**Data sharing policies: a scoping review protocol**

**TITLE**

Data sharing policies: a scoping review protocol

**INTRODUCTION**

**Rationale**

The in-principle support for data sharing is strong. Research participants, biomedical researchers, healthcare consumers and health professionals are generally supportive of sharing of health research, clinical trial and health administrative, particularly if de-identified or anonymised.(1-8) The scientific community has gradually shifted from a cultural perception of data ownership to data custodianship and stewardship, and technological developments and statistical advances have greatly strengthened data sharing possibilities.(9)   
  
However, despite scientific and ethical imperatives, the in-practice commitment to sharing data is low.(10, 11) The practice of data sharing is dictated by data sharing policies. Over the past few decades, a large number of data sharing policies have been developed by a wide range of stakeholders. These data sharing policies are defined by a variety of principles and describe a variety of approaches to addressing issues.(12) However, they have been generally unsuccessful in closing the gap between the high level of in-principle support for data sharing and low level of in-practice willingness to actual do so.(13, 14)

Blasimme et al (2018) conducted a network and qualitative content analysis of 230 data sharing policy documents by 97 organisations over two decades and found the data sharing policy landscape to be fragmented and stakeholder interests and expectations to be divergent.(12) They concluded that the research community should adopt and develop innovative tools, recalibrate and redistribute policy emphasis, and harmonise international data sharing policies.(12) Waithira et al. described the elements of a data sharing policy for institutions, departments or groups.(15) They included aims, data management for data sharing, models of sharing, data access criteria, consent models for participants, and budgeting and cost recovery.

|  |  |
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| **Table 1. Future directions of data sharing policies by themes\*** | |
| **Data sharing policy themes\*\*** | **Future directions** |
| Accountability | **Impact assessment guidance**  Researchers could more effectively conduct impact assessments for privacy or data protection (12)  **Participatory data governance**  Through participant-centred data governance mechanisms and models, researcher participants should be involved in decisions and control of data management, data access and data sharing, and included in data access committees and oversight bodies (12) |
| Attribution | **Data tagging systems**  Researchers should trace credit for data curation (12)  **Data citation incentives**  Research funders should recognise and reward data curators for their role in data sharing (12)  **Recognition**  Researchers could be required to recognise data producers through authorship, acknowledgement or citation |
| Capacity building |  |
| Common good |  |
| Data publication |  |
| Data quality and curation | **Reciprocity-based data-access models**  Through reciprocity-orientated data infrastructure, researchers who access shared data should contribute to its maintenance (e.g., conduct quality-related tasks), curation and development (e.g., contribute new data) (12) |
| Data access |  |
| Development |  |
| Group rights |  |
| Autonomy | **Digital consent technologies**  Through robust informed consent procedure, research participants could make meaningful, granular, case-by-case deliberations throughout the various uses of the data (12) |
| Integrity | **Collaboration**  Researchers should collaborate with data producers when the interpretation of the data requires the experience and knowledge of the data producers |
| Interoperability | **Interoperable data standards**  Research funders should reimburse or rewarding scientific institutions for sharing data with other research organisations (12) |
| Open access publication |  |
| Privacy | **Privacy-preserving technological solutions** (e.g., advanced cryptography techniques and distributed ledger technologies)  Through novel privacy preserving data sharing mechanisms and standards for minimum levels of consent management, data exchange and access-control policy enforcement, researchers could more effectively protect data security and information privacy, promote collaborative research through data sharing, and maintain transparency, traceability and immutability (12, 16-19) |
| Professionalism |  |
| Public engagement |  |
| Regulatory compliance | **Coherent regulatory environment**  Research community should create an integrated, coherent regulatory environment and system framework around the collection, use and distribution of data (12) |
| Risk benefit assessment |  |
| Solidarity |  |
| Sustainability |  |
| Timeliness |  |
| \*Proposals should be introduced through pilot initial and ad hoc data sharing policies and will likely require targeted public investment \*\*Identified by Blasimme et al (2018)(12) | |

Data sharing standards refer to agreed principles and recommended processes for the sharing of data between producers and custodians of data and other users of data, which accommodate variation in individual and group preferences (e.g., research and participant communities).(20). They would support existing data sharing architecture (e.g., legal requirements and organisational governance), inform revisions of current data sharing policies and be incorporated into new data sharing policies. Data sharing standards differ from data sharing policies. Data sharing policies are specific to the aims, interests, expectations and context of stakeholder, sensitive to the regulatory requirements and ethical guidelines of the environment, and developed in consultation and engagement with internal and external groups.   
  
Data sharing standard would be operationalised as either a pragmatic instrument, systematic framework or structured guideline.

