Full/long title of study	Qualitative investigation into mpox in endemic and non-endemic areas
Short title	VERDIQual
Version and date of protocol	Version1.0 draft, 12/09/2023
Sponsor:	University College London (UCL)
Funder (s):	HORIZON Europe
UCL Data Protection Number:	Z6364106/2023/06/162
Chief investigator/Academic Supervisor:	Dr Shema Tariq s.tariq@ucl.ac.uk UCL Institute for Global Health, 3rd Floor, Mortimer Market Centre Off Capper Street London WC1E 6JB

PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Current	1.0 draft	12/09/2023	Dr Marthe Le Prevost/Dr Emily Nicholls	N/A
Previous				

DECLARATIONS

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

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

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

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

Chief Investigator:

Signature: [redacted] **Date 12/09/2023**

Print Name (in full): SHEMA TARIQ

Position: Senior Research Fellow/Honorary Consultant Physician in HIV and sexual health

STUDY SUMMARY

IDENTIFIERS	
UCL Ethics Project ID	6698/005
UCL Data Protection number	Z6364106/2023/06/162
Full (Scientific) title	Qualitative investigation into mpox in endemic and non-endemic areas
Health condition studied	mpox
Study Type	Qualitative study
Target sample size	1. Focus Group discussions: 4-6 focus groups with 4-8 participants 2. Social media analysis: analysis of 2 social media platforms (TikTok and X – formerly known as Twitter). Sample size N/A
STUDY TIMELINES	
Study Duration	12 months
Expected Start Date	24/08/2023
End of Study Date	31/07/24
FUNDING & OTHER	
Funding	HORIZON Europe
Other support	The Penta Foundation provide administration support for all partners in the consortium (e.g. co-ordinating funder reports, tracking of deliverables and milestones, and oversight of programme of work)
KEY STUDY CONTACTS	
Principal Investigator	Dr Shema Tariq, s.tariq@ucl.ac.uk
Study Coordinator	Anya Maclaren, a.maclaren@ucl.ac.uk
Co-Investigator	Dr Davide Bilardi, davide.bilardi@pentafoundation.org
Co-Investigator	Dr Sarah Denford, sarah.denford@bristol.ac.uk
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Co-Investigator	Dr Charlie Witzel, c.witzel@ucl.ac.uk,
STUDY SPONSOR	
Sponsor	University College London

KEY WORDS

mpox; monkeypox; sexual health; emerging infections; qualitative research

CONTENTS

1 INTRODUCTION

1.1 Overall aim

The overarching aim of this study is to gain contextual understanding of the ongoing 2022 mpox outbreak in the UK through qualitative investigation through analysis of print and social media, and focus group discussions with affected communities. This study is part of a larger programme of work investigating the 2022 mpox outbreak globally, led by the European Union (EU) funded VERDI consortium. More broadly, using mpox as an exemplar, we will develop capacity and innovative methods for rapid and agile qualitative research that can be applied to future (re)emerging infections in key populations (such as pregnant people and people attending genitourinary medicine (GUM) clinics).

1.2 The VERDI Consortium

VERDI was initially established in 2021 in response to the SARS-CoV-2 pandemic. It aims to investigate transmission, variants of concern, vaccine strategies and clinical outcomes related to SARS-Cov-2, with a specific focus on children and pregnant women. VERDI is oriented towards pandemic preparedness, allowing data to inform timely recommendations for reducing transmission and clinical management of paediatric and pregnant populations.

This focus on pandemic preparedness, means that VERDI is well-positioned to investigate other (re)emerging infections. In August 2022, VERDI funders (the European Commission, EC) asked the consortium to leverage their existing methods and collaborative networks to investigate the 2022 mpox outbreak, asking partners to expand the remit of work from children and pregnant women to those attending sexual health clinics and people living with HIV.

