Clinical Research Data Sharing Frameworks

Work Package 2: Consultation report on current challenges and practices regarding ethics and governance approval for data sharing

Stakeholder Focus Groups

Lisa Eckstein, Programme Director (CT:IQ)
Vanessa Warren, Senior Research Officer (CT:IQ)

Table of Contents

Acknowledgement of Country 3

Background 3

Scope 3

Purpose 4

Data Collection 4
Recruitment 4
Data collection and management 4

Findings 5
Participants 5
Consultation Findings 7

- What are the governance enablers for clinical research data sharing? 7
- What are the current barriers for clinical research data sharing? 9
- Participants' identification of resources for development 13

Conclusion 16

Acknowledgements 16

Appendix 17

Clinical Research Data Sharing Frameworks received investment (doi.org/10.3565/655K-7H05) from the Australian Research Data Commons (ARDC). The ARDC is enabled by the National Collaborative Research Infrastructure Strategy (NCRIS).

Published by: CT:IQ

Acknowledgement of Country

CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.

Background

The Clinical Research Data Sharing Frameworks project has been established by Clinical Trials: Impact and Quality (CT:IQ) and the Australian Research Data Commons (ARDC) to develop practical principles and guidance for researchers, Human Research Ethics Committees (HRECs), data custodians, research institutions and consumers to support sharing of clinical research data in Australia. The Clinical Research Data Sharing Frameworks project will develop practical principles and guidance to support sharing of clinical research data in Australia. The project seeks to improve efficiency and quality in the application of requirements for the secondary use of research data by Australian researchers, HRECs and governance offices.

The project includes four work packages:

- Work package 1 (WP1): Principles and rules for sharing secondary research data (Governance Framework)
- Work package 2 (WP2): Consultation report on current challenges and practices regarding ethics and governance approval for data sharing
- Work package 3 (WP3): Benchmarking report of HREC data sharing review outcomes
- Work package 4 (WP4): Governance resources

Scope

This report presents the results of the consultative process with research stakeholders in fulfilment of Work Package 2: Consultation report on current challenges and practices regarding ethics and governance approval for data sharing. The consultation process comprised four online semi-structured focus groups with research stakeholders, to seek their views on current barriers to secondary use of clinical research data, and tools or resources that may help to address these barriers. Based on advice from the project Advisory Committee, stakeholders were broadly identified as: researchers, study coordinators, site staff members, and sponsors.

The report has also been informed by the NHMRC Clinical Trials Centre Report *Researcher adherence to journal data sharing policies: cross-sectional meta-research study* (2024), included as Appendix A.

Purpose

The Clinical Research Data Sharing Frameworks project has been established under the HeSANDA program as part of the People Research Data Commons. The project outputs will provide informational resources to HeSANDA's clinical trial partners to support sharing of clinical research data.

Consultation with research stakeholders is an important component in this project, identifying and exploring on-the-ground challenges and support needs to appropriately target resources and responses. The Work Package 2 focus groups are also a key data source in the qualitative triangulation undertaken in the project, sitting alongside data collected in Work Packages 1 and 3. The findings of these three Work Packages will be used to inform Work Package 4, in the development of targeted resources to meet needs of sector and contribute to the advancement of effective and ethical data-sharing in Australia.

Data Collection

Recruitment

Potential focus group participants were recruited through newsletters and social media channels of organisations affiliated with the research team, including the quarterly CT:IQ newsletter, the ARDC Connect Newsletter, the NHMRC Tracker, the Australian Clinical Trials Alliance newsletter, and CT:IQ and ARDC LinkedIn accounts. Advisory Committee members were invited to include the article in newsletters affiliated with their organisation. The study team also directly invited professionals with whom they have existing relationships to participate in the focus groups.

Potential focus group participants were directed to the project webpage to read the Participant Information Sheet and book a place in their preferred focus group through Calendly.

Data collection and management

Four semi-structured online focus groups were held over the period Thursday 10 October 2024 to Tuesday 22 October 2024:

- Focus Group A, Thursday 10 October 12:00-13:00 AEDT
- Focus Group B, Thursday 17 October 08:00-09:00 AEDT
- Focus Group C, Monday 21 October 16:00-17:00 AEDT
- Focus Group D, Tuesday 22 October 12:00-13:00 AEDT

Focus groups were moderated by CT:IQ staff Lisa Eckstein and Vanessa Warren and conducted through Microsoft Teams. Each focus group ran for around 60 minutes, and were similarly structured, with participants invited to respond to the same broad questions relating to:

- Strategies, approaches and resources that have enabled or supported their data sharing practices
- Current barriers, challenges and support needs in data sharing practice
- The most impactful changes or developments that participants would like to see in the governance of data sharing

The full list of questions is available in Appendix B, Focus Group Moderator Guide. In accordance with the semi-structured approach, the focus group moderators adapted lines of questioning, prompts, extensions and information sharing as appropriate as each discussion unfolded. Focus group discussions were recorded, with initial transcripts auto-generated through Microsoft Teams and then manually revised for accuracy and de-identification.

Findings

Participants

Participants self-selected by enrolling in a scheduled focus group through Calendly. All focus group places were initially filled, with 33 participants enrolling. Three participants required rescheduling due to illness/calendar clashes, while five participants did not attend their scheduled focus group.

The completed focus groups included a total of 28 participants from a range of research settings.

The majority (71%) of participants identified as female. All participants were over 35 years old, reflecting a level of seniority in participants' data sharing roles and responsibilities.

Two thirds of participants were from New South Wales and Victoria, and all other states were represented. There were no participants from the Australian Capital Territory or the Northern Territory.

Participants represented a range of data sharing settings, including universities, hospitals, research centres (both private and university/hospital affiliated), government departments, non-government organisations, and independent contractors.

Participants engaged both as end-users of shared data, and as data generators, across a variety of academic and professional roles. Most participants identified themselves as researchers, though many stated that they held multiple roles within and across organisations.

