



MRC-NIHR Trials Methodology Research Partnership: Webinar recording

## **Qualitative data sharing in clinical trials in the UK and Ireland: towards the production of good practice guidance**

*Presented, on behalf of the Health Research Board, by:*

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**17 May 2023**

The slides are available below.

For any queries, please contact [uktmn@nottingham.ac.uk](mailto:uktmn@nottingham.ac.uk)

[https://youtu.be/Wx\\_2FNpKYdg](https://youtu.be/Wx_2FNpKYdg)



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# QUALITATIVE DATA SHARING IN CLINICAL TRIALS IN THE UK AND IRELAND: TOWARDS THE PRODUCTION OF GOOD PRACTICE GUIDANCE

## The QUALSHARE Project



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# QUAL SHARE team



# Background: Data sharing

- Enables researchers to conduct research with previously-collected data sets
- Maximises scientific findings and cost effectiveness and reduces research waste (1)
- A moderated access approach recommended (2)
- Additional challenges for qualitative data sharing (3)
- Pseudonymisation is a major barrier to data sharing (4)
- The public may assume their quantitative data to be shared
- May not be comfortable with sharing their qualitative data



# Qualitative components of trials are valuable for:

- Developing further research hypotheses
- Gathering complementary information to contribute to answering research questions
- Explaining findings
- Developing and evaluating complex interventions (5)
- Addressing recruitment and retention issues
- Ensuring trial designs are appropriate to the population and condition they are addressing
- Assessing whether trial processes are important (6)



# Challenges of qualitative data sharing in trials

Little guidance

Guidance from UK  
Economic and Social  
Research Council applies to  
sharing qualitative data  
generally

Need to incorporate  
consent into complex  
recruitment processes

Sensitive nature of health-  
related data

Lack of proper guidance on  
how to comply with data  
sharing guidelines in a way  
that provides adequate  
anonymity protections (7)

Participants identity may be  
difficult to conceal

# *Overall Aim:* Explore whether and how trial teams share qualitative data collected as part of the design, conduct or delivery of trials

## *Key objectives:*

- To explore key stakeholders' views on whether and how to share qualitative data collected as part of the design, conduct or delivery of clinical trials
- To perform a content analysis of current consent procedures for sharing qualitative data collected as part of the design, conduct or delivery of clinical trials
- To initiate and foster relationships with key stakeholders (Health Research Authority (HRA), UK Clinical Research Collaboration (UKCRC), Irish Clinical Research Facilities (CRF)) to ensure that future work on qualitative data sharing and production of guidance is a collaborative endeavour



# Publication of study protocol

- HRB Open Research
- Peer reviewed
- Open Science Framework

The screenshot shows the HRB Open Research website interface. At the top, there is a blue navigation bar with the text "HRB Open Research" and a button "SUBMIT YOUR RESEARCH". Below this, a secondary navigation bar contains links for "BROWSE", "GATEWAYS & COLLECTIONS", "HOW TO PUBLISH", "ABOUT", "BLOG", and "MY ACCOUNT". The main content area displays a study protocol titled "A study protocol of qualitative data sharing practices in clinical trials in the UK and Ireland: towards the production of good practice guidance [version 2; peer review: 2 approved]". The authors listed are Catherine Houghton, Megan McCarthy, Katie Gillies, Nikki Rousseau, Julia Wade, Carrol Gamble, Elaine Toomey, Karen Matvienko-Sikar, Matthew Sydes, Maura Dowling, Val Bryant, and Linda Biesty. On the right side, there is a sidebar with "ALL METRICS" showing 679 views and 45 downloads, and a "Check for updates" button. Further right, there is a section for "Open Peer Review" showing a "Reviewer Status" of two green checkmarks and "Reviewer Reports" for "Version 2 (revision)" dated 22 Jun 21 and "Version 1" dated 10 May 21.

