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An Umbrella Protocol for Qualitative Research in Infectious Disease Outbreaks

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Rapid qualitative approaches in pandemic research: protocol for an exploratory qualitative multi-method study on mpox in Italy, Nigeria, Thailand and the United Kingdom (VERDIQual)

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We use this protocol and it's working

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Abstract

Abstract

Background

A key barrier to rapid implementation of qualitative studies in an infectious disease outbreak is the development of a study protocol, identification of appropriate methods and ethical approval. Not being able to respond to infectious disease outbreaks in a timely and agile way limits the potential contribution of qualitative methods to pandemic preparedness. Umbrella protocols strengthen the ability to generate high-quality, timely evidence in the face of emerging public health threats. Based on VERDIQual (part of the broader EU-funded VERDI project <https://verdiproject.org/mpox-studies/>), a qualitative study on mpox in four countries, we have developed a Qualitative Umbrella Protocol (QUP).

Methods

This QUP has been designed as a standardised template that can be adapted for designing and obtaining ethical approval for qualitative studies of infectious diseases. It has been designed to be applied to all populations, however we include specific considerations for pregnant people and children. We include an outline structure, and word documents of the QUP, guidance on use of QUP, and methods-specific standard operating procedures (SOPs). Researchers using the QUP will need to adapt it to suit their study and methods used - we include sample text for each section based on our mpox work (in green font, to be deleted when protocol finalised). SOPs can be used to provide practical guidance on methods, and to complete methods section of the protocol.

Discussion

This QUP has been designed to provide a flexible yet standardised framework that accelerates research initiation, supports methodological adaptability, and enables cross-site comparability during rapidly evolving health crises. We include SOPs on commonly used qualitative approaches: semi-structured interviews, focus group discussions, participatory photography (Photovoice), and analyses of both social and news media. Ultimately, the QUP aims to strengthen pandemic preparedness by embedding rapid, rigorous, and context-sensitive qualitative inquiry within outbreak response infrastructures.

Ethics and regulatory requirements

Researchers using this QUP will need to ensure it meets requirements of their local ethics committees and regulatory authorities.

Attachments

				
2025.10.23.VERDIQual...	2025.10.23.VERDIQual...	2025.10.23.VERDIQual...	202510.23.VERDIQual_..	2025.10.23.VERDIQual...
208KB	1.7MB	1.7MB	1.8MB	2.4MB
				
2025.10.23.VERDI_Pho...	2025.10.023.VERDIQua..	2025.10.23.VERDIQual...	2025.10.23.VERDIQual...	2025.10.23.VERDIQual...
1.7MB	1.7MB	1.7MB	1.7MB	1.7MB
				
2025.10.23.VERDIQual...	2025.09.01.VERDIQual...			
1.8MB	4.7MB			



Phase 1: Protocol Setup

- 1
 - Fork Qualitative Umbrella Protocol (QUP) on protocols.io (retain linkage to original).
 - Download full version of QUP (word document in attachments) - once adapted upload as attachment to your fork.
 - Consult relevant Standard Operating Procedures (SOPs) for guidance on methods and other procedures - the SOPs can be used to populate the protocol.

Phase 2: Scope & Framework

- 2
 - Give background and justification for study.
 - Define aims, objectives, research questions.
 - Specify theoretical framing to guide sampling, tools, analysis.

Phase 3: Design & Sites

- 3
 - Choose participating sites.
 - Consider modular, flexible design to select methods that are feasible and relevant to each site.
 - Specify target participant groups and indicative sample sizes.

Phase 4: Governance and Ethics

- 4
 - Prepare Research Ethics Committee submission (protocol, participant information sheet, consent forms, topic guides, adverts).
 - Define amendment process and reporting responsibilities.
 - Informed consent and data protection processes must be clearly outlined.
 - Include safeguards for key populations e.g. pregnant people and children.

Phase 5: Preparing team

- 5
 - Train staff (particularly in rapid qualitative research methods) and maintain delegation/training logs.
 - Convene Community Advisory Board (CAB) and agree values, ways of working and terms of reference.

Phase 6: Recruitment and/or sampling

- 6
 - This will depend on methods selected.
 - **Semi-structured Interviews (SSIs):** likely purposive; healthcare and/or community settings; obtain consent (PIS, e-signature/verbal).

- **Focus Group Discussions (FGDs):** likely purposive; healthcare and/or community settings; obtain consent (PIS, e-signature/verbal).
- **Photovoice:** potentially recruit sub-sample of those interviewed; consent includes image sharing/copyright terms.
- **Social Media:** identify and justify platform selected; define inclusion/exclusion; public data—no consent required.
- **News Media:** define outlets, keywords, period; select via database sampling.

Phase 7: Data Collection

- 7
 - **SSIs/FGDs:** online/in-person; audio-record with consent; take field notes.
 - **Photovoice:** select secure platform if remote; implement staged tasks; secure upload workflow.
 - **Social/news media:** extract metadata/text; maintain screening logs.

Phase 8: Data Management & Security

- 8
 - Develop a data management plan including data flow diagram.
 - Anonymise; assign IDs; store securely.
 - Transcription via GDPR-compliant vendor.

Phase 9: Analysis (methods-specific)

- 9
 - Analyse data using methods appropriate to the approach used and data collected. Analysis may be informed by theoretical framework.
 - Ensure cross-method and site data integration using matrices to visualise data from different methods and sites.
 - Synthesise data across datasets, and identify convergence and divergence.

Phase 10: Knowledge Mobilisation

- 10
 - Develop knowledge mobilisation plan with CAB.
 - Prepare sponsor/funder/REC reports.
 - Publish in open-access journals, present at conferences.
 - Share findings with participants, community based organisations, and stakeholders (e.g. webinars, newsletters).

Phase 11: Close-Out and Archiving

- 11
 - Define end-of-study point. Remove identifiers and archive site file as per institutional policy.

Protocol references

See reference list in relevant SOPs