Participant demographic information

Characteristic		Focus Group A n (%)	Focus Group B n (%)	Focus Group C n (%)	Focus Group D n (%)	Full sample n (%)
Pronouns	She/Her	3 (60%)	6 (75%)	6 (75%)	5 (71.5%)	20 (71%)
	He/Him	1 (20%)	0 (0%)	1 (12.5%)	2 (28.5%)	4 (14%)
	Not specified	1 (20%)	2 (35%)	1 (12.5%)	0 (0%)	4 (14%)
Age	18-24	0 (0%)	0(0%)	0(0%)	0(0%)	0 (0%)
	25-34	0 (0%)	0(0%)	0(0%)	0(0%)	0 (0%)
	35-44	3 (60%)	1 (12.5%)	2 (25%)	3 (43%)	9 (32%)
	45-54	1 (20%)	2 (25%)	1 (12.5%)	4 (57%)	8 (29%)
	55-64	1 (20%)	5 (62.5%)	4 (50%)	0 (0%)	10 (35%)
	65+	0 (0%)	0 (0%)	1 (12.5%)	0 (0%)	1 (4%)

Location	NSW	3 (60%)	3 (37.5%)	2 (25%)	1 (14%)	9 (32%)
	VIC	0 (0%)	3 (37.5%)	4 (50%)	2 (29%)	9 (32%)
	SA	0 (0%)	2 (25%)	1 (12.5%)	1 (14%)	4 (14%)
	QLD	1 (20%)	0 (0%)	1 (12.5%)	2 (29%)	4 (14%)
	TAS	1 (20%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
	WA	0 (0%)	0 (0%)	0 (0%)	1 (14%)	1 (4%)
	ACT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	NT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Role	Researcher	2 (40%)	4 (50%)	1 (12.5%)	3 (43%)	10 (36%)
	Study Coordinator	1 (20%)	1 (12.5%)	1 (12.5%)	0 (0%)	3 (11%)
	Sponsor	0 (0%)	1 (12.5%)	1 (12.5%)	1 (14%)	3 (11%)
	Other (self-reported)	Research Manager/Data Analyst 1 (20%) Researcher/Research and Trial Coordinator 1 (20%)	Cohort Manager 1 (12.5%) Project Manager 1 (12.5%)	Director of Research 1 (12.5%) Consumer Representative 1 (12.5%) Ethics Committee Lay Member 1 (12.5%) Project Manager 1 (12.5%) Cohort Manager 1 (12.5)	HREC manager 1 (14%) Policy Officer 1 (14%) Clinical Trial Project Manager 1 (14%)	12 (42%)
Total participants		n=5 (18%)	n=8 (28.5%)	n=8 (28.5%)	n=7 (25%)	N=28 (100%)

Consultation findings

What are the governance enablers for clinical research data sharing?

Participants were invited to share stories of success in their data sharing activities, and to reflect on the governance processes, strategies, and resources that contributed to those successes.

1. In-house streamlining and standardisation activities

Many consultation group participants noted that they had been able to improve data sharing governance through in-house streamlining and standardisation activities. These were reported to improve internal efficiency and consistency, and to provide a greater sense of reliability and familiarity when engaging with governance bodies.

> *"Having been through [the data sharing process] several times now I have things that I know the Ethics Committee will want to know, and that our internal review committees will want to see, so I am quite proactive now about putting [them] in place from the beginning... now when we're setting up new projects, we kind of have those things pre-written into the plan. So being proactive in setting stuff up from the beginning for future data sharing is making things much easier for future me."*
> (Participant #23, Researcher)

> *"Working closely with our research data management team, we've created this online data management plan. So what we've done is - and I guess the main aim of that data management plan was asking questions, but providing the solution at the same time. So it was getting people to complete these data management plans and asking leading questions and giving them options. And giving them the specific sharing agreements or the specific platforms or the endorsed and approved kind of things that we have at the institution."*
> (Participant #7, Human Research Ethics Manager)

One opportunity for streamlining was an umbrella ethics approval for certain data sharing activities, to lessen or remove the need for individualised applications.

> *"We actually set up through our institution an overarching ethics approval for receiving data and we've been able to use that basically for all of the datasets that we've been accessing"*
> (Participant #6, Researcher)

Another focus group participant advised of a template data sharing statement incorporated into all new study protocols and participant information sheets authorising broad consent for future sharing.

> *"The win we've had there is that we've managed to revise protocol templates, etcetera so that in all new studies patients are consenting for their data to be shared quite broadly. That's let us overcome a lot of hurdles.*
> (Participant #6, Researcher)

2. Engagement activities with ethics review bodies and other governance stakeholders

Focus group participants raised the potential to improve governance processes through shared dialogue and relationship building. This included within and across organisations to build shared understandings, relationships, and data sharing priorities.

> *"I went and spoke to all the different internal stakeholders … our ethics, our research office, our legal department, and got everyone on board and made sure that they all had their say in a very explicit way "here is what we would need for this sort of sharing to occur." And then we built the process from that collaboration and so everyone was very, very on board."*
> (Participant #22, Sponsor)

Participants also described taking HRECs "on a journey" to build relationships, an understanding of the importance of secondary data use, and shared approaches to some of the practical, ethical and legal challenges. One participant advised that their ongoing relationship with a specific HREC has meant that "subsequent use of that data has been very straightforward." (Participant #4, Researcher). Another explained:

> *"I've flown [from QLD] to WA to present to an ethics committee… I find it really helpful ...people can see the whites of your eyes, which is a good thing for them. But I think it's equally good for us and the researchers because [now] you are personally accountable to the people you are talking to."* (Participant #13, Researcher)

3. Consumer engagement

Focus group participants recommended incorporating consumer engagement activities into the data sharing plans from an early time.

> *"We really try to engage people at the grant application stage or at the project stage or at the ethics application stage... because we want people to completely understand what they're participating in"*
> (Participant #13, Researcher)

Several participants also noted the benefits of such engagement for subsequent approvals from ethics review bodies.

> *"It's proving really helpful because we can say to ethics "we've already consulted with the general public...and this is what we've settled on because this is the feedback that we've got"*
> (Participant #13, Researcher)

> *"Our position here is that data-sharing isn't optional, because if one person opts out, then it's game over for sharing the dataset after trial results are published. One of our ethics committees pushed back on that and asked for individual participant consent. We actually went to our Consumer Advisory Board and got their perspectives on that and the consumers group was very strongly in favour of data sharing, which was wonderful. And we went back to the Ethics Committee and said the consumers felt like if the patient information sheet had full disclosure that the data sharing was going to happen, it would be all confidential, they're in favour of that, and the Ethics Committee came back and said 'that's fine, you don't need to make it optional.'"*
> (Participant #24, Clinical Trial Project Manager)

What are the current barriers for clinical research data sharing?

Focus group participants cited many and varied barriers to clinical research data sharing, with this component of the focus groups comprising the bulk of the groups' discussions. The need for consistency and standardisation was a common thread across all four focus groups, including consistent processes and structures for data sharing within and across institutions.

> *"Everybody - data custodians, researchers, ethics and regulatory officers - all want data to be used safely to improve healthcare, but we've all got these different perspectives on how to do it. And partly that's because we're all speaking a different language and following different frameworks."*
> (Participant #19, Study Coordinator)

More specific barriers related to the following:

1. Lack of a shared terminology for data sharing

Focus group participants raised the challenges associated with inconsistent understandings of data sharing words and phrases within and across institutions, including key words such as *de-identified data, re-identified data*, and *partially de-identified data*. They noted the importance of linguistic clarity, especially given the inherent complexities of many data sharing activities.