Review the DISTILL project shared by Lene on OneDrive (<https://unisyd-my.sharepoint.com/personal/lene_seidler_sydney_edu_au/_layouts/15/onedrive.aspx?id=%2Fpersonal%2Flene%5Fseidler%5Fsydney%5Fedu%5Fau%2FDocuments%2FData%20sharing%20project&ct=1635925368941&or=OWA%2DNT&cid=6c0a8b5c%2De84c%2D6312%2D1d57%2D57cd99541c51>)

Consider using the AGREED 2 instrument to compare the consistency or variability between data sharing policies in the cross-sectional studies and the data sharing policy recommendations

The REPRISE project  
<https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-021-01670-0>

Rates and predictors of data and code sharing in the medical and health sciences: Protocol for a systematic review and individual participant data meta-analysis  
<https://f1000research.com/articles/10-491/v2>   
  
Hrynaszkiewicz et al (2018)

Research Data Alliance (RDA) Data Policy Standardisation and Implementation Working Group Research Data Alliance. Data policy standardisation and implementation [Internet]. The Alliance; 2017 [cited 14 Dec 2017]. <https://www.rd-alliance.org/groups/data-policystandardisation-and-implementation>.

**Objectives**

The aim of this scoping review is to systematically synthesise existing policies for data sharing and categorically converge the overarching principles at an aggregate level. This will involve assessing whether data sharing policies exist, whether they recommend or require data sharing, and summarising characteristics of existing policies. This will include data sharing policies by various stakeholders in data sharing that sit at different stages in the life cycle of clinical trials.

**METHODS**

**Protocol and registration**

The research protocol for this scoping review will be prospectively registered, and thereafter accessible, on the Open Science Framework (OSF) (<https://osf.io/>). Any amendments to the research protocol will be contemporaneously documented on the OSF.

**Eligibility criteria**

We will include data sharing policies by various stakeholders in data sharing. These are summarised in Figure 1.  
 **Figure 1.** Data sharing stakeholders by clinical trial stage

Diagram

Description automatically generated

*Health research funders*  
Data sharing policies by health research funders which require data sharing have a large effect on facilitating data sharing and are associated with a high degree of compliance.(9) Health research funders which require data from health research they fund to be shared would minimise research waste and maximise research utility. They would minimise research waste by preventing duplication of data collection activities (especially those which are large, expensive, resource intensive, or nonreplicable), and maximise research utility by supporting timely secondary use of data (i.e., prospectively allocating sufficient resources to data sharing activities) and prospectively planned management (e.g. collection, curation and storage) of data.  
  
A cross-sectional study of the data sharing policies of commercial and non-commercial funders found that only 38% of non-commercial funders had a data sharing policy (of which 60% encouraged data sharing and 40% mandated data sharing) and only 41% of commercial funders had a data sharing policy.(14) A cross-sectional study of the data sharing policies of clinical trial funders in France found that only 29% had a data sharing policy, of which 89% supported data sharing and 11% mandated data sharing.(21) Of clinical trials funders in France with a data sharing policy, 33% specified the type of data shared and the mode of sharing data but restricted the sharing of data to researchers.(21) Another cross-sectional study of life science researchers found that approximately a third of grant reviewers placed no weight on data sharing plans in their reviews.(9)  
  
Health research funders will be stratified into public and philanthropic funders, and private funders. Public and philanthropic funders will be included on the basis of their annual health research expenditure as identified by Viergever & Hendriks (2016)(22). An equivalent number of private funders will be included on the basis of their annual health industry research and development expenditure as identified by the European Union Industrial Research and Development Investment Scoreboard (<https://iri.jrc.ec.europa.eu/scoreboard/2021-eu-industrial-rd-investment-scoreboard>). A total of 55 major public and philanthropic funders (49 major public national or regional funders and 6 major philanthropic funders), and 55 major private funders (44 pharmaceutical and biotechnology companies and 11 health care equipment and services companies) were included.   
  
The type of data (e.g., health-related, research, genetic and genomic, biobank, scientific publications, public health, clinical trial, proteomic or other) and country of funders will be collected.

