

# New *CMAJ* policy on sharing study data

Diane Kelsall MD MEd

■ Cite as: *CMAJ* 2017 August 28;189:E1082. doi: 10.1503/cmaj.170935

**C**MAJ champions knowledge that matters for the health of Canadians and the rest of the world. That includes not wasting the contributions of the many research participants who have risked their own health to help others. In July 2018, we will be implementing a new policy on data sharing for research studies published in the journal.

Last year, the International Committee of Medical Journal Editors (ICMJE) declared that “there is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk.”<sup>1</sup> The committee sought input on a proposal requiring authors to share anonymized individual patient data no later than six months after publication of a clinical trial report in an ICMJE journal.<sup>1</sup>

Although some applauded the idea, not all who offered feedback were enthusiastic.<sup>2,3</sup> Several large groups of academics expressed grave concerns that the proposal could disadvantage researchers who participate in trials by forcing them to hand “the data over to someone else” to analyze and publish.<sup>2</sup>

After considering all feedback, the ICMJE recently published its new requirements on data sharing for clinical trials.<sup>3</sup> As of July 1, 2018, manuscripts reporting the results of clinical trials in ICMJE journals must contain a data-sharing statement, and clinical trials that begin enrolling participants on or after Jan. 1, 2019 must include a data-sharing plan in the registration of the trial.<sup>3</sup>

*CMAJ* has required a data-sharing statement for reports of clinical trials of drugs and medical devices since 2014.<sup>4</sup> We ask authors of trials to indicate whether any, all or portions of the data are available to others; where, through whom, when and on what terms; and how data may be accessed.<sup>4</sup> We do not ask authors to share their data.

*CMAJ*’s purpose in encouraging data sharing was to contribute to the transparency of the scientific record and to facilitate the generation of new knowledge by reuse of data sets. We hoped that researchers submitting their studies to *CMAJ* would embrace this new norm of collaboration — and they have.

Many researchers who have published in *CMAJ* have been willing to share their data with other researchers, not only those publishing trial results. Of papers reporting on clinical trials in *CMAJ*, only one group of authors was unable to share data, because of restrictions by the trial’s funder.

As a journal that follows the ICMJE recommendations, *CMAJ* will adopt the new ICMJE requirements and build on our existing policy. The first ICMJE recommendation outlines specific information that should be included in the data-sharing statement for clinical trials. As such, data-sharing statements submitted to

*CMAJ* should include information on any other documents that will be made available by the authors (e.g., study protocol, statistical analysis plan, analytic codes).

In recent years, the medical academic community has voiced concern that studies are sometimes unnecessarily duplicated, resulting in substantial research waste and putting study participants at potential risk. Such waste may be reduced if data sets are available for reuse and reanalysis.

Because we believe that research waste is not confined to clinical trials of drugs and devices, *CMAJ* will go beyond the ICMJE recommendation and expand our current policy. As of July 2018, we will require a data-sharing statement for *all* research studies.

We recognize that the second ICMJE recommendation — that clinical trials enrolling participants on or after Jan. 1, 2019 must include a data-sharing plan in the trial registration — may be challenging for some researchers.<sup>3</sup> Not all trial registries currently include the necessary elements to enable inclusion of a data-sharing statement; however, we anticipate that this will be resolved over the next months.

Some registries, such as ClinicalTrials.gov, already have the capacity to include information on data sharing. We encourage researchers to start adding their data-sharing plan when registering their study protocol. Changes to the data-sharing plan after registration should be clear in the statement submitted to *CMAJ* and updated in the registry record.<sup>3</sup>

Along with the ICMJE, we recognize that there are unresolved problems with sharing study data.<sup>3,4</sup> As such, we have not mandated sharing trial data at this time. The ICMJE welcomes creative solutions to these problems at [www.icmje.org](http://www.icmje.org).<sup>3</sup> Data sharing is an important component of the ethical conduct of research — researchers must prepare for this reality in the future.

## References

1. Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2016;188:91-2.
2. Murray T. Researchers oppose data-sharing proposal. *CMAJ* 2016;188:E336.
3. Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. *Ann Intern Med* 2017;167:63-5.
4. Fletcher J. New *CMAJ* policy on sharing data from clinical research. *CMAJ* 2014;186:163.

**Competing interests:** See [www.cmaj.ca/site/misc/cmaj\\_staff.xhtml](http://www.cmaj.ca/site/misc/cmaj_staff.xhtml)

**Affiliation:** Editor-in-Chief [interim], *CMAJ*

**Correspondence to:** *CMAJ* editor, [pubs@cmaj.ca](mailto:pubs@cmaj.ca)