> *"We don't have a common lexicon."*
> (Participant #12, Researcher)

> *"[With] a lot of projects, whether they come under the banner of secondary use or not, it can be really hard to put them into one box"*
> (Participant #32, Study Coordinator)

> *"There's just no consistency, I think it's the real problem. I think standardisation of things like language... but also just a desperate need for consensus, within institutions and across Institutions, about definitions of data... the issues between what's truly a de-identified dataset, re-identifiable, partially de identified - and accurate risk awareness by ethics committees and governance officers about those sort of datasets."*
> (Participant #4, Researcher)

2. Differing understandings of ethical and legal acceptability

Focus group participants also raised differing ethical and legal expectations among stakeholders when it came to data sharing activities, without an overarching guidance. Commonly, this related to the acceptability of differing consent practices. Another issue where differing expectations were raised as a barrier to data sharing was resulting intellectual property.

> *"We've had a bit of disharmony also and I guess that's mostly about IP and outputs of data. So you know, yeah, here's our data, you can share our data, but who owns the output? That's where our biggest issues fall down at the end of the day. The result of that data output, the ownership of that the publication, that's been a bit of a bit of a battle for us, just trying to manage that."*
> (Participant #7, Human Research Ethics Manager)

3. Lack of harmonisation within and between governance and ethical reviews

Many focus group participants recounted experiences of duplication, inconsistency, and a lack of harmonisation across Australian governance and ethics review bodies leading to delays and potential risks.

> *"Not having standardised processes is a massive barrier and also a big risk, because it's very difficult to get oversight as to where the data is going and what people are doing with it"*
> (Participant #29, Researcher)

> *"Even within [department], the particular data custodians have their own local processes for the release of that data as well. So it's bringing everyone in line so that there is more of a streamlined and I guess, for lack of a better term, harmonious approach to access to that data is really important."*
> (Participant #17, Policy Officer)

Concerns about lack of standardisation were especially vexed when data sharing was sought for multi-site clinical trials, with the request sometimes being queried by one HREC and then approved in another jurisdiction.

> *"We had a bit of an argy-bargy with the clinician researchers because they're like "well this site approved it, why won't you release it?" - and we were trying to explain the risk but they couldn't see that risk"*
> (Participant #29, Researcher)

> *"The lack of harmonisation across the country is really quite astounding, even between HRECs. I know they're all convened under the same laws, but there are different communications because they are human"*
> (Participant #11, Director of Research)

Many focus group participants recounted experiences of duplication, inconsistency, and a lack of harmonisation across Australian governance and ethics review bodies leading to delays and potential risks.

> *"From the perspective of multi-site trial coordination where every State is, you know, theoretically is working from the same legislative kind of Commonwealth basis, but operationally that is not the same across different States. We do stuff with a new trial like, oh, Victoria has their separate form and then NSW has this separate thing and then WA where has this separate thing and then Queensland has this separate thing with the [Public Health Act]."*
> (Participant #23, Researcher)

> *"We've run into an issue recently with an international sharing request though, because their IRB won't review it because it's an existing secondary dataset. But our committee won't approve it without a review. So the US ethics situation is not the same as the Australian ethics situations, which is a whole other layer of difficulty."*
> (Participant #23, Researcher)

Data sharing across the academic/industry interface also was noted as raising ethical and governance challenges, including uncertainty about the application of waivers of consent for data sharing and a lack of trust between commercial sponsors and investigator-led trialists.

> *"I don't think it exists in Australia, a quality framework that is giving you guidance [for] what is the data that you should be sharing with industry."*
> (Participant #28, Researcher)

> *"We have a fair bit of industry involvement in some of our registries....so that is definitely a regulatory challenge and an ethical challenge... outlining the nitty-gritty details of what is ok to be sharing with industry under a waiver of consent - it's just grey"*
> (Participant #1, Research Manager/Data Analyst)

> *"Work[ing] with an investigator-led study, the sponsor was very reluctant [to share data] and immediately involved four of their lawyers"*
> (Participant #4, Researcher)

While concerns about fragmentation and a lack of harmonisation were generally linked to research governance offices and ethics review bodies, focus group participants also noted 'silent partners' in gatekeeping sharing activities.

> *"I've got an example, which isn't unique, where the ethics committee has provided approval, all of the agreements are in place, but actually the hold up is our IT unit doesn't want to give access to the [other] researchers to do the research"*
> (Participant #32, Researcher)

4. Data sharing context not always accommodated in governance processes and guiding documents

Participants noted barriers from a lack of institution-wide awareness of the purpose of data sharing and, in some instances, an inappropriate 'one size fits all' approach to data sharing queries without close attention to the type of data being shared, or the reason for sharing. This flattened the differing applicability of guidelines. For example, the NHMRC National Statement on Ethical Acceptability in Human Research applies to research activities, while quality assurance activities are guided by the Ethical Considerations in Quality Assurance and Evaluation Activities.

> *"We find if an Ethics Committee doesn't understand the differences between what we're doing, and what someone consenting people to a clinical trial are doing, they'll just not approve it"*
> (Participant #29, Researcher)

> *"My fear is that in Australia we don't necessarily recognise the difference between clinical quality data and data that is being used for clinical research purposes, because I think those two things are very different...we need to recognise that data sharing has very different purposes"*
> (Participant #25, Researcher)

> *"And I think that's something when you look at data sharing, QA, versus a full ethics application, we grapple with that all the time. There are some things we feel that should be QA, and because they've asked for access to particular data that's there, we have to make it - that's with adults - we have to make it HREC approval, which slows the whole thing down as well."*
> (Participant #8, Lay person ethics committee member)

5. Seeking and waiving consent for data sharing

Focus group participants raised questions about how best to seek and waive the requirement for consent. Some focus group participants advised of the need for template data sharing language for data sharing in participant information and consent forms for new clinical research studies:

> *"It took a lot of effort [to convince colleagues to share data]...but we don't have the infrastructure to make it available, like a secure server, or more importantly even the wording to put in an information sheet"*
> (Participant #2, Researcher)

> *"I think the biggest issue that we have and that we try to get our researchers to come on board with, is about the scope of consent. So when you're collecting your data, what kind of consent are you trying to get? So I always encourage our researchers to future-proof their data by trying to get unspecified, or at least extended consent. … I guess what I'd like to get out of this group as well is – and to have some kind of national idea around it is, so when we go for unspecified consent which is essentially, you know, "I consent for you to use this data and any other research project that can use it."*
> (Participant #7, Human Research Ethics Manager)

Other focus group participants commented on uncertainties in the requirements for seeking a waiver of the requirement for consent:

> *"With registry studies it would be really great if we could have clarity around waiver of consent"*
> (Participant #10, Study Coordinator)

> *"I still don't believe HRECs understand waivers of consent. And I've tried to standardise language, I've tried everything..."*
> (Participant #32, Researcher)

6. The need for dedicated funding

Focus group participants advised that their data sharing activities are often under- or unfunded, even where sharing is required under a grant agreement or is in-principle supported.