The screenshot shows the Open Science Framework (OSF) registration page for the study protocol. The title is "Qualitative data sharing practices in clinical trials in the UK and Ireland: Towards the production of good practice guidance". The registration is public. The page includes a "Summary" section with a narrative summary of the registration and a list of supplemental files: Appendix 1. Recruitment emails.docx, Appendix 2. Participant Information Leaflets.docx, Appendix 3. Informed Consent Form.docx, Appendix 4. Distress Protocol.docx, and Appendix 5. Focus group Interview Topic Guide.docx. The "Contributors" section lists Catherine Houghton, Megan McCarthy, Katie Gillies, Nikki Rousseau, Julia Wade, Carrol Gamble, Elaine Toomey, Karen Matvienko-Sikar, Matt Sydes, Maura Dowling, and 2 more. The "Description" section states "Protocol extended files". The "Registration type" is "Open-Ended Registration". The "Date registered" and "Date created" are both "March 26, 2021". The "Registered from" is "osf.io/g5mpf".



# Methods

## **Work package 1:**

Focus groups with members of each stakeholder group: trial managers, clinical trialists, qualitative researchers, members of research funding bodies and trial participants who have been involved in qualitative research.

## **Work package 2:**

Content analysis of current consent procedures for qualitative data collected as part of the conduct of clinical trials.



# Methods: Work Package 1

- A maximum variation approach to sampling to capture the views and experiences of different stakeholder groups across the UK and Ireland
- Separate focus group were conducted with members of each stakeholder group:
  - ✓ Trial managers/clinical trialists
  - ✓ Qualitative researchers
  - ✓ Members of research funding bodies



# Recruiting Participants

VIA:

- UKCRC
  - Irish CRFs
  - HRB-TMRN
  - MRC-NIHR TMRP
  - QUESTS
- Trial managers, clinical trialists, and qualitative researchers who have experience of qualitative research in clinical trials
  - People working with trial funding agencies
  - People who have participated in a completed clinical trial where data has been collected using qualitative methods



**Are you involved in design, conduct or delivery of clinical trials that include the collection of qualitative data?**

**If so, then we invite you to take part in the QUAL SHARE study!**

Data sharing enables trialists to conduct novel research with the same dataset, therefore making the most of scientific findings and reducing research waste. This can be done by sharing datasets across different studies or trials, or by placing datasets in an open repository, which other researchers can access. Guidance is in place for this process for sharing statistical data. We know less about the sharing of qualitative data, which can include videos, interviews and observations. There may be different benefits and challenges around sharing this kind of data and currently, there is less guidance about best practice for this process. We are really interested in hearing your thoughts on whether and how trial teams share qualitative data collected as part of the design, conduct or delivery of clinical trials.

If you are interested in taking part in an **online focus group** please email [megan.mccarthy@nuigalway.ie](mailto:megan.mccarthy@nuigalway.ie) and we will organise a time and date to suit you and send you more detailed information.

This study is conducted by a research team from Ireland and the UK, with funding from the Health Research Board-Trials Methodology Research Network (HRB-TMRN), in collaboration with the MRC-NIHR Trials Methodology Research Partnership (MRC-NIHR TMRP).

**We look forward to hearing from you and hope you stay safe and well during this challenging time.**



# Data Collection and Analysis

- We conducted three focus groups and two individual interviews
- Focus groups were conducted with: qualitative researchers (9), clinical trialists (3), trial funders (3) and trial participants (1)
- Focus group were conducted virtually using Zoom and were audio-visually recorded
- Semi-structured focus groups
- Explored perspectives of sharing qualitative data, potential benefits and challenges, and recommendations for what guidance is needed
- Data was managed using QSR NVivo
- Data from the focus groups was analysed using thematic analysis