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| **Major health researcher funders** | | |
| **Type of funder** | **Name of funder** | **Country of funder** |
| **Public** | | |
| Public | National Institutes of Health (NIH) | United States |
| Public | European Commission (EC) | European Union |
| Public | UK Medical Research Council (MRC) | United Kingdom |
| Public | Institut national de la santé et de la recherche médicale (Inserm) | France |
| Public | United States Department of Defense (US DoD) | United States |
| Public | Canadian Institutes of Health Research (CIHR) | Canada |
| Public | Australian National Health and Medical Research Council (NHMRC) | Australia |
| Public | Deutsche Forschungsgemeinschaft / German Research Foundation (DFG) | Germany |
| Public | National Natural Science Foundation of China (NSFC) | China |
| Public | Centre National de la Recherche Scientifique (CNRS) | France |
| Public | UK Department of Health / National Institute for Health Research (NIHR) | United Kingdom |
| Public | Japan Society for Promotion of Science (JSPS) | Japan |
| Public | Bundesministerium für Bildung und Forschung / Federal Ministry of Education and Research of Germany (BMBF) | Germany |
| Public | Ministero della Salute / Ministry of Health of Italy | Italy |
| Public | Instituto de Salud Carlos III (ISCIII)e | Spain |
| Public | Ministry of Health of China | China |
| Public | Japan Science and Technology Agency (JST)e | Japan |
| Public | Singapore National Medical Research Council (NMRC) | Singapore |
| Public | Korean National Research Foundation (NRF) | South Korea |
| Public | Consejo Nacional de Investigaciones Científicas y Técnicas (CONICET)e | Argentina |
| Public | Vetenskapsrådet-Medicine / Swedish Research Council | Sweden |
| Public | Swiss National Science Foundation (SNSF) | Switzerland |
| Public | ZonMw / Netherlands Organisation for Health Research and Development | Netherlands |
| Public | Sao Paulo Research Foundation (FAPESP)e | Brazil |
| Public | Indian Council of Medical Research (ICMR) | India |
| Public | Fund for Scientific Research - Flanders (FWO) | Belgium |
| Public | Korea National Institute of Health (KNIH) | South Korea |
| Public | Forskingsrådet / Research Council of Norway | Norway |
| Public | Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) | Brazil |
| Public | Fonds zur Förderung der wissenschaftlichen Forschung / Austrian Science Fund (FWF) | Austria |
| Public | South African Medical Research Council (SA MRC) | South Africa |
| Public | Health Research Council of New Zealand | New Zealand |
| Public | Danish Council for Independent Research / Medical Sciences | Denmark |
| Public | Russian Foundation for Basic Research (RFBR) | Russia |
| Public | Danish Council for Strategic Research (two programmes: Individuals, Disease and Society & Health, Food and Welfare) | Denmark |
| Public | Consejo Nacional de Ciencia y Tecnología (CONACYT) | Mexico |
| Public | South African Department of Science and Technology (DST) | South Africa |
| Public | Agencia Nacional de Promocion Cientifica y Technologica (Agenica - ANPCyT) | Argentina |
| Public | Biomedical Research Council of the Singapore Agency for Science, Technology and Research (BMRC of A\*STAR) | Singapore |
| Public | Ministry of Science and Technology of China (MOST) | China |
| Public | Indian Department of Biotechnology (DBT) | India |
| Public | Indian Department of Science and Technology (DST) | India |
| Public | King Abdulaziz City for Science and Technology (KACST) | Saudi Arabia |
| Public | Le Fonds de la Recherche Scientifique (FNRS) | Belgium |
| Public | Lipi Indonesian Research Council | Indonesia |
| Public | Ministry of Healthcare of the Russian Federation | Russia |
| Public | National Research Foundation South Africa (NRF SA) | South Africa |
| Public | Tubitak / Scientific and Technological Research Council of Turkey | Turkey |
| Public | Turkish Academy of Sciences (TUBA) | Turkey |
| **Philanthropic** | | |
| Philanthropic | Wellcome Trust | United Kingdom |
| Philanthropic | Howard Hughes Medical Institute (HHMI) | United States |
| Philanthropic | Bill & Melinda Gates Foundation (BMGF) | United States |
| Philanthropic | Institut Pasteur | France |
| Philanthropic | Oswaldo Cruz Foundation (Fiocruz) | Brazil |
| Philanthropic | Rockefeller foundation | United States |
| **Private (pharmaceuticals and biotechnology)** | | |
| Private (p&b) | ROCHE | Switzerland |
| Private (p&b) | JOHNSON & JOHNSON | United States |
| Private (p&b) | BRISTOL-MYERS SQUIBB | United States |
| Private (p&b) | MERCK US | United States |
| Private (p&b) | PFIZER | United States |
| Private (p&b) | BAYER | Germany |
| Private (p&b) | NOVARTIS | Switzerland |
| Private (p&b) | SANOFI | France |
| Private (p&b) | ABBVIE | United States |
| Private (p&b) | GLAXOSMITHKLINE | United Kingdom |
| Private (p&b) | ASTRAZENECA | United Kingdom |
| Private (p&b) | GILEAD SCIENCES | United States |
| Private (p&b) | BOEHRINGER SOHN | Germany |
| Private (p&b) | TAKEDA PHARMACEUTICAL | Japan |
| Private (p&b) | ELI LILLY | United States |
| Private (p&b) | AMGEN | United States |
| Private (p&b) | BIOGEN | United States |
| Private (p&b) | MERCK DE | Germany |
| Private (p&b) | ABBOTT LABORATORIES | United States |
| Private (p&b) | NOVO NORDISK | Denmark |
| Private (p&b) | DAIICHI SANKYO | Japan |
| Private (p&b) | INCYTE | United States |
| Private (p&b) | ASTELLAS PHARMA | Japan |
| Private (p&b) | OTSUKA | Japan |
| Private (p&b) | UCB | Belgium |
| Private (p&b) | VERTEX PHARMACEUTICALS | United States |
| Private (p&b) | EISAICO | Japan |
| Private (p&b) | BEIGENE | China |
| Private (p&b) | ALEXION PHARMACEUTICALS | United States |
| Private (p&b) | CSL | Australia |
| Private (p&b) | TEVA PHARMACEUTICAL INDUSTRIES | Israel |
| Private (p&b) | SERVIER | France |
| Private (p&b) | SEAGEN | United States |
| Private (p&b) | MODERNA | United States |
| Private (p&b) | SAREPTA THERAPEUTICS | United States |
| Private (p&b) | ILLUMINA | United States |
| Private (p&b) | FOSUN INTERNATIONAL | China |
| Private (p&b) | BIOMARIN PHARMACEUTICAL | United States |
| Private (p&b) | H LUNDBECK | Denmark |
| Private (p&b) | ONO PHARMACEUTICAL | Japan |
| Private (p&b) | VIATRIS | United States |
| Private (p&b) | BIONTECH | Germany |
| Private (p&b) | MERIEUX ALLIANCE | France |
| Private (p&b) | SHIONOGI | Japan |
| **Private (health care equipment and services)** | | |
| Private (hce&s) | MEDTRONIC PUBLIC LIMITED | Ireland |
| Private (hce&s) | THERMO FISHER SCIENTIFIC | United States |
| Private (hce&s) | BOSTON SCIENTIFIC | United States |
| Private (hce&s) | BECTON DICKINSON | United States |
| Private (hce&s) | CARL ZEISS | Germany |
| Private (hce&s) | STRYKER | United States |
| Private (hce&s) | FRESENIUS | Germany |
| Private (hce&s) | EDWARDS LIFESCIENCES | United States |
| Private (hce&s) | ESSILORLUXOTTICA | France |
| Private (hce&s) | OLYMPUS | Japan |
| Private (hce&s) | INTUITIVE SURGICAL | United States |