> *"All our projects here are funded by NHMRC or [Medical Research Futures Fund] predominantly. And their five-year grants, they don't fund data sharing work, that happens at the end of the project. So a lot of this data sharing activity is unfunded. And we really struggle as a not-for-profit group to accommodate data sharing when there's no funding for it, because it does take time and resources."*
> (Participant #24, Clinical Trial Project Manager)

> *"It's an unfunded activity. We're all paid through project grants from MRFF and NHMRC and then we do that on top of our other roles, hence the delays and the work involved."*
> (Participant #26, Researcher)

Some focus group participants directly linked the lack of funding for data sharing with the market-based models that medical research is increasingly required to satisfy, which can jeopardise the ongoing viability of sharing activities:

> *"We run on cost recovery because that's the only way we can survive, no one funds us anymore, and I have a concern, though, that people are starting to add value to data and biospecimens and that I think some degree of greed will come into this setting [others nod] and that will cause bigger problems than all of the governance and ethics issues. So that's sort of my worry for the future, that the generosity of the patients that have consented to all these projects are all going to be undermined with this - you know how much money people can get back from sharing the data with other parties."*
> (Participant #30, Cohort Manager)

Participants' identification of resources for development

Focus group participants engaged deeply with the question of what resources could meaningfully be developed to assist in governance for future data sharing activities. These included the following:

1. Templates for data sharing activities, including shared definitions, data management plans, data sharing statements in participant information sheets and consent forms, and related resources.

These should delineate between the different types of data and data sharing activities.

> *"The underpinning confidence comes from knowing there are processes there, and so templates or resources such as I understand you're developing are absolutely vital"*
> (Participant #33, Cohort Manager)

> *"Standard[ising] for future and unspecified use of the data... I think would do wonders in hopefully negating or removing some of these barriers for a lot of projects having to reapply again and again for the secondary use of the data"*
> (Participant #32, Researcher)

> *"Standardisation across the board. It's just makes it so much harder when you're trying to deal with different institutions, even within my own state in the local health districts, across states. You know, you're just jumping through all the regulations and you always waste so much time."*
> (Participant #7, Human Research Ethics Manager)

More specifically, participants suggested the merits of an equivalent to the standardised Medicines Australia Clinical Trial Research Agreement (CTRA) for data sharing agreements:

> *"The CTRA with the Medicines Australia template is kind of easy because everybody knows what that is. And there is no equivalent for other aspects of trials work, especially for data sharing."*
> (Participant #23, Researcher)

> *"I think if there was an industry standard for data sharing agreements that would be incredibly useful because my organisation, they're insisting that the template must be our template that we developed as an organisation."*
> (Participant #26, Researcher)

2. Clarification of data sharing expectations across the research ecosystem, including the acceptability of opt-in consent versus opt-out, criteria for waivers of consent, and other normative questions:

> *"Probably standardisation of how we govern data, collect data, share data. Just very clear rules on what we expect of people and what it means when you say we're going to share data... every project you try to reinvent the wheel, it's just a lot of work."*
> (Participant #27, Researcher/Research and Trial coordinator)

3. A "safe space" to ask data sharing questions

Participants noted there were few people in their respective institutions with the expertise to answer questions. Often those individuals with the relevant expertise—for example, an HREC chair or member—were seen as a 'regulator' and therefore participants were reluctant to ask questions in case it was held against them in future decision making.

"I certainly couldn't go to ethics [to discuss] a lot of the things that I actually want to do"
(Participant #13, Researcher)

4. Education and support for researchers, ethics review body members, and others to engage with consumers in research design and assessment

Focus group participants valued the inclusion of consumers in developing and interpreting data sharing frameworks and suggested that they more routinely be included across the lifecycle of data sharing activities.

"The commentary [consumers] made on one of my research projects was so powerful, I was absolutely gobsmacked that it was dismissed by the researchers "we're the clinicians, we are making the decisions"
(Participant #12, Researcher)

"I think consumers do play a big part, and I think we underestimate what they want. Trying to get a bigger consumer voice would be helpful"
(Participant #31, Project Manager)

5. Support for funding sustainability, including identifying the commercial value of data

"A real tricky challenge for us is the industry involvement and the fact that, you know, sometimes you think, oh, we want to have data available for research, data should just be available for everyone, but at the same time we are sustainable because we have a commercial value in our data as well. So a way to sort of value data could be really helpful. And to understand, you know, the different aspects in terms of balancing what should be available research and how to keep things sustained and funded. So just some sort of metrics or guidelines around valuing data would be really cool."
(Participant #1, Research Manager/Data Analyst)

"It was really interesting to see that in some of those external groups, not naming names, but some of those external groups charge a fee for data sharing, and that it's OK to do that. How much they charge, I don't know, but it's actually made us think well, maybe we need to do that if it's got to be something that's a sustainable part of our day-to-day operations.
(Participant #24, Clinical Trial Project Manager)

6. Legislative and regulatory change to facilitate data sharing activities

While outside the scope of this project, focus group participants also suggested broader regulatory changes to facilitate data sharing.

"Bringing everyone in line so that there is more of a streamlined and I guess, for lack of a better term, harmonious approach to access to that data is really important"
(Participant #17, Policy Officer)

"FAIR isn't sufficient for health systems and for health data. It doesn't make ethics explicit, it doesn't make reciprocity with patients explicit, it doesn't make the responsibility of all of the different stakeholders explicit, or sustainability of using data or transparency in using and reusing data. So I'm advocating for the fair-est health principles in data sharing"
(Participant #19, Study Coordinator)

"I don't know if many people understand the code [Australian Code for the Responsible Conduct of Research, 2018] is written by universities for universities and when you come out to industry - which includes healthcare - the Code doesn't work very well. So of anything else that I would have a wish list for, it would be we rewrite the [Code] with people who are not university academics on the committee. That is my absolute wish. I don't think I'm ever going to get it. I love the Code, but when you sit outside it becomes really difficult to interpret, including the description of research. It just does not work as soon as you step across the boundaries of a university."
(Participant #11, Director of Research)

Conclusion

The consultation process provided key information on barriers, enablers, and opportunities for additional guidance to promote the efficient and effective sharing of clinical research data. In particular, focus group participants raised the benefits that can come from greater standardisation of data sharing tools and guidance, as well as the concomitant challenges when such standardisation is not available. These challenges are especially acute when data is being shared across traditional divides, be those jurisdictional and/or between public and private institutions. However, standardisation activities must remain attuned to the nuances of data sharing, including the importance of recognising relevant regulatory and ethical differences that arise from variation from collection practices, participant consent (and lack thereof), and the purposes for which data is being shared.

