exclusion criteria

The following people will not be eligible to participate in this study:

— People with experience of selling sex who: are aged under 18 years old; are not capable of providing informed consent; have not exchanged direct sexual services for money, drugs or other material goods, in the past three months.

— People with experience of working in the sex industry (other than selling sex).

Recruitment

Participants will be sampled using several approaches. Firstly we will use time-space sampling[16] where sex work locations will be mapped out through the qualitative study and the neighbourhood walks and by mapping sex workers' on line advertisements (off-street and independent workers). Key characteristics of sex workers (gender identity, ethnicity, numbers) and locations including busy times will be documented for use by the research team only using codes to indicate specific streets, they will not be made public at any point during the course of the research. Locations will then be selected randomly, and every individual in each location is approached to participate in the study. At the end of the research any information related to the mapping will be destroyed.

Secondly, further snowball sampling and targeted recruitment will be conducted to maximise the number and diversity of study participants (i.e. street, off-street and by gender).

Thirdly we will recruit participants through NHS sex worker-specific services (clinics and outreach), sex worker/community organisations, snowballing and by directly contacting sex workers through co-researcher contacts.

We will recruit sex worker participants via the following NHS sites: Open Doors outreach services; sex worker clinics at Newham University Hospital, Homerton University Hospital; the Royal London Hospital (in collaboration with Barts Health); 56 Dean St and CliniQ. The latter two services are located outside of East London but run clinics specifically for gay/bisexual men and transgender people, respectively, including but not limited to people who sell sex.

We also plan to recruit participants via: (i) local sex worker and community organisations who work with sex workers (e.g. Sex Worker Breakfast/X-talk; the English Collective of Prostitutes, Sex Worker Advocacy and Resistance Movement, Doctors of the World, U-turn; SASH); (iii) by advertising on National Ugly Mugs and other websites/social media fora aimed at sex workers, and through a project Twitter account (see attached recruitment advertisement); (iv) via social networks, asking participants to refer other people they know who fit the study eligibility criteria to the research team; (vi) approaching sex workers and sex work venues directly (via online/newspaper advertisements), subject to the advice of our co-researchers, collaborating partners and advisory group.

At NHS and other collaborators' sites, we will ask staff to facilitate recruitment of participants (see 'Confidentiality and Anonymity'). For NHS sites, this will take place after we have received the approval of research/clinical leads at each site, Research Passports for interviewers, and relevant ethics and research governance approvals (see 'Approvals'). Members of the research team will be available to attend clinics, drop-ins, outreach sessions and so on, where this has been agreed with collaborating organisations in advance, so that staff may introduce potential participants to the researchers, and/or the researchers may inform them about the study directly.

Data collection

Prior to beginning data collection, we will pilot the questionnaire and assess feasibility of recruitment approaches (see Participatory Approach). Interviews will take place in a private room in collaborating clinical or community organisation settings, at LSHTM, in a quiet café/outdoor space or the participant's workplace or home if (s)he wishes, and subject to risk assessment and concerns for confidentiality (see Confidentiality, and Researcher Safety & Well-being).

Cohort study – baseline survey (wave 1)

We will build on the mapping (during neighbourhood walks) conducted through the qualitative study by immediately prior to the survey start, mapping on-line sex work adverts and websites. Following the mapping a list of sex work locations will be drawn up and a random selection of sites will be chosen. (see Recruitment above) All mapping will take place in a private room in collaborating clinical or community organisation settings, at LSHTM, in a quiet café/outdoor space or the co-researchers' workplace or home if (s)he wishes, and subject to risk assessment and concerns for confidentiality (see Confidentiality, and Researcher Safety & Well-being). Maps of sex work locations will be stored in locked cabinet. Maps will be anonymised and a separately stored code used to identify street names, in order to protect inadvertent disclosure of sensitive information.