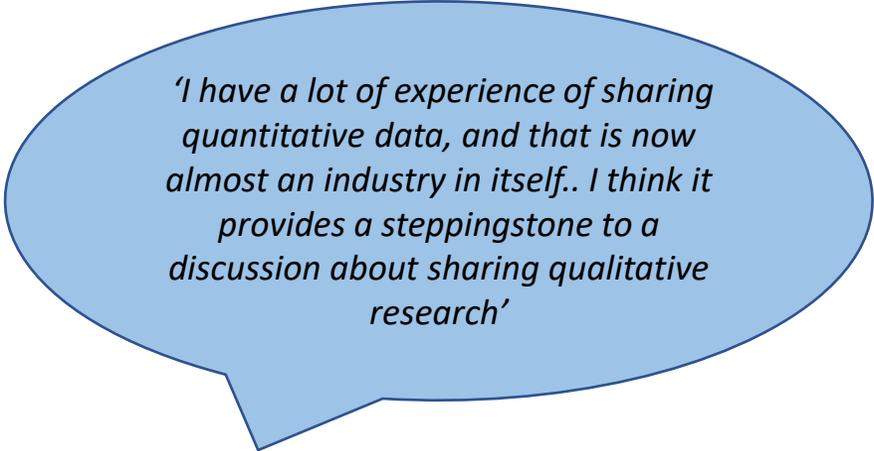
## Key themes from our findings:

- ***Understanding and experiences of data sharing***- Explores participants' perceptions of why data sharing in trials can be useful and their experience of data sharing practices
- ***Concerns about qualitative data sharing***- Examines the ethical issues and potential loss of context through pseudonymisation
- ***Future guidance and funding***- Describes how qualitative data sharing in trials can be better supported



# Understanding and experiences

- Views were based on knowledge of, rather than experience of data sharing
- Very limited experience of qualitative data sharing
- For participants who did have experience of data sharing, this was often in the context of quantitative data sharing
- While experiences of sharing qualitative data were limited, the potential benefits were recognised in terms of:
  - Analysing qualitative data in new ways
  - Making the most of available data to answer new questions and reduce research waste



*'I have a lot of experience of sharing quantitative data, and that is now almost an industry in itself.. I think it provides a steppingstone to a discussion about sharing qualitative research'*



*'I guess to me what it means is researchers collecting data and then storing it and having consent from the participants that they can then share that data with individuals outside the research team for future research'*

# Understanding and experiences

- Participants did not know how to share or where to share the data
- Recognised the value of qualitative data and need for better use of data
- Sharing data for multiple purposes provides additional benefits by helping reduce research waste
- A sense of duty to share in order give something back to research participants who have provided time and energy
- Sharing to reduce the burden placed on participants

*'So I always walk away from a data set thinking oh...there's so much more there that I'm not making you know not valuing what they have given me enough. But in end you have to go where you are next going'*

*'And again just wanting to do something out of a duty, not a duty of care but you know out of wanting to do something for people who have contributed their time and energy into collecting that data and contributing to that data too'*

**Theme 1: Understandings and experiences of the potential benefits of sharing qualitative data from trials. Key findings and coding density by participant type**

Participant Type	Understanding and experience of qualitative data sharing in trials	Experiences of quantitative data sharing	Sharing to make the most of valuable data	Sharing to enhance transparency	Sharing to reduce research burden waste
Qualitative researcher in trial	48	4	20	4	7
Trialist	7	2	7	0	6
Trial funder	8	2	2	0	21
Trial participant	1	0	4	0	3

# Concerns around sharing qualitative data

- “How to share” issues regarding ethics
- Accessing qualitative data from trials proved challenging and not a process they were familiar with
- Controlled access data sharing approach
- Inadequate data protection controls
- Rigorous consent process required for data sharing in trials
- Lengthy process involved in obtaining consent

*‘In one of our trials we had huge difficulties getting through ethics for one of the qualitative elements of it which was with people who had refused to be randomised. And the prospect of actually adding in layers onto our consent when getting ethics in the first place was so complex. The trial was almost easy, it was all the other bits that the ethics committee was really struggling with is I think a challenge’*