Recognising the need for standardised data sharing tools and templates for the Australian research sector, as well as the nuance required for those tools and templates to be fit-for-purpose, will form a key consideration in the development of future resources under this project.

Acknowledgements

This project was approved via the expedited process of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC), Project Number 19943.

CT:IQ wishes to thank all focus group participants for giving so generously of their time. This would not have been possible without your engagement. Thanks are also warranted to additional CT:IQ staff and advisors who assisted with the consultation process, including Ms Gudrun Wells and Dr Rebekah McWhirter, as well as Dr Kristan Kang from the Australian Research Data Commons. CT:IQ has been fortunate to have ongoing guidance from its Project Advisory Committee, to which it extends its gratitude.

- Jose Valencia-Klug, Institute of Haematology, Royal Prince Alfred Hospital
- Sarah Amos, Genesis Care
- Sonya McColl, Genesis Care
- Martijn Oostendorp, NHMRC Clinical Trials Centre
- Jacqui Cumming, Peter Mac Centre for Biostatistics and Clinical Trials
- Sara Gottliebsen, Health Translation Queensland
- Salma Fahridin, NHMRC Clinical Trials Centre
- Suzie Lavoie, Orygen
- Drazenka Macic, Orygen
- Jeremy Kenner, NHMRC
- Cathy Schapper, NHMRC
- Anna Megalakakis, ARCS
- Katie Ozdowska, University of Melbourne
- Marina Skiba, Monash University
- Sharmani Barnard, Curtin University
- Parmeet Kaur, Safer Care Vic
- Tori Furner, University of the Sunshine Coast
- Shihab Mundekkadan, University of Western Australia
- Alison McIvor, Consumer

Appendix

a. NHMRC Clinical Trials Centre *Researcher adherence to journal data sharing policies: cross-sectional meta-research study* (2024)

CT:IQ REPORT

Authors: Aidan Christopher Tan, Yiyi Lin, Michellie Lian, Zhilin Ren, Tony Lian, Angela Webster, Anna Lene Seidler

Title

Researcher adherence to journal data sharing policies: cross-sectional meta-research study

HIGHLIGHT

To inform resources, what do we need to be telling researchers to be more comfortable with sharing data?

- The most common reason for intending to not share data - that the availability of aggregate data was perceived as sufficient – reflects a misunderstanding of the concept of data sharing and the reasons why individual participant data are important. We need to provide researchers with a clear, unambiguous definition of data sharing and individual participant data, and an explanation of the utility of individual participant data compared to aggregate data.
- Researcher's intentions to share data rarely align with best practice. Most studies which intended to share data only intended to share data with researchers, for purposes and by mechanisms at the discretion of, and subject to approval by, the principal investigator; and only intended to share data underlying the published results without supporting documents or specified timeframes. We need to provide researchers with additional guidance on best practices to operationalise data sharing, including what data and supporting documents to share, when to start and stop sharing data, who to share data with, what to share data for, and what mechanisms by which to share data.

SUMMARY

Background: Sharing study data improves the transparency of findings and confidence in results.

Methods: This was a cross-sectional study of all original research published in the highest-impact medical journals in 2022. Journals were included if they ranked among the top five in impact factor for each of the 59 fields of medicine identified from the 2020 Journal Citation Reports, had a data sharing policy which either required or recommended sharing data, and published original research. Articles were included if they were original research. Data were manually collected on study characteristics and initial and final data sharing plans, and descriptively analysed.

Results: 134 journals were included. Over a quarter of journals required data sharing (n=34, 27%) and the remainder recommended data sharing (n=98, 73%). 1,868 interventional studies (74% RCTs, 26% non-RCT interventional studies) and 10,368 observational studies (46% cohort studies, 40% cross-sectional studies, 11% case control studies, 3% case series/reports) were included. Only about half of interventional studies (55%) and observational studies (45%) in journals which recommend or require data sharing, actually intended to share data. Most of these (x%) only intended to share data underlying the published results; with researchers, for purposes and by mechanisms at the discretion of, and subject to approval by, the principal investigator; and without supporting documents or specified timeframes. Factors that increased intention to share data included journal policies which required data sharing and data sharing statements, and industry involvement and COVID-19 relevance for interventional studies. Journal policies which required data sharing improved the extent of data and supporting documents to be shared, timeliness to share, extent of researchers to share with and purposes to share for, and ease of access.

Conclusion: Existing journal policies requiring data sharing are effective but insufficient, and researcher's intentions to share data rarely align with best practice. In addition to requiring data sharing and data sharing statements, journals should define and explain data sharing and individual participant data, alongside better review of data sharing statements and the reasonableness of justifications to not share data. Journals should also provide additional guidance on the operationalisation of data sharing in accordance with best practice.

INTRODUCTION

Background

Sharing study data improves the transparency of findings and confidence in results.

Objectives

We aimed to systematically describe researcher adherence to journal data sharing policies across health research. This included describing what factors increase intention to share data and how journal policies requiring data sharing impact intended data sharing.

METHODS

Study design

This was a cross-sectional study of all original research published in the highest-impact medical journals in 2022. The protocol was retrospectively registered on the Open Science Framework (https://doi.org/10.17605/OSF.IO/ERVUK). This study is reported according to the Strengthening the Reporting of Observational Studies in Epidemiology Statement.(1)

Journals

Journals were included if they ranked among the top five in impact factor for each of the 59 fields of medicine identified from the 2020 Journal Citation Reports(2), had a data sharing policy which either required or recommended sharing data, and published original research. Books and duplicate records for journals listed in more than one field of medicine were excluded. For the characterisation of journal data sharing policies, see Tan et al (2024)(3).

Articles

Articles were included if they were original research.

Variables

Data were collected on study characteristics and initial (in a publicly available research protocol) and final (in the final publication) data sharing plans. Study characteristics included study type, industry involvement (commercial sector as a funding source, primary sponsor, secondary sponsor or other collaborator) and COVID-19 relevance. Initial data sharing plans included the publicly available research protocol (presence of a study registration record or published study protocol), initial data sharing statement (presence of a

statement by the authors in a publicly available research protocol whether they will or won't share data) and initial data sharing intention (decision by the authors in an initial data sharing statement whether they will share data). Final data sharing plans included the final data sharing statement (presence of a statement by the authors in the published results article whether they will or won't share data) and final data sharing intention (decision by the authors in the final data sharing statement whether they will share data). If the final data sharing intention was to not share data, data was collected from the final data sharing statement on the authors reason. If the final data sharing intention was to share data, data were collected on the authors decisions on what, when, with whom, why and how to share data. Where both the initial and final data sharing intentions were available, data were collected on whether and, if so how, these were different.