Self-completed questionnaire

LSHTM staff and co-researcher will assist participants to complete a structured questionnaire on hand-held computers to collect self-reported data on:

- Experience or fear of the following police enforcement sanctions of sex work, ever and in the past 6/12 months: warnings or arrests for soliciting, loitering, brothel keeping (sex workers); working in areas where warnings/arrests are issued for kerb crawling (clients); receipt of anti-social behaviour or dispersal orders for engagement in sex work; raids and issue of brothel-closure orders on one's working premises; confiscation of condoms as evidence of sex work, or of sex workers' funds under the Proceeds of Crime Act (2002); and imprisonment for sex work-related offenses.
- Demographic characteristics including age, gender identity, ethnicity, years of education, condom use, number of clients, immigration status
- Access to health and social services including housing, welfare and social services, drug and alcohol services, STI clinics, sex worker support services, sex worker/community organisations, harm reduction, sexual violence services, primary/secondary health care services, mental health, legal support, immigration advice, dentists, reproductive health and gender transitioning.
- Working practices, environments and conditions including sex work income, work venue type, level of autonomy, security strategies, collective working, working hours, services, condom use, reporting to police, mobility across boroughs, duration and nature of client selection and screening,
- Experience of physical or sexual violence (enacted, threatened or attempted) by clients, other parties at work, police, non-paying partners and others outside of work, ever and in the past 12 months. Physical violence includes being hit, attacked with a weapon or kidnapped. Sexual violence includes forced sex; touched against one's will; and forced/tricked into providing a sexual service (e.g. unprotected sex) without consent or payment.
- Emotional health outcomes, including depression and anxiety.
- Sexual practices with paying and non-paying partners including condom use.
- Drug and alcohol use including type and frequency.

Questionnaires will be self-completed by participants on a hand held computer and translated into key languages spoken by sex workers in the boroughs (e.g. Lithuanian, Portuguese, Romanian, Russian, Spanish). For participants who cannot read, we will use an audio device that read out questions, for those whose language is not represented, we will use a translation service (see Translation below).

For participants recruited online via online adverts, we will email them a web link that will allow them to access a secure and encrypted version of the questionnaire to be self-completed online.

HIV and STI testing

Each participant will be offered voluntary testing for HIV, via oral fluid samples, and Chlamydia and Gonorrhoea, via self-collected NAAT vaginal swabs (ci gender women), rectal swabs and urine samples (cis gender men and transgender participants).

Participants will be offered a test for HIV antibodies through oral fluid collection device 'oraquick' (positive predictive value: 97.7%; negative predictive value: 99.6%2). All positive tests will be followed by a confirmatory HIV 4th generation antibody test, with sensitivity and specificity of 99.9% and 98.8% respectively.[17] Self-collected tests for Chlamydia and Gonorrhoea will comprise Hologic, Aptima Combo 2 Assay (Panther System) (rectal and pharyngeal swabs for all genders; vaginal swabs for women; rectal urine samples for male and transgender participants), the sensitivity and specificity of which are high (CT 95%CI: vaginal 91-100%, male urine 95-99% throat 100%, rectal 71-100%; NG: vaginal 84-100%, male urine 97-100%, throat 88-100%, rectal 75-100%).[18] Co-researchers will follow protocols to collect biological samples, under the direction of Sarah Creighton (co-I) and as used by Open Doors on outreach. Samples will be sent by post in self-sealed envelopes to The Doctor's Laboratory (TDL), at the end of each fieldwork day, for testing. Automated text messages will be sent from The Doctor's Laboratory to inform participants of their results (see clinical protocol). In the case of a positive result, LSHTM staff will facilitate access to counselling and treatment by Sarah Creighton who will report back to the participants the results of the test. The clinical protocol is attached in a separate document.

Data collection will be aligned with existing services as far as possible. For participants registered with Open Doors, we will ask permission to access their last test results (within the last month), to avoid the inconvenience and potential deterrent of having to provide a biological sample.

For others, we will offer testing for HIV using oral fluid tests, and Chlamydia and gonorrhoea via self-collected vaginal swabs and rectal/urine samples. We will ensure that data collection occurs in a location where there is a toilet so that participants can use the vaginal/rectal/urine swabs comfortably and in private.

Testing and access to clinic test results will be optional and not a requirement for participation in the study.