Data will be collected from the official website, online reports and other information sources. Data will be confirmed with the representatives of the health researcher funders. Health researcher funders will be advised of the data we have collected and the information sources from where the data was collected, and asked to add, amend or confirm the data.  
  
**NHMRC Open Access Policy**  
[https://www.nhmrc.gov.au/about-us/resources/open-access-policy?utm\_medium=email&utm\_campaign=Tracker%20-%201%20November%202021&utm\_content=Tracker%20-%201%20November%202021+CID\_df6913d5612e708479ca77004b5081b9&utm\_source=Mailbuild&utm\_term=report#](https://www.nhmrc.gov.au/about-us/resources/open-access-policy?utm_medium=email&utm_campaign=Tracker%20-%201%20November%202021&utm_content=Tracker%20-%201%20November%202021+CID_df6913d5612e708479ca77004b5081b9&utm_source=Mailbuild&utm_term=report)

NIH Data Sharing policy  
Wellcome Trust data sharing policy  
Gates Foundation data sharing policy  
  
*Research ethics committees*Research ethics committees which recommend data from research they review be shared would strengthen the social licence and public acceptability of health research, and support the production of high quality datasets. Data sharing standards can support research ethics committees, who often consider whether proposals for data sharing meet ethical and regulatory standards.(23)   
  
National ethics committees will be included as identified by Hummel et al (2021).(24) A total of 124 national ethics committees were included, with 41 national research ethics review committees (i.e., review research protocols and projects), 12 national research ethics committees (i.e., develop research policies and guidelines), 50 national bioethics committees (i.e., work on general bioethical issues), 16 multi-purpose national ethics committees (i.e., more than one function) and 5 non-specific national ethics committees (i.e., unclear function).(24)

Health research funders will be stratified into public and philanthropic funders, and private funders. Public and philanthropic funders will be included on the basis of their annual health research expenditure as identified by Viergever & Hendriks (2016)(22). An equivalent number of private funders will be included on the basis of their annual health industry research and development expenditure as identified by the European Union Industrial Research and Development Investment Scoreboard (<https://iri.jrc.ec.europa.eu/scoreboard/2021-eu-industrial-rd-investment-scoreboard>). A total of 55 major public and philanthropic funders (49 major public national or regional funders and 6 major philanthropic funders), and 55 major private funders (44 pharmaceutical and biotechnology companies and 11 health care equipment and services companies) were included.   
  
