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Reporting on data sharing: executive position of the EQUATOR Network

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The EQUATOR (Enhancing the Quality and Transparency Of health Research) Network supports the practice of data sharing, and the reporting of data management and sharing plans, in all reports of biomedical research. Both practices should be included as checklist items when developing new or updating reporting guidelines. More focus should be given to structuring and standardising data management and sharing plans to help provide a similar impact as reporting guidelines.

In 2006, the late Doug Altman, from the Centre for Statistics in Medicine, University of Oxford, and colleagues, established the first EQUATOR (Enhancing the Quality and Transparency Of health Research) Centre. As of February 2024, EQUATOR is a network comprising five centres (Australasia, Canada, China, France, and the UK) and an executive group. The remit of EQUATOR is “to achieve accurate, complete, and transparent reporting of all health research studies to support research reproducibility and usefulness.”¹ While EQUATOR offers several toolkits and other resources to help researchers achieve transparency in reporting their research, the most recognised feature is the open online library of reporting guidelines.²

Reporting guidelines

In 2010 EQUATOR proposed a working definition of a reporting guideline as “a checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology.”³ The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist is a prime example of a mature reporting guideline, now in its third edition. PRISMA 2020 includes a 27 item checklist, a flow diagram, and a large explanation and elaboration pedagogical document. Reporting guidelines are popular and widely recommended and endorsed by journals and editorial groups. Several articles on these guidelines are among the most cited in biomedicine.⁴ Reporting guidelines are also becoming more recognised as relevant to the broader research ecosystem. Australian funders now endorse the use of

reporting guidelines to improve the transparency and completeness of a research product,⁵ which is also happening in other jurisdictions.⁶ Complete, clear and accurate reporting is one essential element of open science processes, and the EQUATOR reporting guidelines assist with standardised and accessible guidance.

Open science

More recently, many players in the research ecosystem have focused their attention on other open science practices, such as registration and full transparency in all aspects of the research study. These practices are core to EQUATOR and have been since its inception in 2006. Open science is quickly becoming ubiquitous in Europe. As defined by the United Nations Educational, Scientific, and Cultural Organisation, open science is a movement away from “me” science towards something more broadly useful to society.⁷

Data sharing is a component of open science (see below). Highlighting the rotating leadership of the European Union, France chose to highlight the importance of open science. On 4-5 February 2022, the French government hosted the virtual Paris Open Science European Conference.⁸

Data sharing

In August 2022, the US White House’s Office of Science and Technology Policy (OSTP) announced that as of January 2026, publications resulting from US federally funded research will have to be immediately accessible to the public.⁹ Covid-19 publications might foreshadow what 2026 will look like, more generally. During the pandemic, many paywalled and hybrid publishers committed to making covid-19 research openly available immediately to researchers and the public.

The second part of the OSTP announcement is the requirement of immediate availability of the data underpinning the results of the research product at the time of publication. Data sharing refers to the practice of making the underlying data, analytical code, and other materials from a completed study available to other stakeholders, including other researchers, study participants, and the broader public. In surveys of patients who have participated in clinical trials and other types of research, they indicate support for sharing their data to help advance knowledge.^{10 11}

What is meant by “data”? The management of data for a research project ideally starts with a broad research data management (RDM) document. How the data will be defined, collected, and managed during a study and shared following the study’s completion is typically contained in a data management and sharing

SUMMARY POINTS

The EQUATOR (Enhancing the Quality and Transparency Of health Research) executive supports the practice of data sharing when reporting all research

Data sharing is important and should be a checklist item in all reporting guidelines

To avoid the potential research waste and confusion to research teams due to differing organisation and funder data management and sharing plans, the EQUATOR executive supports structuring and standardising them, similar to the approach taken with reporting guidelines

plan (DMSP) document. This document describes plans to share data collected during a research project. It also describes how the code used to analyse the data to arrive at the reported results will be shared. A third component of the DMSP is the sharing of relevant materials used (eg, manual or video used for delivering the intervention to patients; cell line) when conducting the research study. Some funders now require an RDM document including a DMSP as part of a grant submission. The Canadian Institutes of Health Research are piloting a new requirement for RDM and DMSP documents in some of their grant applications in anticipation of a broader rollout of the requirement.¹² Similar requirements are occurring elsewhere.¹³⁻¹⁵ Some researchers have argued for a broader concept of data sharing using a mazlovian pyramid of data sharing needs, starting with study registration, moving to protocol availability, and finally to availability of data.¹⁶

However, biomedical researchers do not always share all these elements of their data.¹⁷ One reason could be related to the omission, with rare exception,¹⁸ of this request from reporting guidelines until recently. Item 27 of PRISMA 2020 asks authors to report on data sharing and is a more recent addition to reporting guidelines. Authors are asked to report on the “availability of data, code, and other materials,” and to “report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.”¹⁹

EQUATOR executive position on the reporting of data sharing

EQUATOR does not develop reporting guidelines itself. Members of EQUATOR, including the executive, are involved in various reporting guideline initiatives (eg, TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis), CONSORT (Consolidated Standards of Reporting Trials), PRISMA). The EQUATOR Network is committed to ensuring that the reporting guidelines are developed appropriately and that research is reported

comprehensively and transparently. The executive believes that it is important to advocate for improving completeness of reporting. Data sharing is one such concept and practice that should be incorporated in new and updated reporting guidelines. EQUATOR embraces data sharing initiatives. Our focus is on the reporting of data sharing in planned (protocols) and completed research projects. We believe that those groups developing or updating reporting guidelines should incorporate the five behaviours or practices discussed in box 1. The items in box 1 do not constitute a reporting guideline checklist for data sharing, and were not formally developed. They represent our experiences in developing reporting guidelines and peer reviewing research articles, and reflect our knowledge of open science, including data sharing.