Data sources

The official websites of included journals were searched to identify all original research published in 2022. Data were manually extracted by comparing the relevant information against structured criteria on a pre-piloted data extraction form.

Statistical methods

We descriptively analysed articles by their characteristics, initial and final data sharing plans, and journal data sharing policies. Inferential analyses and statistical significance tests were not conducted because we were looking at the entire population of original research published in the highest-impact medical journals in 2022 (not population sub-samples from which inferences need to be drawn). We described categorical variables by absolute and relative frequency and continuous variables by median and interquartile range.

Patient and public involvement

Patients or public were not involved in this study.

RESULTS

Included journals

We included 134 journals. Over a quarter of journals required data sharing (n=34, 27%) and the remainder recommended data sharing (n=98, 73%). Almost two-thirds of journals required data sharing *statements* (n=84, 63%) and the remainder either recommended (n=40, 30%), mentioned (n=8, 6%) or had no policy on (n=2, 1%) data sharing statements. Only 2 (1%) journals specifically recommended sharing data from

COVID-19 studies. The median number of original research articles per journal was 120 (interquartile range 69-208).

Included articles

We identified 22,007 original research articles. This included 1,868 interventional studies (74% RCTs, 26% non-RCT interventional studies), 10,368 observational studies (46% cohort studies, 40% cross-sectional studies, 11% case control studies, 3% case series/reports) and 9,771 other study types. All articles were published in English language, although this was not an inclusion or exclusion criteria. The results of the interventional and observational studies will be reported in this manuscript, and the results of the other study types will be reported separately. Article summary data are displayed in **Table 1**. Over a quarter of interventional studies had industry involvement (n=530, 28%) and few were related to COVID-19 (n=84, 4%). Few observational studies had industry involvement (n=661, 6%) or were related to COVID-19 (n=869, 8%).

Interventional studies

Although almost three quarters of interventional studies had a publicly available research protocol (n=1,376, 74%), less than half had an initial data sharing statement (n=835, 45%) and few initially intended to share data (n=279, 15%). More than half of interventional studies had a final data sharing statement (n=1,137, 61%) and ultimately intended to share data (n=1,023, 55%). Compared to the initial data sharing plans, final data sharing plans were mostly the same (n=222, 12%) or less restrictive (n=271, 15%).

Of interventional studies who ultimately intended to *not* share data, the most common reason was that the authors reported that sharing data was not appropriate as their study investigated and analysed aggregate data, and they planned to publish only summary findings (n=47, 41%). Interventional studies who ultimately intended to share data most commonly intended to only share data underlying the published results (n=805, 79%) with researchers on a case-by-case basis at the discretion of the principal investigator (n=621, 61%), for purposes determined on a case-by-case basis at the discretion of the principal investigator (n=635, 62%), and through access subject to approval by the principal investigator (n=696, 68%). The supporting documents (excluding the data dictionary) that would be shared (n=906, 89%) and the time when data would start (n=813, 79%) and stop (n=967, 95%) being shared were most commonly not specified.

Observational studies

Few observational studies had a publicly available research protocol (n=617, 6%), fewer had an initial data sharing statement (n=318, 3%) and even fewer initially intended to share data (n=98, 1%). More than half of observational studies had a final data sharing statement (n=5715, 55%) and less than half ultimately intended to share data (n=4,511, 44%).

Of observational studies who ultimately intended to *not* share data, the most common reasons were that the authors reported that sharing data was not appropriate as their study investigated and analysed aggregate data, and they planned to publish only summary findings (n=361, 30%), or they included data for which they or the sponsors were not the sole data custodians (n=274, 23%). Similar to interventional studies, observational studies who ultimately intended to share data most commonly intended to only share data underlying the published results (n=3,781, 84%), with researchers on a case-by-case basis at the discretion of the principal investigator (n=2,935, 65%), for purposes determined on a case-by-case basis at the discretion of the principal investigator (n=3,014, 67%), and through access subject to approval by the principal investigator (n=3,103, 69%). The supporting documents (excluding the data dictionary) that would be shared (n=3,896, 86%) and the time when data would start (n=3,433, 76%) and stop (n=4,450, 99%) being shared were also most commonly not specified.

What factors increase intention to share data?

Journal policies which require data sharing

Journal policies which required data sharing were more effective at increasing researcher intention to share data than those which only recommended data sharing. In journals which required data sharing, 68% (364/533) of interventional studies and 58% (1475/2529) of observational studies ultimately intended to share data, compared to 49% (659/1335) and 39% (3036/7839), respectively, in journals which only recommended data sharing. The effectiveness of journal policies which required data sharing is supported by studies whose final data sharing plan was less restrictive than their initial data sharing plan. For studies which initially intended to *not* share data, 58% (118/203) of those published in journals which required data sharing ultimately intended to share data, compared to 42% (242/573) of those published in journals which only recommended data sharing. Journal policies which specifically recommended sharing data from COVID-19 studies were more effective than those which did not. Of the 2 journals which specifically recommended sharing data from COVID-19 studies, 63% (21/33) of COVID-19 studies ultimately intended to share data, compared to 41% (376/920) in journals which did not.

Journal policies which require data sharing *statements*

Likewise, journal policies which required data sharing *statements* were more effective at increasing intention to share data than those which only recommended data sharing statements. In journals which required data sharing statements, 71% (839/1181) of interventional studies and 58% (3398/5819) of observational studies ultimately intended to share data, compared to 26% (113/439) and 25% (870/3418), respectively, in journals which only recommended data sharing statements.

Industry involvement for interventional studies

Industry involvement increased the intention to share data for interventional studies. Among interventional studies, 62% (329/530) of those with industry involvement ultimately intended to share data, compared to 52% (694/1338) of those without industry involvement. However, among observational studies, 48% (319/661) of those with industry involvement ultimately intended to share data, compared to 43% (4192/9707) of those without industry involvement.

COVID-19 relevance for interventional studies

COVID-19 relevance also increased the intention to share data for interventional studies. Among interventional studies, 67% (56/84) of those related to COVID-19 ultimately intended to share data, compared to 54% (967/1784) of those not related to COVID-19. However, among observational studies, 39% (341/869) of those related to COVID-19 ultimately intended to share data, compared to 44% (4170/9499) of those not related to COVID-19.

What factors do not increase intention to share data?

Publicly available research protocol, with or without an initial data sharing statement

The presence of a publicly available research protocol, with or without an initial data sharing statement, did not substantially increase intention to share data. Overall, 56% (766/1376) of interventional studies and 46% (282/617) of observational studies with a publicly available research protocol ultimately intended to share data, compared to 52% (257/492) and 43% (4229/9751), respectively, without a publicly available research protocol. Of those with a publicly available research protocol, 54% (452/835) of interventional studies and 41% (131/318) of observational studies with an initial data sharing statement ultimately intended to share data, compared to 58% (314/541) and 51% (151/299), respectively, without an initial data sharing statement.