*‘how do we as researchers know what data people have and how we can access it and what the processes are to access that because you can’t necessarily go on some university website and say fine I want to access your data, the qualitative data from your trials. I would have no idea how to go about doing that’*

# Concerns around sharing qualitative data

- The importance of pseudonymisation was understood but concerns about losing context through this process were identified
- Importance of pseudonymising raw transcripts to remove identifiable information
- Concerns that study participants may be worried if they could be potentially identifiable from transcripts and may not be as open if they knew that their transcript would be shared
- Challenging to pseudonymisation in smaller site studies/studies with a particular context

*"Your worries might be that if people know that the entire transcript is going to be out there then that might make them behave differently"*

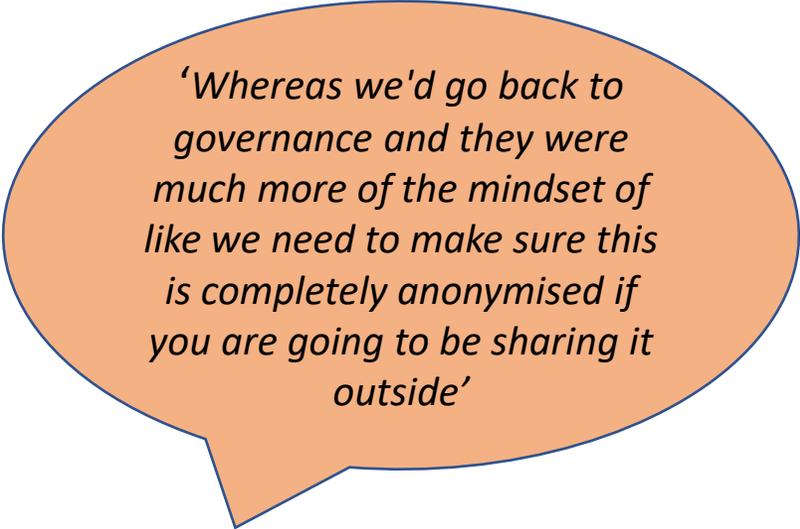
*"the whole point of qualitative is that its meaning in context. Do we want to lose the context of what the researcher brings to it?...I think if the transcripts are there independently it could even in some cases be quite hard you know how much of it would you need to cut out"*

# Concerns around sharing qualitative data

- Time consuming nature of the consent process
- Importance of research participants understanding all aspects of their informed consent
- Qualitative researchers can be protective of study participants and the data that has been generated

## ***Challenges in relation to:***

1. Receiving ethical approval
2. Adhering to governance guidelines in relation to data sharing
3. Ensuring research participants' pseudonymisation (often referred to by participants as anonymisation)
4. Sharing outside of teams due to lack of context



*'Whereas we'd go back to governance and they were much more of the mindset of like we need to make sure this is completely anonymised if you are going to be sharing it outside'*

**Theme 2: Concerns about sharing qualitative data from trials. Key findings and coding density by participant type**

Participant Type	Concern regarding governance, ethics, and consent	Concerns regarding data protection	Feeling protective towards participants	How and where to share qualitative data	Pseudonymisation versus context
Qualitative researcher in trial	13	15	13	32	36
Trialist	8	2	0	1	9
Trial funder	0	3	0	5	1
Trial participant	3	2	0	1	1

