

International Clinical Trials Registry Platform. HD, ES, and BG declare no competing interests.

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Authors' reply

We thank the COMPare project team for acknowledging their error in coding. When criticising others' work it is important to be rigorous in your own.

The COMPare team is correct in that there are minor differences in the secondary outcomes in our submitted protocol and those in the trial registry. Our trial entry at ClinicalTrials.gov (number NCT00756600) lists the primary outcome as the Wechsler Preschool and Primary Scale of Intelligence—Third Edition (WPPSI-III) full-scale intelligence quotient (IQ) score and the secondary outcomes as the Bayley neurodevelopmental scale, and frequency and characteristics of apnoea in the postoperative period. Our ANZCTR entry (ACTRN12606000441516) also lists WPPSI-III full-scale IQ score as the primary outcome, and the Bayley neurodevelopmental scale and postoperative apnoea as secondary outcomes. As stated in our previous letter,¹ our paper² and submitted protocol also indicated that the primary outcome was WPPSI-III full-scale IQ score and that secondary outcomes were postoperative apnoea, and the cognitive, motor, language, social-emotional, and adaptive behaviour scales of the Bayley neurodevelopmental scale,

the MacArthur-Bates Communicative Development Inventory, and the presence of cerebral palsy, or reduced vision or hearing. We acknowledge that the trial registry entry does not mention some of the less important secondary outcome measures—the MacArthur-Bates Communicative Development Inventory, presence of cerebral palsy, or reduced vision or hearing—and we agree that we should have put more details in the entry. However, it is pertinent to note that none of these outcomes were emphasised in the paper; indeed, most were not even analysed because of low event rates.

The COMPare project found that in a sample of papers from the five most prestigious medical journals only nine of the 67 trials either accurately reported outcomes based on trial registry entries or indicated why they had not done so. The COMPare project is keen to expose outcome switching or “fishing expeditions”.³ These are indeed causes for concern and are most egregious and misleading when authors change outcomes of interest when they already know the results. We support the COMPare team in their effort to reduce this occurrence. In the GAS trial,² the submitted protocol is proof that we did not undertake such “fishing”, selective reporting, or outcome switching. The COMPare team might well catch some true outcome switching and “fishing”; however, in their net they are also catching researchers who have not switched outcomes or selectively reported, but have simply made minor errors of omission in their registry entries. That is an entirely different kettle of fish.

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Trial registration records, updates, and protocols

Scrutiny of the GAS trial¹ by the COMPare project team and the subsequent correspondence^{2,3} highlight important issues regarding measures to minimise selective outcome reporting in clinical trials.

The GAS trial was registered with ANZCTR in 2006 and ClinicalTrials.gov in 2008. Since then, registries have improved their outcome reporting mechanisms, and most registries now require separate listings for each outcome and more specific information regarding their method and timepoints of measurement.⁴ Additionally, ANZCTR now allows PDF files of full protocols and other relevant documents to be uploaded. This functionality was not available when the GAS trial was initially registered.

Given the inability to upload a full protocol to ANZCTR when the GAS trial was registered, why did the *The Lancet* publish only a summary protocol in 2009? Had the full version been published as submitted by the trialists, none of this Correspondence would likely have been necessary.

In ANZCTR, trialists can include up to 43 outcomes (three primary and 40 secondary outcomes), so



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For more on the COMPare project
see <http://www.COMPareTrials.org>