Data sharing provides some additional advantages to the research ecosystem. For example, conducting a meta-analysis of individual patient data allows for the examination of questions that might not typically be answered in an individual study. Replication research likely benefits when data from original studies are shared, although this notion has not been investigated extensively in biomedicine so far.²⁰ Transparently reported research is fundamental to examining reproducibility,²¹ as is sharing data.

Box 2 includes some important data sharing elements for prospective authors to describe in their completed study. This list is not formally developed or meant to be exhaustive, nor is it a checklist on how to report data sharing (none currently exists). The list is based on an informal review of the literature (eg, Peller et al²²) and on our collective experiences conducting research and developing DMSPs. Prospective authors can include other information that will help readers understand and gain access to all data sharing of completed studies. The Open Science Framework is also providing information on easier ways to enable metadata sharing.²³

Implementing the reporting of data sharing

Implementation of data sharing requires planning and resources. Funding to enable data sharing is pivotal and some funders are now budgeting for this.²⁴ Similarly, there is an urgent need for local experts to help researchers integrate data sharing into their research processes, although resources to facilitate data sharing have become increasingly available.²⁵⁻²⁸ Too few faculty and staff are aware of open science, including what is required and how to create RDMs and DMSPs. An institutional structure is needed in place that includes pedagogical learning. Similarly, in some jurisdictions it is unclear as to whether grant applicants are allowed to include a budget line item for data sharing. We believe that funders should make data sharing a normative practice expectation of grantees. Without funding to enable it, meaningful data sharing is unlikely to become a reality any time soon. Most journals have suboptimal policies regarding data sharing,²⁷ although there are a few exceptions.²⁸⁻²⁹

Box 1: Data sharing elements to consider when creating or updating a reporting guideline

- Include an item(s) explicitly asking authors to describe data sharing when reporting their protocol and completed research study. PRISMA 2020 (item 27) is a reasonable template for reporting guideline developers to consider.
- Reporting guideline checklists should always include other items related to reporting data sharing, such as reporting on analytical code sharing, sharing of other materials, study registration details including registration number, and where to obtain the study protocol.¹⁶
- Developers updating an existing reporting guideline should include an item(s) on data sharing.
- Reporting guideline developers are encouraged to engage in developing guidance for reporting protocols and for this guidance to include an item about data sharing.
- Initiatives that promote reporting transparency across all research, including data sharing, should be encouraged and supported.

Box 2: Main items for prospective authors to consider when reporting on sharing data and related materials

- How the data were defined, collected, and managed, including copies of any forms.
- Data dictionaries.
- Relevant materials (eg, manual or video used for delivering the intervention to patients).
- Describing the management of data including missing data, data freeze dates, and data checking.
- Reporting the statistical analysis plan used, any changes (and when in the study process) to the statistical analysis plan from what was planned, and the analytical code.
- Use of the FAIR (findable, accessible, interoperable, reusable; CARE for indigenous populations) principles to locate and access the data.
- Barriers to sharing data and other materials from this study.
- Metadata, such as name of funder and associated funding ID data freeze dates.

Without additional efforts by journals and publishers, data sharing is unlikely to improve.

The prevailing view is that data sharing is optimised through the development of a DMSP. The Digital Research Alliance of Canada and other international groups (eg, US National Institutes of Health) have started developing templates for these plans. DMSPs are likely to be useful in biomedical research; for example, randomised controlled trials probably need separate DMSPs for preclinical animal trials and for trials for clinical interventions. Such DMSPs are likely to differ from those for clinical prediction model studies, for example.

What is less clear is the agreement of items and explanations to include for a DMSP across groups developing templates. For example, for organisations that have developed these plans for clinical randomised controlled trials, it should be established whether there is agreement of the data sharing items; whether the items and explanations for their inclusion are evidence based; and how these plans are optimally reported. These questions are important, and the answers will help optimise the development and implementation of DMSPs. For an international trial, which DMSP should be followed? Similarly, if DMSP templates differ across agencies, will this result in confusion for trial research teams, and will different DMSPs result in research waste or reduce the quality of reporting these plans? Would an effort aimed at structuring and standardising DMSPs provide similar impact as reporting guidelines? We believe that developing a standardised approach for reporting DMSPs is a real possibility and that the EQUATOR Network are well positioned to contribute to.

Researcher assessment

Beyond the inclusion of data sharing in reporting guidelines, its uptake and implementation might also benefit from using data sharing as part of researcher assessment. While only launched in 2022, more than 350 organisations from 40 countries have signed the Coalition for Advancing Research Assessment, a group commitment to reimagining the research assessment process.³⁰ Giving researchers credit for reporting data sharing activities fits this thinking.

Data sharing in biomedicine needs to become an expected and standard practice. We believe that the EQUATOR Network is well positioned help support initiatives to standardise and authors in reporting all aspects of data sharing related to their planned and completed research projects. We also hope to be able to contribute to the development of guidance for the optimal reporting of DMSPs.

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