<u>HIV/STI testing for participants recruited online</u>

Participants recruited online will be offered the option of using an online testing service via TDL that provides standard clinical tests through an anonymised testing service. Participants will need to provide their phone number to receive negative results and an address to which the test can be sent. These will be entered on the secured LSHTM online server. Once submitted an automated encrypted email with the address will be sent to TDL patient team, Addresses will be deleted from TDL once the order has been fulfilled. All negative test results and positive Chlamydia or Gonorrhoea results will be sent via an automated text message. Positive HIV test results will be delivered by Sarah Creighton the research team in order to facilitate access to treatment.

All samples receive attention on the day of receipt and results are available within 24 to 72 hours of receipt. Once the laboratory has completed its analysis, it transfers results securely by the HL7 message framework to TDL. TDL will deliver results to participants using the same SMS content as described above. Participants will also be asked their date of birth. They won't have any other identifying information on

the participants and positive results will be followed up by a clinical team led by Sarah Creighton who will contact them within 10 working days of the SMS (or 3 working days in the case of HIV). The research team will have access to the database used by TDL so that data can be extracted on participants using a unique code.

Follow up

After the completion of the questionnaire at wave 1, we will seek participants' consent to re-contact them and store their contact information in a secure database, accessible only to the research team, to facilitate follow-up (see attached for consent sheet and contact information form).

Contact information will include: participant's name (or a pseudonym if preferred); mobile number and e-mail address; and other telephone numbers where the participant can be reached without risk of unintended disclosure.

For participants using Open Doors' services, we will seek their consent to re-contact them via the outreach team. A study website will provide updates on study progress and links to support agencies (with content guided by peer interviewers, collaborators and the advisory group) with a log-in area for participants only. This will help people to interact with the study, to encourage participation and facilitate follow-up. Involving co-researchers in recruitment will help to reach and maintain contact with study participants throughout the project.

Cohort study - follow-up (wave 2)

For those consenting to be followed up we will re-contact participants via their preferred method of communication after 7 months. Participants will be asked to complete the same self-completed questionnaire (see self-completed questionnaire) and offered testing for HIV, gonorrhoea and chlamydia (see HIV/STI testing).

We anticipate that up to 20% of participants will be lost to follow up at wave 2 (7 months after wave 1). We aim to follow up 360 participants including 64 cisgender men and 64 transgender women at wave 2.

Retraining

Prior to data collection we will undertake further training of newly employed co-researchers or refresher courses for existing team members in all aspects of the study protocol. Training will include strategies for re-contacting participants.

Translation

For potential participants who do not understand or speak sufficient English to be able to consent to and/or participate in the cohort study without translation, we will offer in-person or phone-based simultaneous translation (depending on the participant's preference), with a qualified interpreter. Interpreters will be experienced in simultaneous translation, as well as providing interpreting services in healthcare and/or research in relation to sensitive issues. They will be fully briefed on the study focus and will be bound by a confidentiality agreement and Terms of Reference, requiring that they do not discuss any aspect of the interview or the participant with anyone other than the research team.

Debriefing

Jocelyn and Lucy will be available to debrief with co-researchers at the end of each field work day. We will hold monthly meetings during the course of the data collection, during which, Lucy, Jocelyn and the eight co-researchers (and Pippa and qualitative co-researchers, depending on availability) will review the characteristics of the sample recruited and future data collection needs. We will also invite co-researchers to contribute to the interpretation of the data, write up and dissemination, subject to interest, availability and resources.

Ethics and Research Governance (Component B)

Informed Consent

All potential participants will be provided with complete information about the study, in order to allow them to fully consent before taking part. We have designed information sheets and consent forms (see attached) to be understandable to people aged 18 and above. We have piloted these documents with community and other representatives of the study advisory group(s) for acceptability and comprehensibility. Information leaflets and consent forms will also be translated into the main languages spoken by sex workers in East London (e.g. Lithuanian, Portuguese, Romanian, Russian, Spanish).