# Future funding and guidance

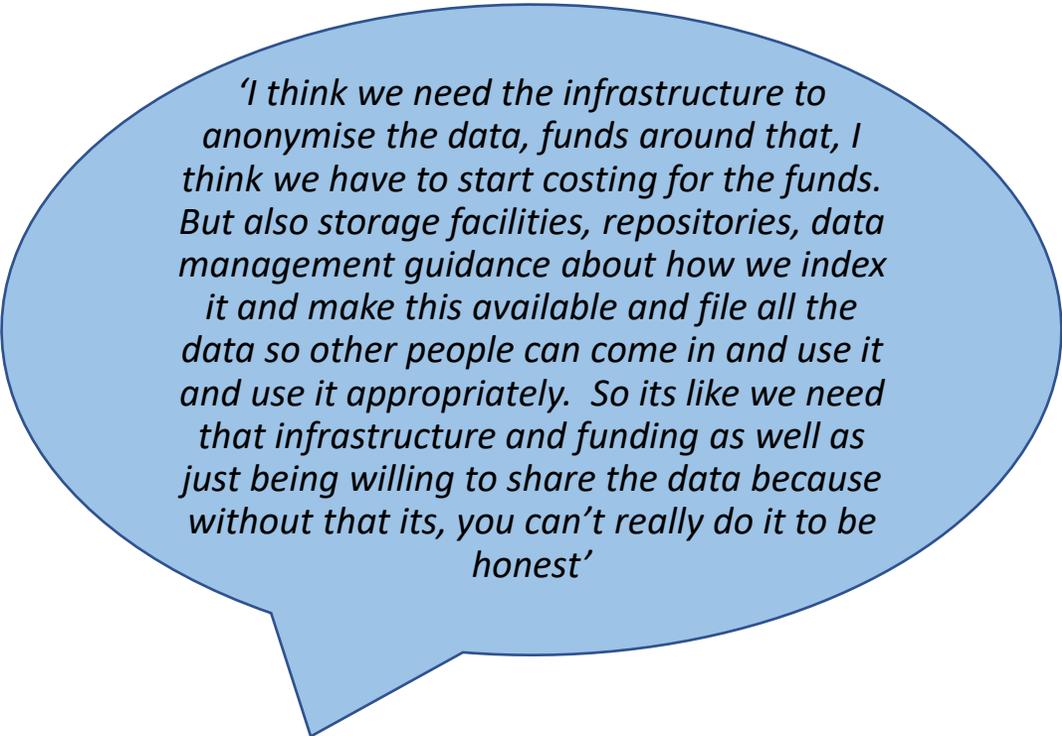
- Concerns over the lack of guidance and funding available for qualitative data sharing in trials
- Absence of clear standards and established guidelines explaining where, when and how to share data
- Urgent need for clear guidance and good practice when pseudonymising qualitative data
- Need for guidance in the format of clear and practical examples
- Sample consent forms and participant information leaflets were identified as practical resources
- May already be guidance but participants did not know where to look or who to turn to for guidance
- Importance and necessity of including data sharing when planning the study design
- Participants recognised that planning data sharing can often be a complex process

*But I think the difficulty I found as well is where there wasn't a clear sort of guidance in exactly how to do this or best practice maybe I found that going to governance they were very much of the side you know very strict of what we need to share'*

*'I think the wording that goes into the consent form you know what words people have used in the past and just simple good examples that people have'*

# Future funding and guidance

- Need for the availability of sufficient funds for sharing of qualitative data
- The sharing of qualitative data was identified as not feasible without sufficient funds and resources
- Infrastructure is not always available for the sharing of qualitative data
- Cost and time involved in the thorough pseudonymisation of qualitative data needs to be considered when writing grant applications
- Need to acknowledge the cost and time of data sharing processes in grant funding



*'I think we need the infrastructure to anonymise the data, funds around that, I think we have to start costing for the funds. But also storage facilities, repositories, data management guidance about how we index it and make this available and file all the data so other people can come in and use it and use it appropriately. So its like we need that infrastructure and funding as well as just being willing to share the data because without that its, you can't really do it to be honest'*

**Theme 3: Future guidance and funding for sharing qualitative data from trials. Key findings and coding density by participant type**