2 BACKGROUND AND RATIONALE

Monkeypox virus is a zoonotic Orthopox virus first described in the Democratic Republic of Congo in 1970. It is a disease of global significance, with cases reported in 11 African countries and sporadic cases reported outside Africa as a result of zoonotic transmission and travellers returning from endemic areas (1). However, despite the global burden of monkeypox (renamed mpox in 2022), research into it has historically been neglected.

In May 2022, cases of mpox were reported in non-endemic countries in people without any history of travel to endemic areas. By September 5th 2023, 89,752 people had been diagnosed with mpox in 114 countries globally, with 157 reported deaths (2). A case series of 528 patients in 16 countries, reported that 98% of cases were in gay or bisexual men, with 41% also living with HIV (3). Sexual contact has been found to be the dominant method of transmission in this outbreak. In this case series, the hospitalisation rate was 13%, mainly for pain management, bacterial super-infection, and fluid management.

This current outbreak of mpox is, like many communicable and non-communicable diseases, a complex biosocial phenomenon, disproportionately impacting marginalised communities, whilst exposing and amplifying global health inequities. While current efforts are largely directed towards preventing mpox from being endemic in Western Europe and North America, it has been relatively neglected in terms of research and funding in endemic areas, where it has significant morbidity and

mortality. The 2022 outbreak has been concentrated amongst men who have sex with men thus far. However, there is a careful balance to be struck between on one hand targeting public health messaging and, on the other, reinforcing existing stigma, creating barriers to uptake of testing, treatment and prevention, and encouraging complacency about risk amongst other groups of people. Previous experience in HIV (4), and more recently during the COVID-19 pandemic (5), highlight the importance of situating emerging infections within a broader social context in order to deliver effective interventions whilst avoiding unintended consequences. Qualitative approaches are key if we are to understand these complex dynamics and inform the development of effective public health messaging while minimising the potential for harm. However, there are as yet few qualitative engagements with mpox, with this small number of studies highlighting the importance of understanding sexual behaviour change and vaccine choices (6, 7).

3 OBJECTIVES

There are no studies exploring social representations of mpox on commonly used platforms such as TikTok, and an urgent need to develop robust methodological approaches. Characterising the spread of information and misinformation in digital and physical environments is essential in informing public health messaging, countering misinformation and stigma, and understanding community concerns. Moreover, there is a clear need to understand experiences and understandings of mpox, attitudes towards transmission-reducing behaviours, sources of information and attitudes towards public health messaging and policies.

In building and training a research team with expertise in rapid qualitative research and media analysis, we will develop capacity and innovative research methods that can be applied to future emerging infections in Europe and globally, especially within marginalised populations (such as those from sexually minoritised groups, and those living with HIV).

Our research objectives are to:

- Understand social media representations of mpox
- Understand social media messaging and public discourse on mpox vaccination
- Describe attitudes to and recommendations for public health messaging
  Develop capacity and methods for rapid qualitative research and media analysis for emerging infections.

4 STUDY DESIGN & METHODS OF DATA COLLECTION

This study is part of a larger programme of work conducted by the VERDI consortium. This current study falls within the mpox work package, which includes a number of other tasks mainly employing on quantitative methods investigating seroprevalence of mpox across a number of sites.

This qualitative study comprises social media analysis and focus group discussions (FGDs).

4.1 Social media analysis

We will conduct quantitative and qualitative analysis of social media platforms including TikTok and X (formerly known as Twitter). Platforms have been selected following initial scoping studies of social media use in various geographical regions.

X is a widely used microblogging platform with over 300 million active users. There are established quantitative and qualitative approaches for analysing tweets. X has been used for disease surveillance, tracking and forecasting, (8); for assessing polarisation of the public opinion about vaccination before and during COVID-19; and for understanding complex phenomena such as attitudes towards mask mandates during COVID-19. (9) A small number of studies have looked at mpox on X (10, 11) however, most of these have been quantitative.

We will also conduct content analyses of the newer platform TikTok, a social media platform where users share videos between 15 second to 3 minutes long (usually self-created). We will develop and use a novel methodology which will include the analysis of both visual and text content.