Potential participants will be given as much time as they need to decide whether or not to take part in the study. We will encourage participants to discuss any concerns they have regarding participation with the interviewer, an outreach/support worker (e.g. from Open Doors, National Ugly Mugs) and/or a sex worker organization (e.g. English Collective of Prostitutes, Sex Worker Advocacy and Resistance Movement). We will be available to answer any questions that potential participants have about the study, in person or by telephone.

We will ask all participants to consider whether or not their participation in the study could cause them any personal or professional problems (see Participant Information Sheet).

We will stress to potential participants, and to recruiting clinical and community staff: the confidentiality and anonymous nature of the study; that participants are fully entitled to refuse participation, and to withdraw from the study at any point without giving a reason; and that this will have no implications for their care, treatment or support from recruiting services. It will also be stressed that their participation in this study does not form a part of their health care and/or support provided by these organisations. If, having read and understood the information sheet and had all their questions addressed, participants feel willing and ready to participate, we will offer the opportunity to take part on the same day, or to schedule the activity for a later date that is convenient to them.

For participants who have specific physical or emotional health needs, or who use drugs or alcohol, it is important to consider the potential effects on their ability to provide informed consent. The researcher will be mindful of, and assess, each participant's mental and physical state before beginning a neighbourhood walk/interview. If the participant appears to be in pain or distress, significantly intoxicated, experiencing severe drug withdrawals or intrusive treatment side effects, it will be tactfully arranged with the participant for the interview to be conducted at another time.

Participants will be asked to sign and date a written consent form (see attached).

In the case that a participant is unable to read the participant information sheet or consent form, a third-party witness other than the interviewer (e.g. a staff member/volunteer from a collaborating organisation not involved in the research) will provide a verbal summary of the information sheet and outline of the research process before written consent is obtained. If the participant is unable to provide a written signature, (s)he will be asked to mark the consent form with an 'X' in the presence of the third-party witness who will also sign the consent form ('witness' name and signature' section).

During the informed consent process, the interviewer will make participants aware that we are obliged to report any harm to a child (e.g. physical or sexual abuse), or significant and immediate danger to participants themselves (e.g. suicidal feelings), that we become aware of during interviews. We will stress that we would only do so after informing the participant, and ideally with their consent. In this case, we will seek guidance from Open Doors and SWISH to ensure we fulfil our duty of care while minimising harm to participants.

Confidentiality and Anonymity

All data will be treated as confidential, except when an issue of serious potential harm to the participant or a child is disclosed. Confidentiality will be broken if the participant tells us about harm to a child (e.g. abuse) or significant and immediate danger to themselves (e.g. suicidal feelings). When seeking participants' informed consent, we will make them aware of this (see Informed Consent, above).

Participants will be assured that their personal information will be protected at all times, and that they do not need to provide us with their real name; instead they can use a work name, a nick name or any other name they choose. This is in accordance with ethical good practice for research and service provision with sex workers[26], on the basis of concerns around disclosure, stigma and criminalisation.

For participants recruited via collaborating clinics/outreach services and for those who do not wish to undergo testing for HIV, gonorrhoea and chlamydia but consent to having the results of a recent test shared with the research team, it will be necessary for field workers to collect information from the participant in order to extract test results from clinical records. The information shared would include two out of three items of information: (1) Clinic number; (2) date of birth (this does not have to be the real DOB just the one the provided the clinic); (3) name used at registration of clinical services (this does not have to be a real name). This identifying information would be linked to the participant's research identification number via a code stored in a separate database but unlinked from other behavioural data collected through the questionnaire (see Data Storage and Protection).

The consent process would involve three stages. The research staff would first gauge his/her interest in receiving an HIV/STI test as part of the research. If (s)he declines, the research team will seek the participant's consent to extract results of recent tests for HIV, chlamydia and gonorrhoea from Open Doors or other GUM clinic. Staff/volunteers will transfer this information to the research team using secure nhs.net email (see clinical protocol). At no point will participants' personal information be transferred on an open access answer-phone or non-nhs.net email.