*Clinical trial registries*Clinical trial registries which require data from clinical trials they register to be shared would expediate the validation of research (e.g., reproduction and replication through complete re-analysis of data) and synthesis of evidence.  
  
Clinical trial registries will be identified by the World Health Organisation (WHO) Registry Network (International Clinical Trials Registry Platform) (<https://www.who.int/clinical-trials-registry-platform/network>) and the United States (US) Department of Health and Human Services’ (HHS) Office for Human Research Protections (OHRP) (<https://www.hhs.gov/ohrp/international/index.html>), including their listing of clinical trial registries (<https://www.hhs.gov/ohrp/international/clinical-trial-registries/index.html>) and their International Compilation of Human Research Standards (<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>). Clinical trial registries will be included if they are a primary registry or data provider, in accordance with the International Committee of Medical Journal Editors’ (ICJME) clinical trial registration policy which only accepts registration of clinical trials in a primary registry or ClinicalTrials.gov (<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>). Clinical trial registries which are partner registries, disease-specific, device-specific, procedure-specific or other databases will be excluded. The included clinical trial registries are summarised in Table 4.

|  |  |  |
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| **Table 4. Clinical trial registries** | | |
| **Primary registries** | | |
| **1** | ANZCTR | Australian New Zealand Clinical Trials Registry (<https://www.anzctr.org.au/>) |
| **2** | ReBec | Brazilian Clinical Trials Registry ([www.ensaiosclinicos.gov.br](http://www.ensaiosclinicos.gov.br)) |
| **3** | ChiCTR | Chinese Clinical Trial Registry (<http://www.chictr.org.cn/enIndex.aspx>) |
| **4** | CRiS | Clinical Research Information Service, Republic of Korea  (<https://cris.nih.go.kr/cris/info/introduce.do?search_lang=E&lang=E>) |
| **5** | CTRI | Clinical Trials Registry – India (<http://ctri.nic.in/Clinicaltrials/login.php>) |
| **6** | RPCEC | Cuban Public Registry of Clinical Trials (<https://rpcec.sld.cu/en/home>) |
| **7** | EU-CTR | EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu/ctr-search/search>) |
| **8** | DRKS | German Clinical Trials Register (<https://www.drks.de/drks_web/>) |
| **9** | IRCT | Iranian Registry of Clinical Trials (<https://www.irct.ir/>) |
| **10** | ISRCTN | ISRCTN (<https://www.isrctn.com/>) |
| **11** | JPRN | Japan Primary Registries Network (<https://rctportal.niph.go.jp/en/>)  **1** │JapicCTI │ Japic Clinical Trials Information (<https://www.japic.or.jp/>)  **2** │JMACCT CTR │ Japan Medical Association Centre for Clinical Trials Clinical Trial Registry (<http://www.jmacct.med.or.jp/en/>)  **3** │jRCT │ Japan Registry of Clinical Trials (<https://jrct.niph.go.jp/>)  **4** │UMIN CTR │ University hospital Medical Information Network Clinical Trial Registry (<https://www.umin.ac.jp/ctr/>) |
| **12** | LBCTR | Lebanese Clinical Trials Registry (<https://lbctr.moph.gov.lb/>) |
| **13** | TCTR | Thai Clinical Trials Registry (<https://www.thaiclinicaltrials.org/>) |
| **14** | NTR | The Netherlands Trial Register (<https://www.trialregister.nl/>) |
| **15** | PACTR | Pan African Clinical Trial Registry (<https://pactr.samrc.ac.za/>) |
| **16** | REPEC | Peruvian Clinical Trial Registry (<https://ensayosclinicos-repec.ins.gob.pe/en/>) |
| **17** | SLCTR | Sri Lanka Clinical Trials Registry (<https://slctr.lk/>) |
| **Data providers** (excluding primary registries) | | |
| **18** | ClinicalTrials.gov | ClinicalTrials.gov (<https://clinicaltrials.gov/>) |
| **Partner registries** (not included) | | |
|  | CCRBCTR | Centre for Clinical Research and Biostatistics – Clinical Trials Registry (<https://www2.ccrb.cuhk.edu.hk/web/?page_id=746>) |
|  | AMCTR | Acupuncture-Moxibustion Clinical Trial Registry ([www.acmctr.org](http://www.acmctr.org)) |
| **Other databases** (not included) | | |
|  | HC CTD | Health Canada's Clinical Trials Database (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html>) |
|  | SNCTP | Swiss National Clinical Trials Portal (<https://www.kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/>) |
|  | PHRR | Philippine Health Research Registry (<https://registry.healthresearch.ph/index.php/registry>) |
|  | SANCTR | South African National Clinical Trial Register ([www.sanctr.gov.za](http://www.sanctr.gov.za)) |
|  | TzCTR | Tanzania Clinical Trial Registry (<http://www.tzctr.or.tz/faq.php>) |
|  | NMRR | National Medical Research Register (<https://www.nmrr.gov.my/fwbLoginPage.jsp>) |
|  | ReNIS | National Registry of Health Research (<https://www.argentina.gob.ar/salud/registroinvestigaciones>) |
|  | NCTR | Nigerian Clinical Trials Registry (<https://nhrec.net/nigeria-clinical-trials-registry/>) |