We will restrict analyses to accounts that are unlocked and therefore publicly available; usernames of social media users will not be included in published outputs. Material published by closed (or "locked") accounts will not be included in analyses.

4.2 Focus Group Discussions

FGDs are particularly effective when exploring sensitive issues and for understanding group views, beliefs and actions. We will recruit people at risk of mpox and/or who have had confirmed mpox, through local community organisations and/or social media. We anticipate conducting 4-6 FGDs (either remotely or face-to-face).

Topics will include experiences of mpox, attitudes towards transmission-reducing behaviours (including vaccination, and in endemic settings vaccination in pregnancy), sources of information, attitudes towards public health messaging and policies, social and emotional impact of the mpox outbreak.

FGD composition will reflect the epidemiology of the outbreak and is likely to primarily include men who have sex with men. We will ensure at least one FGD is for racially minoritised people, and one for people living with HIV.

4.3 Settings

The overall qualitative study will be conducted in three countries: Italy, Nigeria and the UK. This will allow for comparison of findings, in order to generate novel insights into how the mpox outbreak varies by geographical region. This protocol pertains to work being conducted in the UK only. International collaborators will be seeking their own ethical approval as per their respective country requirements).

4.4 Data from study participants

4.4.1 Social media data

4.4.1.1 TikTok data

TikTok posts will be accessed to conduct a content analysis. They will be saved in a password protected folder on a UCL computer. Only study team members will have access to this. Some posts will be identifiable. We will only access posts that are publicly available and will not include any identifiable data in the presentation of results.

4.4.1.2 X data

We will request a X archive using the following terms (monkeypox, pox, #monkeypox, #mpox). These data will be saved in a password protected folder on a UCL computer. Only study team members will have access to this. Some accounts will be identifiable. We will only access Tweets that are publicly available and will not include any identifiable data in the presentation of results.

4.4.2 Focus Group Discussion data

Names and contact details of interested participants will be emailed to the UCL study team by local community organisations, or participants will contact the team themselves if they are interested. Contact details will be kept in a password protected, encrypted Excel spreadsheet on university computers. Should a participant decline, or be uncontactable, their details will be permanently deleted.

We will conduct 4-6 face-to-face and/or online FGDs with adults from communities affected by mpox. Participants will complete a short demographic questionnaire (recording age, ethnicity, country of birth, gender, history of mpox infection and vaccination) on paper or on a survey platform called Alchemer that has ISO 27001 and SOC2 Type 2 Certifications, as well as EU GDPR compliance. All data collected on paper will be entered onto a secure spreadsheet and paper copies will be shredded. FGDs will be audio-recorded using a digital voice recorder if face-to-face or online (to avoid video recording in MS Teams). The FGD will cover topics such as experiences of mpox, attitudes towards transmission-reducing behaviours including vaccination, sources of information, attitudes towards public health messaging and policies, and the social and emotional impact of the mpox outbreak. Audio data will be transcribed by a professional transcription company.

5 STUDY SCHEDULE

5.1 Recruitment

5.1.1 Social media analysis

N/A. No recruitment required as will comprise analysis of publicly available social media content (i.e. content not posted by locked accounts).

5.1.2 FGD recruitment

Participants will be sampled purposively to represent diverse genders, sexual orientations, ethnicities, age and HIV status. Participants will be recruited through community-based organisations (facilitated by community partners see Section 9 Patient and Public Involvement), and via e-mail lists and social media including through targeted advertising.

Advertising materials will contain a link to a demographic survey for participants to fill in if they are interested in participating as well as the contact details of the local research team if they have questions or would like to discuss this.

Eligibility and suitability (regarding the purposive sampling frame) will be ascertained from the demographic survey. Those invited to participate in the FGDs will be given written information in the form of a participant information sheet (PIS) and given the opportunity to discuss with the local

research team further. If participants remain interested, they will be booked into a face-to-face or online FGD depending on their preference.

Prior to conducting the FGD, the researcher will go through informed consent procedures verbally, electronically using Docusign, or on paper (if in-person). It will be emphasised throughout the consent process that consent is voluntary, and that access to any services will not be affected by a decision not to take part.