Similarly, for those participants wishing to undergo testing for HIV, chlamydia or gonorrhoea or who consent to be followed-up at the second wave, contact information will be collected. TDL will follow relevant standard clinical pathology and Good Clinical Practice guidelines. TDL will only be given a mobile phone number and the gender of the participant. Participants can also opt out of automated text

message and for the LSHTM research team to communicate results instead. TDL will follow their standard clinical guidelines to protect confidentiality of participants including using plain envelopes to send STI kits and identifying results through a unique code. A separate consent procedure will be administered for those wishing to be followed-up (see attached). Again, this information would be linked to the participant's research identification number via a code stored in a separate database but unlinked from other behavioural data collected through the questionnaire (see Data Storage and Protection).

When summarising findings of the survey, participants will not be named or otherwise identified in research reports. No individual-level data will be presented that could inadvertently identify a person. All data included in published and unpublished reports will be aggregated, removing any potentially identifiable demographic markers, to ensure that participants' anonymity is protected (see Data Storage and Protection). No details of specific locations (e.g. maps, street names, escort agency websites) will be made publicly available in any reports or presentations arising from the study, in accordance with good practice guidance published by the Global Network of Sex Work Projects [18].

Incentives and Expenses

Participants will be provided with a cash[1] incentive worth £20 for participating in an interview. This is not to be seen as an inducement to participation but rather as a recompense for the time and effort participants have contributed. This value is in line with other recent and ongoing studies at LSHTM and in London.

Managing Potential Risks and Referral to Support Services

There are no specific risks to participating in this study. However, the topics explored in the questionnaire are sensitive and may identify additional support needs. During all aspects of the research we will take a sensitive, non-judgmental approach, assuring participants of the confidential and anonymous nature of the questionnaire, and that they do not need to answer any questions that they do not wish to. All participants will be encouraged to take breaks and/or close the interview when they feel it is necessary to do so.

Our collaborators will be well briefed on the focus of questionnaire, and are able to provide participants with additional support, including through existing referral pathways. However, some participants may not be currently in contact with services. We will provide all participants with information and contact details for sex worker organisations, and sex worker-friendly health and social care services that they can contact, or that the research team can contact on their behalf if they so wish. We will provide information on organisations that provide support and advice on health, safety, legal aspects of sex work, and related health/social care issues (e.g. sexual assault, housing, benefits, immigration, sexuality and gender identity, drug treatment). This information will be made available in the main languages spoken by sex workers in East London. For participants concerned about their eligibility for care or support (e.g. migrants/asylum seekers), we will refer them to services that can provide immediate care and help them access NHS and other

[1]Cash will be offered where this has been agreed to in advance with the clinic/community organisation that the participant has been recruited through, to ensure that we do not conflict with organisational policy regarding monetary incentives. Offering cash instead of vouchers is strongly recommended by sex worker/community members of our advisory group and research team.

services (e.g. Doctors of the World). For participants recruited and completing the questionnaire online, we will email copies of the relevant support information and advice lines. These will also be available on our website.

Provision of biological samples, or consent to accessing clinical test results will be optional. Should testing be taken up we will ensure that there is a toilet in which participants can use the self-collected devices comfortably and unobserved. Clinical results from diagnostic tests will be reported back to participants and treatment offered through GUM consultant and co-I Sarah Creighton to ensure that duty of care towards participants is observed.

Potential Benefits to Study Participants

This study will not directly affect the care and treatment that participants receive. However, we will use the findings to inform advocacy for policies and practices that protect sex workers' safety, health, access to services and broader rights. We will seek to maximise the community impact of the study by feeding findings into advocacy efforts through our participatory research approach, and through our engagement with sex workers, local communities, activists, practitioners and policy makers in the fields of sex work, health and social care, and criminal justice (see Reporting, Outputs and Dissemination).

Maintaining Contact with Participants

We will provide all participants with a contact phone number and email address for the research team. We will also ask participants if they would like us to keep in touch with them about the project and the results. If they do, they will have the option of following project updates on the website, following the project on twitter, signing up to a regular newsletter by email (including project updates and links to useful information/services), or of providing us with a contact phone number or email address so that we can inform them about future events and publications. For those participants who consent to being followed-up in wave 2, we will re-contact them via their chosen method (see follow-up) after 7 months. We will also send these people an automated text message at 1 month and 5 months to remind them of the project and to let them know that a member of the research team will be contacting them soon.