*Peer-reviewed scientific journals*

Peer-reviewed scientific journals which require data from articles they publish to be shared would enhance the transparency of findings (i.e., openness of information irrespective of outcome) and confidence in results (e.g., accuracy and validity). The Principles of Transparency and Best Practice in Scholarly Publishing (<https://doaj.org/apply/transparency/>), by the Committee on Publication Ethics (COPE), Directory of Open Access Journals (DOAJ), Open Access Scholarly Publishers Association (OASPA) and the World Association of Medical Editors (WAME), requires member journals to have a policy on data sharing and reproducibility, and the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (<http://www.icmje.org/recommendations/>), by the International Committee of Medical Journal Editors (ICJME), requires clinical trials submitted to member journals to have a data sharing statement in the manuscript and a data sharing plan in the trial registration.(25) Publisher conformance with these guidelines and best practices is required for a journal to be indexed in MEDLINE or PubMed Central by the National Library of Medicine (<https://www.nlm.nih.gov/medline/medline_policies.html#pubpractices>).

Additionally, data publication, citation and altmetrics have been proposed as possible mechanisms to recognise data generation and incentivise data sharing.(26, 27) As these alternative scholarly crediting systems are implemented, data standards relating to data curation are required to protect the reliability and value of published data and prevent novel forms of research misconduct. This is particularly important given that there is only one evidence-based incentive (using open data badges) to promote data sharing.(28) However, the impact of data sharing policies by peer-reviewed scientific journals depends on author compliance and journal enforcement,(29) with data availability in less than half of RCTs in two journals (BMJ and PLOS Medicine) with strong data sharing policies. Suboptimal data availability despite strong data sharing policies is related to inability to contact corresponding author, inadequate resources by authors to prepare datasets, different data sharing practices, and infrequent formal or informal sanctions for non-compliance.(9, 30)

A cross-sectional study of life, health and physical science journals found that 44% had no data sharing policy, 18% had a data sharing policy which encouraged data sharing and 38% had a data sharing policy which expected or mandated data sharing.(31) A cross-sectional study of biomedical journals found that 32% had no data sharing policy, 9% had a data sharing policy which mentioned data sharing, 23% had a data sharing policy which encouraged data sharing, 9% had a data sharing policy which required data sharing but not as a condition of publication, and 12% had a data sharing policy which required data sharing as a condition of publication.(31) Additionally, it found that most data sharing policies had no specific guidance on the practices of data sharing. A cross-sectional study of biology, clinical science, mathematics, physics and social sciences journals found that 44% had no data sharing policy, 5% had a data sharing policy which mentioned data sharing, 41% had a data sharing policy which encouraged data sharing, 8% had a data sharing policy which required data sharing but not as a condition of publication, and 3% had a data sharing policy which required data sharing as a condition of publication.(32) A cross-sectional study of ten high-impact surgical journals found that only one journal had a data sharing policy which required data sharing.(33)

Higher strength of data sharing policy is associated with higher impact factor.(31, 32, 34) Strength of data sharing policy was not associated with model of publication (open access or subscription).(34)  
  
Peer-reviewed scientific journals will be included if they are ranked in the top five journals by Journal Impact Factor in each of the 59 categories in clinical medicine in the 2020 Journal Citation Reports.   
  
The online author instructions and editorial policies for included journals will be reviewed. Other journal characteristics will be extracted, including the subject area, Journal Impact Factor, volume of publications, model of publication (e.g., open access or subscription), type of journal publisher (e.g., commercial or non-commercial) and geographical location of journal publisher.  
  
*Research data repositories*Research data repositories and other online infrastructure have a large effect on facilitating data sharing.(9) Research data repositories which recommend data they store be shared would motivate data sharing and improve data governance.   
  