Participant Type	Examples of consent forms for sharing qualitative data within a trial	Need for additional funds and resources for pseudonymisation etc	Need for established guidance	Need to plan for sharing from the outset	PPI and advocacy involvement
Qualitative researcher in trial	1	7	16	4	0
Trialist	5	1	11	5	0
Trial funder	1	1	7	3	2
Trial participant	0	0	0	0	1

# Work Package 2

- Content analysis of current consent procedures for qualitative data collected as part of the conduct of clinical trials
- Collected documents including participant information leaflets and consent forms by contacting:
  - Trials managers and researchers involved in using QRiT
  - HRA
  - UKCRC
  - CRF's
  - HRB-TMRN
  - MRC-NIHR TMRP



Are you involved in design, conduct or delivery of clinical trials that include the collection of qualitative data?

If so, we are looking for your help with Part II of the QUAL SHARE study!

Data sharing enables researchers to do further research using the same dataset, therefore making the most of scientific findings and reducing research waste. Some guidance is in place for this process for sharing statistical data.

We know less about the sharing of qualitative data, which can include videos, interviews and observations. We are conducting focus groups to explore this topic further, but we also plan to do a content analysis of approximately 40 **Participant Information Leaflets** and **Consent Forms**, for qualitative data collection in trials, from the UK and Ireland, and within the last five years.

This project will provide a baseline on the prevalence of qualitative data sharing, as well as explore some of the strategies being employed to do so. We will also analyse the purpose for which sharing of qualitative data is being requested, for example, within a group of trials, or for broader open science purposes.

If you are willing to share your **Participant Information Leaflets** and **Consent Forms** from within the last five years, please email [megan.mccarthy@nuigalway.ie](mailto:megan.mccarthy@nuigalway.ie).

We do not need any individual's data from the trials, only the blank Participant Information Leaflets and Consent Forms. We will not identify any individual trial in the dissemination of our study report, and all documents will be stored with restricted access available only to the core research team. Thank you in advance for considering this request.

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# WP 2: Content analysis

21 PILs and 21 CF

We developed a tailored data extraction form

Extracted whether specific clauses for data sharing are included in consent forms

Analysed whether and how consent is being obtained for qualitative data sharing

Analysed the purpose for which sharing of qualitative data is being requested

# Content analysis (n=16 PILs/CFs)

Feasibility trials, treatment trials, screening trials and prevention trials were among the types of clinical trials conducted.

11 PILs and CFs were from the UK and five PILs and CFs were from Ireland.

All the Irish trials were funded by the Health Research Board (HRB) and the UK trials were funded by the National Institute for Health Research (NIHR) and the Medical Research Council (MRC).

# Content analysis (n=16 PILs/CFs)



The benefits of data sharing for participants were only explained in two of the study documents



8 of the study documents specified the conditions under which access to the data may be granted to others directly related to the research project



15 study documents indicated how data will be de-identified in practice.



Information regarding the qualitative data being available in a repository was only specified in one study document.



11 of the study documents indicated whether qualitative data could be used for future research

# Conclusions



- Insight into the existing practice of sharing of qualitative data in clinical trials
- Insight into current issues and opportunities
- Help guide future research
- Development of guidance to encourage maximum learning to be gained from this valuable data
- Development of more cohesive best practice recommendations guidance on sharing qualitative data collected in clinical trials
- Limitations.. Of course

# Dissemination

Publication of study in HRB Open Research

Presentation of findings to the European Health Psychology Society (EHPS)

Dissemination of findings through social media:

- MRC-NIHR TMRP
- HRB-TMRN
- Qualitative Research in Trials Centre (QUESTS)

Use findings to inform further grant applications to develop more cohesive best practice recommendations guidance

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# Acknowledgements

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Funder: HRB-TMRN

MRC-NIHR TMRP

Participants for their time and insights



Health Research Board  
**TMRN**  
Trials Methodology Research Network



Trials Methodology  
**TMRP**  
Research Partnership

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<https://hrbopenresearch.org/articles/6-10>



Thank You!  
Any Questions?

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