6 ELIGIBILITY CRITERIA

6.1 Social media eligibility

6.1.1 Inclusion Criteria

Publicly available material in English concerning mpox shared by unlocked accounts on X and TikTok.

6.1.2 Social Media Exclusion Criteria

Material published by closed (or "locked") accounts will not be included in analysis. We will not be analysing non-English content.

6.2 FGD eligibility

6.2.1 FGD inclusion criteria

- Aged ≥18 years,
- perceive themselves to be (or having been) at risk of mpox acquisition,
- living in the UK (or ordinarily resident in the UK),
- able to give informed consent,
- consent to audio recording of FGD.

6.2.2 FGD exclusion criteria

- Aged <18 years,
- Never lived in the UK,
- unable or unwilling to give informed consent,
- unable to speak English.

7 CONSENT

7.1.1 Social media consent

No consent required from individuals. Consent sought from X to access data.

7.1.2 FGD consent

Once a participant has expressed interest in participating in an FGD and has been identified as eligible, a study team member will send the potential participant a copy of the participant information sheet and consent form. This will happen at least 24 hours prior to the FGD and any questions potential participants may have will be answered by a member of the study team.

Participants will have three options for giving consent, depending on their preference and whether the FGD is online or face-to-face:

- Online FGDs: participants can a) request to be sent the participant information sheets (PIS) and consent form via email prior to the FGD, and sign the consent form with an electronic signature or DocuSign (set up and sent by the researcher), or (b) give verbal consent in which case the researcher will arrange to speak to them prior to the FGD and create an audio record of the consent process (which will be saved separately to the FGD recording).
- Face-to-face: any of the options above or participants can sign the consent form in person when attending the FGD, in which case time will be set aside for participants to read the PIS and go through consent procedures.

8 DATA ANALYSIS

All analyses will be proposed on the VERDI concept sheet and reviewed by the study co-investigators and Community Advisory Board (CAB). Finalised analysis concept sheets will be shared with the VERDI SMT.

8.1 Social media analysis

By means of network analysis and Natural Language processing tools (e.g., topic modelling), we will conduct a discourse analysis to identify topics around representations of mpox, framing of responsibility, and mpox vaccination. We will use network analysis tools to explore information and misinformation diffusion, clustering of opinions and attitudes (e.g., assess the presence of echo chambers), as well as a sub-group analysis of links posted in tweets to assess credibility of linked information and how the shared information correlates with users' opinions/attitudes. Should other, newer platforms be analysed (e.g., TikTok), then we will develop new methods to undertake this work.

8.2 FGD analysis

FGDs will be recorded using digital audio recorders and sent securely to a UCL approved transcription company. On receipt of transcripts from the transcribers, text will be de-identified. The researchers will redact participant names, geographical references and any other potentially identifying information. Once transcripts are checked for accuracy, audio files will be permanently deleted.

FGD data will be synthesised during data collection using a modified Rapid Assessment Procedure (RAP) sheet which will capture findings by topic in real time. Each qualitative researcher will have a RAP sheet to complete with observations as data are collected. This will allow us to quickly identify emerging findings (including gaps in data collection that need to be addressed or topics to be further explored) and facilitate consistency across settings.

Following initial rapid assessment, data will be analysed thematically using NVivo. We will use some a priori codes developed from literature review and rapid assessment results, but the emphasis will be on inductive coding. Initial findings from the rapid and thematic analyses will be presented to community partners to allow for feedback and insights We will also conduct comparative analyses across participating sites (comparing geographical regions).

9 PATIENT AND PUBLIC INVOLVEMENT (PPI)

Community involvement and PPI is central to this study and will occur at several points during the project. We have costed for community partners in local settings (in a consultancy capacity) to facilitate recruitment, conduct and dissemination, as well as to be involved in analyses:

- NAZ: sexual health charity with 29 years of experience working across London, working to address sexual health inequalities in Black, Brown and Global Majority communities.
- European AIDS Treatment Group (EATG): a patient-led NGO, which has been advocating for the rights and interests of people living with or affected by HIV/ AIDS and related co-infections within the WHO Europe region since 1992.

