exclusive for analytical purposes. In our initial analysis we separated out various ethnic groups, but during the peer review and revision process we were asked to present pooled results for our Table 1 and for the final logistic regression. Nevertheless, we did specifically discuss differences between ethnic groups in our Results section. With regard to potential underpowering, we acknowledged small numbers as a limitation of the study and understand that there may have been a lack of power to detect other potential differences.

We believe it is both scientifically and ethically sound to view this study as having the potential to improve the lives of people who have suffered and continue to suffer health disparities.

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References

1. Wenman WM, Joffres MR, Tataryn IV, Edmonton Perinatal Infections Group. A prospective cohort study of pregnancy risk factors and birth outcomes in Aboriginal women. *CMAJ* 2004;171(6):585-9.
2. Mohatt GV, Hazel KL, Allen J, Stachelrodt M, Hensel C, Faith R. Unheard Alaska: culturally anchored participatory action research on sobriety with Alaska Natives. *Am J Community Psychol* 2004;22:263-73.
3. Wenman WM, Tataryn IV, Joffres MR, Pearson R, Grace MGA, Albritton WL, et al. Demographic, clinical and microbiological characteristics of maternity patients: a Canadian clinical cohort study. *Can J Infect Dis* 2002;13(5):311-8.

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[Dr. Cass responds:]

Janet Smylie appropriately stresses the need for mutual respect, understanding and partnership if research relating to indigenous communities is to truly benefit those communities. Her argument is supported by our research in the Northern Territory of Australia, which explores the extent of miscommunication in health care delivery and its impact on quality of care.[1] In that study health care professionals used participatory action methodology to collaborate with Aboriginal patients and community members in planning and conducting the research and then in using the results to improve delivery of services for people with chronic kidney disease.

Smylie also expresses concern about use of the categorization "Aboriginality" in health research, arguing that it has "little grounding in the day-to-day realities of the heterogeneous groups to which it refers." Despite concerns regarding the quality of indigenous identification in health data sets, this categorization can be used to demonstrate inequitable access to care and inequitable health outcomes.[2] Such data will be required to support efforts to improve health equity.

As outlined in my commentary,[3] the "indigenous" or "Aboriginal" label needs to be unpacked to determine which specific factors maintain health disparities and which particular characteristics of individual communities should shape policy interventions so that they are both appropriate to local conditions and sustainable.

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References

1. Cass A, Lowell A, Christie M, Snelling PL, Flack M, Marrnganyin B, et al. Sharing the true stories: improving communication between Aboriginal patients and healthcare workers. *Med J Aust* 2002;176(10):466-70.
2. Tonelli M, Hemmelgarn B, Manns B, Pylypchuk G, Bohm C, Yeates K, et al. Death and renal transplantation among Aboriginal people undergoing dialysis. *CMAJ* 2004;171(6):577-82.
3. Cass A. Health outcomes in Aboriginal populations [editorial]. *CMAJ* 2004;171(6):597-8.

DOI:10.1503/cmaj.1050039

Clinical trials registry

The requirement of the International Committee of Medical

Journal Editors (ICMJE) that clinical trials be prospectively registered, before commencement,[1] is an important step, but of equal or greater importance would be better regulation of trial data and their handling before publication.

Typically, a pharmaceutical company or its hired agent, such as a contract research organization, maintains all of the data collected during a trial. The analysis of the data and its statistical evaluation are generally performed by the company's statisticians. Even principal investigators are not usually privy to this information.

I propose the creation of a third-party organization, independent of the clinical trial sponsor, to perform the vital role of keeper of the trial database, as well as the data analysis according to the primary and secondary trial outcomes specified at the outset. Too expensive, some might say. However, funds are already being paid by the sponsor to have these same tasks done by employees within the company or by a contract research organization. Others might argue that this requirement would represent undue hardship for a company that is making a huge investment to develop its product and hopefully take it to market. This hardship would be lessened if it was applied uniformly to all major clinical trials. If the ultimate objective is to improve the lives of our patients, then the fidelity of clinical trial information is of paramount importance.

A clinical trial registry only provides transparency in terms of the existence of a trial. Third-party handling of trial data and their analysis will ensure transparent evaluation and reporting of the results. We need to enter an era wherein a high-quality trial is evaluated independent of those with a direct financial interest in its outcome.

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Reference

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2004;171(6):606-7.

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Bravo to the International Committee of Medical Journal Editors (ICMJE)! Registration of clinical trials in a publicly accessible registry as a prerequisite for publication[1] is a welcome step beyond the current voluntary registration. This requirement could be strengthened by expanding its application beyond the journals represented on the ICMJE, all of which are either general or internal medicine journals. For example, most clinical trials dealing with child and mental health issues are published in pediatrics and psychiatry journals, which are not represented on the ICMJE, but publication bias is undoubtedly a concern to the editors of these journals as well.

I strongly encourage the ICMJE to enlist the support of major journals in other branches of medicine (such as pediatrics, psychiatry, obstetrics and gynecology, surgery, family practice and emergency medicine) and to lobby government agencies responsible for licensing drugs (e.g., the Therapeutic Products Directorate of Health Canada) to require such registration for, at the very least, phase III clinical trials.

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Reference

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2004;171(6):606-7.

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The editors of *CMAJ*, 10 other journals and MEDLINE recently announced that, starting in 2005, they will publish only clinical trials that were registered at inception.[1] Two reasons are offered for this decision: first, the widespread practice of concealing the results of trials with unfavourable results distorts the evidence base, and second, patients volunteering for clinical trials deserve to know that their contribution to improving human health will be available to inform health care decisions, and this knowledge ought to be accessible to everyone. It appears, then, that pharmaceutical companies have an ethical as well as a scientific responsibility to register their clinical trials.

It seems to us that many patients do participate in clinical trials for altruistic reasons; moreover, the consent forms they sign usually appeal, either explicitly or implicitly, to this motivation. If pharmaceutical companies have an ethical responsibility to register the clinical trials for which they seek patients as participants, should not institutional review boards require registration of large clinical trials as a condition of ethical acceptability? Have any institutional review boards taken a position on this subject?

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Reference

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2004;171(6):606-7.

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Correction

The DOI published in a recent News item[1] was mistakenly listed as 10.1503/cmaj.1050134. It should have been read 10.1503/cmaj .050134.

Reference

1. Sibbald B. Feeling the pressure. *CMAJ* 2005;172 (6):735.

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