Data Storage and Protection

The names and contact details of participants used for: (1) follow-up for reporting back results of HIV/STI tests undertaken; or (2) follow-up for re-contacting participants at wave 2); or (3) information provided by participants to extract clinical data (see Confidentiality and Anonymity), will be kept separately in password-protected Excel spreadsheets. Each of these three databases will use different passwords to each other. Behavioural data from the questionnaire will be stored in a fourth database with a unique research ID number, stored in a password protected file. Biological data (HIV/STI test results) will also be stored under the same research ID number (database 5) in order to link behavioural and biological data together. A separate unique contact code will be used that can link all contact information to the research ID number. This code will be kept separately in a sixth database in a password protected file and only used when necessary to link contact information for reporting back test results. Otherwise the linked biological and behavioural data will be unlinked from all identifying information (e.g. consent forms, contact information) to protect the identity of individuals. A monitoring log will also be kept

recording key demographic characteristics of the sample alongside the Research ID number in order to monitor the characteristics of the sample during recruitment. Data will be saved on a shared LSHTM drive, accessible only to members of the research team via their unique LSHTM login. The database (6) linking unique codes to Research ID numbers will be kept on a separate computer and not on a shared LSHTM drive. Data will be stored in accordance with the Data Protection Act 1998 and to ensure it is compliant with the revised General Data Protection Regulations

Database	**Contents**	**Identifier**
1	Contact information for reporting back HIV/STI results	Contact code
2	Contact information for re-contacting participants at Wave 2	Contact code
3	Contact information to extract previous test result from clinical data	Contact code
4	Behavioural data from questionnaire	Research ID
5	HIV/STI test results	Research ID
6	Database to link Unique ID with Contact code	
7	Monitoring log	Research ID

Researcher Safety and Well-Being

For fieldwork conducted outside of collaborators' premises and/or in the absence of staff/representatives from these organizations, interviewers will work in pairs and we will operate an 'on-call' system, whereby another member of the research team is aware of the researchers' whereabouts and expected finish time and has a contact phone number for them. Researchers will ensure that their mobile phones are charged and will inform the on-call researcher if they anticipate poor reception or low battery. The researchers will contact the on-call researcher on arrival at the fieldwork site and again at the end of fieldwork. If the on-call researcher doesn't hear from the researchers within 2.5-3 hours of the start time, (s)he will call/text them at 30-minute intervals until (s)he is able to make contact. Given the sensitivities around police contact in the context of this project, the on-call researcher would only call the police as a last resort (i.e. in the exceptional circumstance of being unable to make contact with either researcher, having exhausted all means of communication).

In addition to weekly debriefs, Lucy and Jocelyn will ensure that all co-researchers have adequate and ongoing opportunities to talk through any difficulties or concerns they have experienced/felt in relation to the field work. They will discuss these issues with Maggie and Pippa, as appropriate, to ensure that the necessary support is in place. Co-researchers will be provided with information on how to access free and confidential counselling services through LSHTM

(http://www.lshtm.ac.uk/humanresources/counselling/), and/or by referral to appropriate NHS counselling services if preferred.

Approvals

We will seek ethical approval of this study from the LSHTM Ethics Committee, and an NHS Research Ethics Committee, seeking site-specific approval for each collaborating clinic. All interviewers will apply for Research Passports from the R&D departments of the NHS trusts corresponding to collaborating clinics, to allow us to recruit and interview participants in/via collaborating clinical services.

Ethics in Progress

We will monitor and document any ethical concerns arising during the project, via individual debriefs immediately after interviews, written field notes (see 'Data Collection' and 'Analysis'), and ongoing, minuted discussion of these and other potential ethical issues, with the project PI and across the research team (during team meetings). Where necessary, we will discuss these concerns with our collaborators and participants, in accordance with the above outlined provisions to protect anonymity and confidentiality (see 'Confidentiality and Anonymity'). Jocelyn and Lucy, in discussion with Pippa, George and Maggie where necessary, will ensure that any safety and/or ethical concerns are addressed promptly, and that appropriate action is taken when needed.