These community partners will establish a CAB, recruiting community representatives from diverse groups and across geographical regions. CAB members will review documents, contribute to analyses and inform dissemination and further research plans. All of our PPI work has been costed and we reimburse our community representatives at the rates recommended by the UK's National Institute of Health Research (NIHR) INVOLVE, in recognition of their time and expertise.

10 FUNDING

This study is funded by Horizon Europe under the Grant Agreement No. 101045989 as part of the VERDI (SARS-CoV2 variants Evaluation in pRegnancy and paeDIatrics cohorts) project.

11 DATA MANAGEMENT

The Principal Investigator (PI) will act as custodian for the data. In compliance with the Data Protection Act 2018, the research team and the PI understand that it is their responsibility to ensure that all research data is appropriately handled, stored both during and after the study and in compliance with UCL guidelines. A data management plan will be drafted. We will use UCL's DSH to handle and manage data. The UCL DSH has been certified to the ISO27001 information security standard and conforms to the NHS Information Governance Toolkit. The folder in the DSH is only accessible to named members of the UCL research team, all of whom have had to undergo Information Governance Training to gain access to the DSH. The PI will ensure training is up to date for all team members.

This study has been registered with the UCL Data Protection Office, as data will be stored in the UCL DSH. The study is registered under reference No. Z6364106/2023/06/162.

11.1 FGD data management

Contact details of interested participants will be emailed to the UCL study team and then stored in a password protected folder in the DSH. These details will be securely deleted once a participant has attended a FGD, or declined involvement.

Hardcopies of consent forms will be scanned as a PDF and stored electronically as an encrypted document in a password protected file. Where consent is given virtually, soft copies will be stored in

the password protected folder until completion of the project. Verbal consent will be stored as an audio file on the DSH, separate from audio-recorded FGD data.

Audio FGD data will be recorded on an encrypted digital voice recorder with password protection. Personal identifiers (e.g., names) will be removed shortly after recording and transferred to the DSH (as soon as possible and definitely within 72h hours). Audio files on voice recorders and local encrypted computers/drives will then be deleted. Audio files will be transcribed by a professional transcription company (TP Transcription) that is GDPR compliant and widely used by universities, banks and courts, including UCL. The supplier has confirmed that an up-to-date data processing agreement is in place with UCL. Audio files and FGD transcripts will be transferred to/from the transcription company using an encrypted link. Pseudonymised FGD transcripts will be stored and analysed in the DSH. Audio files will be deleted from the DSH once transcripts have been checked for accuracy.

11.2 Social media data management

Data analysed as part of this part of the study will comprise tweets and TikTok videos that individuals have shared to a public forum. By doing so they may have been aware that their data may be analysed, however, they have not explicitly provided consent. We will minimise the risk of harm by not including usernames in any written materials and not sharing visual material or identifiable information. Data downloaded from social media sites will be stored on UCL servers in a password protected folder only accessible to the research team..

12 ASSESSMENT AND MANAGEMENT OF RISK

Members of the research team will explain study procedures to potential participants, giving them ample time to review the Participant Information Sheets and Consent Forms, and to ask any questions they may have. Research staff are trained to assess participants' understanding of the study procedures and may make the decision to end 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 at any time, without giving a reason, and without affecting any services they may be accessing via collaborating community organisations.

- The subject matter of focus group discussions may be delicate and emotive. Participants will be informed that they are not obliged to answer questions they find difficult.
- We have a departmental distress protocol that we can refer to in the event of a participant experiencing distress as a result of participation in the study. If the participants appear upsetting they will be given the opportunity to take a break. The team will follow the agreed distress protocol in the event of distress, including liaising with the community organisation who are co-hosting the FGD.
- The UCL research team are experienced qualitative researchers with substantial experience of working within HIV and sexual health. The study is overseen by Dr Tariq (PI), an experienced consultant HIV/sexual health physician and medical anthropologist with extensive experience in conducting qualitative research on sexual health.