How do journal policies requiring data sharing impact intended data sharing?

Journal policies which required data sharing improved the extent of data and supporting documents to be shared, timeliness to share, extent of researchers to share with and purposes to share for, and ease of access. However, they did not impact the duration to share. Among studies which ultimately intended to share data, in journals which required data sharing:

- 21% (859/3996) intended to share *all data collected during the study*, compared to 8% (543/6735) of those in journals which only recommended data sharing;
- 26% (1033/3996) intended to share *one or more supporting documents* (excluding the data dictionary), compared to 12% (814/6735) of those in journals which only recommended data sharing;
- 46% (1855/3996) intended to share data *immediately following publication*, compared to 22% (1484/6735) of those in journals which only recommended data sharing;
- 1% (33/3996) intended to share data *indefinitely*, compared to 3% (231/6735) of those in journals which only recommended data sharing;
- 48% (1931/3996) intended to share *to anyone who wishes to access the data*, compared to 26% (1754/6735) of those in journals which only recommended data sharing;
- 48% (1907/3996) intended to share data *for any purpose*, compared to 23% (1577/6735) of those in journals which only recommended data sharing; and,
- 32% (1297/3996) intended to share data *with unrestricted access through a third party website*, compared to 18% (1219/6735) of those in journals which only recommended data sharing.

Table 1. Article summary data

	Interventional	Observational
	N=1,868 (%)	N=10,368 (%)
Study type, n (%)		
Randomised controlled trial	1,383 (74)	-
Non-RCT interventional study	485 (26)	-
Cohort study	-	4,814 (46)
Cross-sectional study	-	4,166 (40)
Case control study	-	1,100 (11)
Case series/report	-	288 (3)
Other	-	-
Industry involvement, n (%)		
Yes	530 (28)	661 (6)
No	1,338 (72)	9,707 (94)
COVID-19, n (%)		
Yes	84 (4)	869 (8)
No	1,784 (96)	9,499 (92)
Journal data sharing policy, n (%)		
Requirement	533 (29)	2,529 (24)
Recommendation	1,335 (71)	7,839 (76)
Journal data sharing statement policy, n (%)		
Requirement	1,091 (58)	5,224 (50)
Recommendation	437 (23)	3,351 (32)
Mention	130 (7)	609 (6)
Absent	210 (11)	1,184 (11)
Journal COVID-19 data sharing policy, n (%)		
Recommendation	33 (2)	115 (1)
Mention	42 (2)	147 (1)
Absent	1,793 (96)	10,106 (97)
Publicly available research protocol, n (%)		
Yes	1,376 (74)	617 (6)
No	492 (26)	9,751 (94)
Initial data sharing statement, n (%)		
Yes	835 (45)	318 (3)
No	541 (29)	299 (3)
NA	492 (26)	9,751 (94)
Initial data sharing intention, n (%)		
Yes	279 (15)	98 (1)
No	556 (30)	220 (2)
NA	1,033 (55)	10,050 (97)
Initial vs final plans, n (%)		

Less restrictive	271 (15)	89 (1)
Not different	222 (12)	61 (1)
More restrictive	10 (1)	8 (0)
NA	1,365 (73)	10,210 (98)
Final data sharing statement, n (%)		
Yes	1,137 (61)	5,715 (55)
No	731 (39)	4,653 (45)
Final data sharing intention, n (%)		
Yes	1,023 (55)	4,511 (44)
No	114 (6)	1,204 (12)
NA	731 (39)	4,653 (45)
If no, why not? n (%) *****		
Analyse aggregate data	47 (41)	361 (30)
No reason	28 (25)	287 (24)
Not data custodian	9 (8)	274 (23)
Protect participant privacy	9 (8)	90 (7)
Research team only	6 (5)	23 (2)
Comply with legislation	3 (3)	46 (4)
Lack ethical approval	6 (5)	37 (3)
Lack participant consent	1 (1)	33 (3)
Unsuitable study design	1 (1)	14 (1)
Lack sponsor/collaborator approval	4 (4)	25 (2)
Intellectual property restrictions	-	5 (0)
Protect commercial interests	-	3 (0)
Sensitive study population	-	3 (0)
Ethical restriction	-	2 (0)
Undecided	-	1 (0)
If yes, what data? n (%) *****		
All data collected during the study	147 (14)	443 (10)
Only data underlying the published results	805 (79)	3,781 (84)
Not specified	71 (7)	287 (6)
If yes, what documents? n (%) *****		
Analytic code	35 (3)	515 (11)
Analytic code, Materials	-	4 (0)
Clinical study report	5 (0)	1 (0)
Ethical approval	-	-
Informed consent form	3 (0)	3 (0)
Materials	16 (2)	55 (1)
Materials, Study Protocol	-	1 (0)
Statistical analysis plan	19 (2)	12 (0)
Statistical analysis plan, Study protocol	8 (1)	1 (0)
Study protocol	30 (3)	22 (0)

Study protocol, Informed consent form, Ethical approval	-	1 (0)
Study protocol, Statistical analysis plan, Informed consent form	1 (0)	-
Not specified	906 (89)	3,896 (86)
If yes, when start? n (%) *****		
Immediately following publication	163 (16)	1,042 (23)
Before a pre-determined period following publication	47 (5)	36 (1)
Not specified	813 (79)	3,433 (76)
If yes, when stop? n (%) *****		
No end date	27 (3)	46 (1)
After a pre-determined period following publication	29 (3)	15 (0)
Not specified	967 (95)	4,450 (99)
If yes, which researchers? n (%) *****		
Any person	143 (14)	1,049 (23)
Investigator discretion	621 (61)	2,930 (65)
Research proposal	82 (8)	239 (5)
Sponsor discretion	78 (8)	114 (3)
Independent committee	76 (7)	105 (2)
Not specified	23 (2)	74 (2)
If yes, what purpose? n (%) *****		
Any purpose	128 (13)	1,039 (23)
Investigator discretion	635 (62)	3,009 (67)
Research proposal	155 (15)	247 (5)
Sponsor discretion	68 (7)	118 (3)
Replication of results	7 (1)	15 (0)
IPD meta-analysis +/- systematic reviews	2 (0)	0 (0)
Exploratory analysis	0 (0)	2 (0)
Not specified	28 (3)	81 (2)
If yes, what distribution? n (%) *****		
Third party website	141 (14)	836 (19)
Publishing journal website	72 (7)	367 (8)
Principal investigator contact	697 (68)	3,104 (69)
Primary sponsor contact	88 (9)	119 (3)
University data warehouse	11 (1)	43 (1)
Not specified	14 (1)	42 (1)