Reporting, Outputs and Ongoing Dissemination

See attached, project-wide dissemination plan

Appendices

Participant information sheet

Consent form

Draft questionnaire

Clinical protocol

Follow-up contact form

Follow-up consent form

References

1. Ward H, Day S, Weber J. Risky business: health and safety in the sex industry over a 9 year period. STI. 1999 Oct;75(5):340-3

2. Mc Grath-Lone L, Marsh K, Hughes G, Ward H. The sexual health of female sex workers compared with other women in England: analysis of cross-sectional data from genitourinary medicine clinics. STI. 2014 Jun;90(4):344-50

3. Mc Grath-Lone L, Marsh K, Hughes G, Ward H. The sexual health of male sex workers in England: analysis of cross-sectional data from genitourinary medicine clinics. STI. 2014 Feb;90(1):38-40

4. National Institute for Health and Care Excellence. Health inequalities and population health 2012. Available from: https://www.nice.org.uk/advice/lgb4/chapter/introduction.

5. Deering KN, Amin A, Shoveller J, Nesbitt A, Garcia-Moreno C, Duff P, Argento E, Shannon K. A systematic review of the correlates of violence against sex workers. AJPH. 2014 May;104(5):e42-54

6. Platt L, Grenfell P, Bonell C, Creighton S, Wellings K, Parry J, Rhodes T. Risk of sexually transmitted infections and violence among indoor-working female sex workers in London: the effect of migration from Eastern Europe. Sex Transm Infect. 2011 Aug;87(5):377-84

7. Shannon K, Strathdee SA, Goldenberg SM, Duff P, Mwangi P, Rusakova M, Reza-Paul S, Lau J, Deering K, Pickles MR, Boily MC. Global epidemiology of HIV among female sex workers: influence of structural determinants. Lancet. 2015 Jan 3;385(9962):55-71

8. Pitcher J, Wijers M. The impact of different regulatory models on the labour conditions, safety and welfare of indoor-based sex workers. Criminol Crim Justice. 2014;14(5):549-64

9. Shannon K, Kerr T, Strathdee SA, Shoveller J, Montaner JS, Tyndall MW. Prevalence and structural correlates of gender based violence among a prospective cohort of female sex workers. BMJ. 2009;339:b2939

10. Shannon K, Rusch M, Shoveller J, Alexson D, Gibson K, Tyndall MW. Mapping violence and policing as an environmental-structural barrier to health service and syringe availability among substance-using women in street-level sex work. IJDP. 2008 Apr;19(2):140-7

11. Crago AL. Arrest the violence. Human Rights abuses against sex workers in Central and Eastern Europe and Central Asia. Sex Workers' Rights Advocacy Network in Central and Eastern Europe and Central Asia, 2009.

12. Mai N. Migrant Workers in the UK Sex Industry: Final Policy-Relevant Report. London Met Univ: 2009.

13. Scoular J, O'Neill M. Regulating Prostitution: Social Inclusion, Responsibilization and the Politics of Prostitution Reform. Brit J Criminol. 2007;47:764 - 78

14. Levy J, Jakobsson P. Sweden's abolitionist discourse and law: Effects on the dynamics of Swedish sex work and on the lives of Sweden's sex workers. Criminol Crim Justice. 2014;14:593

15. Abel G. A decade of decriminalization: Sex work 'down under' but not underground. Criminol Crim Justice. 2014;14(5):580-92

16. Stueve A, O'Donnell LN, Duran R, San Doval A, Blome J. Time-space sampling in minority communities: results with young Latino men who have sex with men. Am J Public Health. 2001 Jun;91(6):922-6

17. Chavez P, Wesolowski L, Patel P, Delaney K, Owen SM. Evaluation of the performance of the Abbott ARCHITECT HIV Ag/Ab Combo Assay. J Clin Virol. 2011;52 (S1):S51-5

18. NSWP. POLICY BRIEF Mapping and Population Size Estimates of Sex Workers PROCEED WITH EXTREME CAUTION. Edinburgh: Global Network of Sex Work Projects, 2015.