- The research team has a resource pack containing helpline numbers and health promotion materials in order to provide information to participants, if required.
- The research team believes that consent is a dynamic process. 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.

- Our CAB members have provided feedback on research plans to help shape them in an ethically responsible and appropriate way. We will continue to have regular input from the CAB as the study progresses.

13 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

As the sponsor of the study, UCL is solely responsible for complying with any safety reporting obligations towards competent authorities, ethics committees or Institutional Review Boards (IRBs), within the required timelines. All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor via research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form) and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

13.1 Protocol deviations and notifications of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The PI will monitor protocol deviations. A protocol violation is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

The PI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

13.2 Personal Data Breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer [data-protection@ucl.ac.uk], (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data), and to the Sponsor via the UCL REDCAP incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply).

13.3 Protocol deviations and notification of protocol violations

Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree: –

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study

The PI and Sponsor will be notified immediately of any case where the above definition applies via research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form.

13.4 Complaints from research participants

In the first instance, research participant complaints will be reported to the PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy.

14 MONITORING AND AUDITING

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

The PI will inform the Sponsor should she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

The Study Management Team (SMT) consists of the study Chief Investigator, Senior Research Fellows, Research Fellows, Research Assistant and the VERDI Project Manager. This team oversees the day to day running of the study and meets regularly to discuss all aspects of the study. The VERDI Project Steering Committee will be contacted if relevant issues arise and the SMT will feed back as appropriate to the VERDI Project Steering Committee via the Work Package 7 lead.

The study Community Advisory Board will review documents, contribute to analyses and papers (as co-authors) and inform dissemination and further research plans. The CAB will meet 2-4 times a year to discuss the overall study and more regularly at specific time points (e.g. during an analysis) as required.

Finally, a broader group of qualitative researchers working on mpox from across the UK has been set up to take part in the Investigators Group. They provide guidance as to the direction and focus of the study and to minimise cross over with existing UK qualitative Mpox projects. It meets approximately twice a year for reviews and updates.

15 TRAINING

The PI will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files

UCL research team staff working with patient identifiable data in UCL's DSH will undergo specific training under the supervision of UCL's Information Governance Team. All members of the research team will be expected to read and comply with local SOPs.

16 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent.

17 ARCHIVING

UCL recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The PI confirms that she will archive the study master file at UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 10 years from the study end.

18 PUBLICATION AND DISSEMINATION

In order to acknowledge the level and nature of contribution of key individuals in publications arising from the project, we will follow The International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations 2013) which recommends that authorship be based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
- Drafting the work or revising it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The PI or last author are responsible for identifying who meets these criteria when planning the work, making modifications as appropriate as the work progresses. All publications will reference "and the VERDI Consortium". Contributors are those who meet fewer than all 4 of the above criteria for authorship. They will not be listed as authors, but they should be acknowledged. Because acknowledgment may imply endorsement by acknowledged individuals of the study's data and conclusions, editors (the WP Lead and lead or last author) are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals. All outputs will also include at least one CAB member as a co-author, where possible.

All manuscripts must be sent to the VERDI Project Manager at least 30 calendar days before the planned publication date. Any objection by partners must be made by writing to the Project Coordinator and to the partners proposing the publication within 15 calendar days. If no objections are received within the time limit, the paper can be submitted for publication.

A full dissemination strategy will be formulated in conjunction with the CAB in order to maximise the impact of this work on clinical care and policy. The dissemination strategy will include:

Presentations at major international infectious diseases/HIV conferences such as the International AIDS Society Conference and AIDS Impact,

- Lay summary of research findings to be distributed to participating community organisations and individuals where requested,
- Regular updates on the Verdi study website and via the study's X account.

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20 APPENDICES

List of supplementary information and documents that will support the protocol

- Patient Information Leaflets
- Consent Forms
- Focus Group Discussion Demographic Survey
- Focus Group Discussion Topic Guide