Research data repositories will be included if they were registered in re3data in 2021 and their subject is medicine. Data will be directly abstracted on the type of regulations to (a) accessing the research data repositories (open, restricted, closed or embargoed), (b) accessing the research data provided by the research data repositories (open, restricted or closed), and (c) submitting research data to the research data repositories (open, restricted or closed) (<https://www.re3data.org/search?query=&subjects%5B%5D=22%20Medicine>)

*Other*

Clinical trialist, research groups, academic departments and research institutions which require data they produce to be shared would improve the findability, accessibility, interoperability and reusability (FAIR principles) of their data, and the output of their research. They would support data producers by specifying agreed levels of data curation (e.g., collecting and organising data in a clear and consistent way) and anonymisation (e.g., reducing the risk of re-identification by eliminating direct identifiers and superfluous data and modifying indirect identifiers).(35) They would support data custodians by specifying agreed levels of data management (e.g., determining data access, use and exchange by validating secondary users research background and question, implementing data use agreements and approval processes, requiring statistical software programs to open datasets, or depositing data in research community accessible repositories).(35) They would also support data users with secondary analyses, study replication and individual participant data analysis. This could involve setting a minimum list of information for shared data to be understood, original analyses to be replicated, and raw data to be included in individual participant data analyses.   
  
Trialists may benefit from data sharing through additional scholarly citations (29) and research impact, or additional research collaborations and funding opportunities. However, in our retrospective cohort study of interventional trials, we found that only one in five committed to sharing data.(13) A cross-sectional study of trialists who were willing to share data found that approximately half had a data sharing plan, of which approximately half were written and half were discussed.(36)

*Health research regulators*

In the fields of genomics, the Global Alliance for Genomics and Health has adopted the Framework for Responsible Sharing of Genomic and Health-Related Data.(37)

**Information sources**

Informational sources will include

Two authors will be involved in all stages of the review process; conflicts will be resolved by consensus. Data will be extracted independently using a pre-piloted data extraction template. Conflicts will be resolved by consensus.

**Search**

***\_***

**Study selection**

All phases of policy selection will be piloted and performed in duplicate by two independent reviewers, with resolution of disagreements by discussion and a third reviewer.

**Data collection process**

Data will be extracted from included policies in duplicate by two independent reviewers using a data extraction form developed and piloted by the reviewers (Appendix X), with resolution of disagreements by discussion and a third reviewer. If required, authors of included policies will be contacted to request missing or additional data.

**Data items**

Data sharing policies will be assessed by their presence or absence, and by the magnitude of their recommendations or requirements. This is summarised in Table 1.

|  |
| --- |
| **Table 1. Assessment of data sharing policies\*** |
| **1 Absent data sharing policy**  No data sharing policy |
| **2 Weak data sharing policy: mention**  Data sharing policy which neither recommends nor requires data sharing |
| **3 Moderate data sharing policy: recommendation**  Data sharing policy which recommends, but does not require, data sharing  This could be subcategorised into data sharing policies which encourage data sharing   and those which expect data sharing (i.e., mandate a data availability statement) |
| **4 Strong data sharing policy: requirement**  Data sharing policy which requires data sharing  Thiscould be subcategorised into data sharing policies which also mandate data peer-  review |
| \*Not applicable to commercial health research funders because, rather than recommend or require data sharing, these internal policies typically advise how external researchers can request data |

Data sharing policies which recommend or require data sharing will be described by the **(a)** studies, data and documents to be shared, and the exceptions, **(b)** start and stop of data sharing, **(c)** people to share with, **(d)** purpose for sharing data, and **(e)** distribution of shared data. These are summarised in Table 2.