***** For the variable, *If no, why not?*, the relative frequencies were calculated using the number of studies whose final intention was to not share data as the denominator. For variables beginning with, *If yes,* the relative frequencies were calculated using the number of studies who final intention was to share data as the denominator

NA = not appliable

DISCUSSION

Statement of principal findings

Only about half of interventional studies (55%) and observational studies (45%) in journals which recommend or require data sharing, actually intended to share data. Most studies which intended to share data only intended to share data with researchers, for purposes and by mechanisms at the discretion of, and subject to approval by, the principal investigator; and only intended to share data underlying the published results without supporting documents or specified timeframes. Factors that increased intention to share data included journal policies which required data sharing and data sharing statements, and industry involvement and COVID-19 relevance for interventional studies. Journal policies which required data sharing improved the extent of data and supporting documents to be shared, timeliness to share, extent of researchers to share with and purposes to share for, and ease of access.

Strengths and weaknesses of the study

We assessed an entire population of original research published in the highest-impact medical journals in 2022, giving the most systematic picture of journal data sharing policies in practice to date. However, there were some limitations. For studies whose final data sharing intention was to share data, classification of data on the authors decisions on what, when, with whom, how and why to share data into our pre-specific categories was sometimes difficult due to brevity and ambiguity.

Meaning of the study

Existing journal policies requiring data sharing are effective but insufficient

Journals which required data sharing had a 19% absolute increase in both interventional and observational studies which intended to share data and a 16% absolute increase in studies which initially intended to *not* share data in a publicly available research protocol but which ultimately intended to share data in the final publication, compared to journals which only recommended data sharing. This provides evidence to support journals to require data sharing for articles they publish. Interestingly, journals with policies which required data sharing *statements* (but not necessarily data sharing) had a larger absolute increase (45% for interventional studies and 33% for observational studies) in studies which intended to share data. This may be partly explained by closer adherence by researchers to journal submission guidelines than journal editorial policies, and provides evidence to support journals to require investigator statements of data sharing intentions at the time of manuscript submission.

However, almost a third (32%, 169/533) of interventional studies and a larger proportion (42%, 1052/2529) of observational studies in journals which required data sharing intended to *not* share data. This may be partly related to the accessibility, prominence, actionability and enforcement of the journal data sharing policies. These policies should be easy to find, obtain, follow and be used by researchers without experience of sharing data, and enforced by the journal. The most common reason for intending to not share data - that the availability of aggregate data was perceived as sufficient – reflects a misunderstanding of the concept of data sharing and the reasons why individual participant data are important. Journal data sharing policies should include a clear, unambiguous definition of data sharing and individual participant data, and an explanation of the utility of individual participant data compared to aggregate data. Journals with data sharing policies which require data sharing should also review the data sharing statements of studies which do not intend to share data at manuscript submission and ensure that their justification is reasonable (e.g., proprietary interests, incentives for commercial development, or agreements with third parties).

Researcher's intentions to share data rarely align with best practice

Most studies which intended to share data only intended to share data with researchers, for purposes and by mechanisms at the discretion of, and subject to approval by, the principal investigator, and only intended to share data underlying the published results without supporting documents or specified timeframes. In short, most studies which intended to share data only stated they would share data on request, and this has been shown to be both inefficient and ineffective.

Reassuringly, journal policies which required data sharing improved the extent of data and supporting documents to be shared, timeliness to share, extent of researchers to share with and purposes to share for, and ease of access. Therefore, if these policies were supplemented with additional guidance on the operationalisation of data sharing in accordance with best practice, data sharing might be improved.

REFERENCES

1. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. The Lancet. 2007;370(9596):1453-7.
2. Krampl A. Journal citation reports. Journal of the Medical Library Association: JMLA. 2019;107(2):280.
3. Tan AC, Webster AC, Libesman S, Yang Z, Chand RR, Liu W, et al. Data sharing policies across health research globally: Cross-sectional meta-research study. Research Synthesis Methods.n/a(n/a).

Appendix

b. Focus Group Moderator Guide

Before the Focus Groups

After participants have expressed an interest in taking part in one of the focus groups, they will be directed to a project website (https://ctiq.com.au/projects/) that includes:

1. A pdf of the Participant Information Sheet
2. A Calendly link to indicate consent, which focus group they would like to attend, and to collect basic demographic information (age range, state/territory of residence, primary role in the sector – researcher, research site/governance, funder/sponsor, other (please specify)).
3. An automated email will be sent through Calendly, including log-in details for the selected focus group

Start of Focus Groups
Check recording is on.

Acknowledgment of country

We are holding this focus group to hear people's thoughts on the governance of clinical research data sharing, including common barriers and potential enablers to accessing and sharing data. We are particularly interested in governance issues – role of institutions, ethics review bodies, data access committees, inter-institutional agreements.

We will use the information we gather to help us produce a toolkit of information to help researchers, sites and others designing governance for future clinical research projects. Information from these focus groups will ensure that we are developing resources that are as targeted as possible to the needs of the sector. We will be conducting four online focus groups. Once we have synthesised information from these focus groups, we will launch a survey to see whether the information captured during these focus groups reflects the needs of the research sector more broadly.

You should all have read the Participant Information Sheet. Please let me know if you have not. I have included a link in the meeting chat which you can go to now. I would like everyone to verbally confirm whether you are happy to proceed – make sure this is included in the recording. Thank you. If a participant decides they do not wish to proceed, inform them they can leave the meeting now.
Prompt participants to remember privacy/confidentiality.

Ask participants to give a one sentence intro with consent and share a recent data sharing win.

Any questions before we begin?

Semi-structured Focus Group Questions

a. Let's start with some reflections on the clinical research data sharing wins that you shared. What worked well here, to make this win a success for you?

b. What about more challenging experiences? What sort of roadblocks have you encountered? (Eg. Information gaps, processes, ethics, institutional/funding requirements...?)

c. When you were navigating those data sharing issues, what source or sources of guidance were most useful for you? (E.g., privacy laws, institutional policies, the National Statement on Ethical Conduct in Human Research, advice from a person at your institution, etc.

d. Were there gaps in information or supporting resources? What aspects could be better supported? Are there additional sources of guidance that could have helped you navigate these clinical research data sharing issues? What forms/approaches would be most useful for you in your context, eg, templates, guidance documents, case studies, etc.

e. If this project could manage to make a difference in just one area, what would your number one priority be?

f. Are there any other aspects of data sharing (challenges, support, priorities) that we haven't touched on that you'd like to discuss, or return to? Any additional comments regarding the secondary sharing of clinical research data that you would like to share with the project team?

Conclusion

Thank you for your time.