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

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The slides are available below.

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https://youtu.be/Wx_2FNpKYdg

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

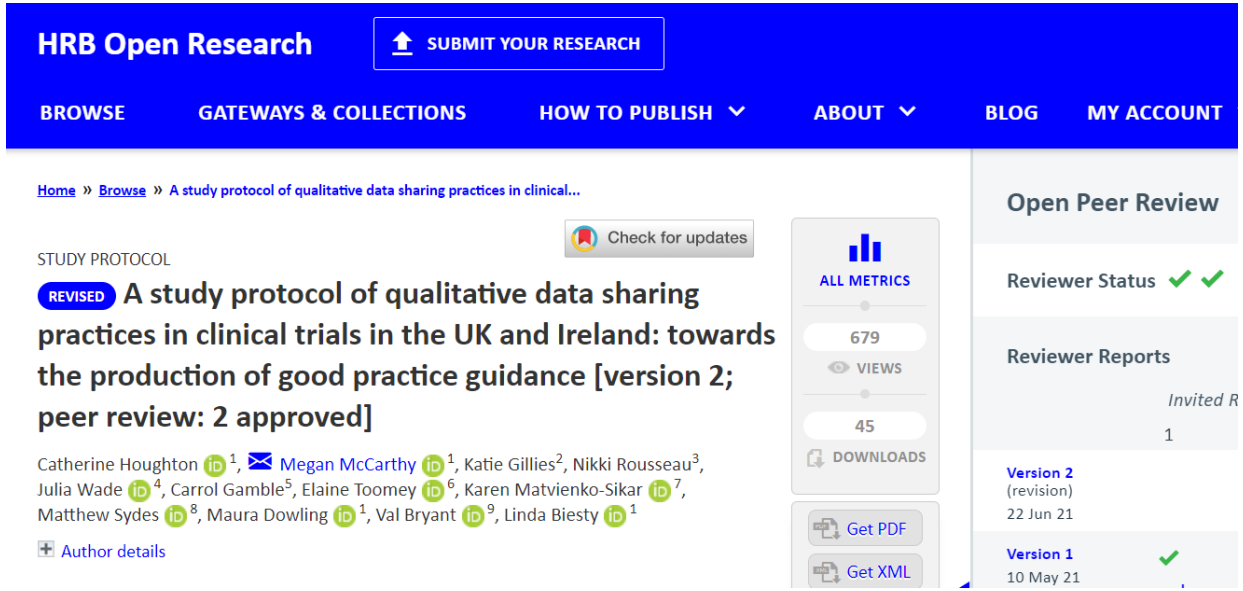
Overall Aim: Explore whether and how trial teams share qualitative data collected as part of the design, conduct or delivery of trials

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



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

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

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

Health Research Board TMRN Trials Methodology Research Network

QUESTS

Trials Methodology TMRP Research Partnership

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QUESTS

QUALITATIVE RESEARCH IN TRIALS CENTRE

Thank You!

Any Questions?

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

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