|  |  |
| --- | --- |
| **Table 2. Description of data sharing policies which recommend or require data sharing** | |
| **What** |  |
| **1 Studies**  What studies are  recommended or  required to share data? | **1** All studies  **2** Only interventional studies  **3** Only observational studies |
| **2 Data**  What data are  recommended or  required to be shared? | **1** All collected IPD  All IPD collected during the study  **2** Only underlying IPD  Only IPD underlying the published results  **3** Not specified |
| **3 Documents**  What supporting  documents (excluding  the data dictionary) are  recommended or  required to be shared? | **1** Study protocol  **2** Statistical analysis plan  **3** Informed consent form  **4** Clinical study report  **5** Ethical approval  **6** Analytic code  **7** Not specified |
| **4 Exceptions**  What are the  exceptions to  recommendations or  requirements to share  data? | **1** Justified  **2** Unjustified  Examples include proprietary interests, incentives for commercial development, and agreements with third parties |
| **When** |  |
| **5 Start**  When are data  recommended or  required to start being  shared? | **1** Immediately following publication  Immediately following publication **2** Before pre-determined period  Before a pre-determined period following publication (e.g.,   after an embargo or exclusive access period)  **3** Not specified |
| **6 Stop**  When are data  recommended or  required to stop being  shared? | **1** No end date  No end date **2** After pre-determined time  After a pre-determined period following publication  **3** Not specified |
| **Who** |  |
| **7** **People**  Who are data  recommended or  required to be shared  with? | **1** Any person  Anyone who wishes to access the data  **2** Research proposal  Only researchers who provide a methodologically sound  proposal, with ethical approval if appropriate  **3** Independent committee  Investigators whose proposed use of IPD has been   reviewed, assessed and approved by an independent data   access committee identified for this purpose  **4** Scientific journal  Scientific journal  **5** Investigator discretion  Case-by-case basis at the discretion of the principal  investigator  **6** Known colleague  Colleagues only  **7** Sponsor discretion  Case-by-case basis at the discretion of the primary sponsor **8** Not specified **9** Other  Participant protections (e.g., appropriate consent processes,  institutional review board review and technical and statistical  database safeguards)  Investigator protections (e.g., signed data access  agreements) |
| **Why** |  |
| **8 Purpose**  What are data  recommended or  required to be shared  for? | **1** Any purpose  Any purpose  **2** Research proposal  Only to achieve the aims in the approved proposal, with  ethical approval if appropriate  **3** IPD meta-analysis  For IPD meta-analysis +/- systematic reviews  **4** Exploratory analysis  For exploratory analysis  **5** Investigator discretion  Case-by-case basis at the discretion of the principal  investigator  **6** Replication  Replication of results only  **7** Sponsor discretion  Case-by-case basis at the discretion of the primary sponsor  **8** Not specified |
| **How** |  |
| **9 Distribution**  What are the   mechanisms by which   data are   recommended or   required to be shared? | **1** Third party website  Unrestricted access through a third party website  **2** University data warehouse  Access through a university data warehouse  **3** Publishing journal website  Access through the publishing journal website (e.g.,   supplementary material to a journal article)  **4** Principal investigator contact  Access subject to approval by the principal investigator  **5** Primary sponsor contact  Access subject to approval by the primary sponsor  **6** Principal investigator or primary sponsor contact  Access subject to approval by either the principal  investigator or primary sponsor  **7** Principal investigator and primary sponsor contact  Access subject to approval by both the principal investigator  and primary sponsor  **8** Not specified |
|  | |

A preliminary literature search and expert consultations did not identify any pertinent publications, and this seeming scarcity of relevant research lends itself to a scoping review approach. A preliminary search of MEDLINE, Cochrane Database of Systematic Reviews and JBI Evidence Synthesis did not identify any current or underway systematic reviews or scoping reviews on the topic.

**Summary measures**

The principal summary measures will be descriptive statistics (e.g., frequency and proportion). The results of the search and policy selection (e.g., number of policies screened, assessed for eligibility, included in the review and excluded at each stage with reasons) will be reported with a flow diagram. For each policy, the characteristics for which data were extracted will be reported in a table.

The policy themes identified by Blasimme et al (2018)(12) will be coded from the full text of each policy by two independent coders using qualitive research software (Nvivo). The agreement and kappa between the two coders will be calculated.

**Synthesis of results**

Data will be managed throughout the review in Microsoft Excel. Policies will be narratively described, qualitatively synthesised and visually represented as a map or framework. The main findings will be summarised, and their relevance to key groups will be considered. The limitations at policy and outcome level, and at review-level (e.g., incomplete retrieval of identified policies or reporting bias) will be discussed. A general interpretation of the results in the context of current evidence, practice and policy, implications of the review and recommendations for future research will be provided.

**FUNDING**

There are no sources of financial support for this review.

**DELPHI STUDY**

The concept modelling from this scoping review will inform a Delphi study to develop consensus within the wider scientific community of best practices on an individual level. The Delphi study will develop consensus by consulting a multi-stakeholder cross-disciplinary, cross-sectoral and cross-jurisdictional consortia of data sharing and standards development experts, and by engaging the public.(38)

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- Reproducible Health Data Services WG (<https://www.rd-alliance.org/node/61938/case-statement>)

- Raising FAIRness in health data and health research performing organisations (HRPOs) WG (<https://www.rd-alliance.org/node/69831/case-statement>)   
- Research Data Alliance (RDA) Data Policy Standardisation and Implementation Working Group  
- RDA Privacy Implications of Research Data Sets IG (<https://www.rd-alliance.org/node/50796/charter>)   
- Health Data Interest Group (<https://www.rd-alliance.org/node/50708/charter>)   
FAIRsharing (<https://fairsharing.org>)   
Force 11

- FAIR Data Principles (<https://www.force11.org/group/fairgroup/fairprinciples>)

- Research Data Publishing Ethics (<https://www.force11.org/group/research-data-publishing-ethics>)

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