

# Critical Care and Resuscitation's response to the Boldt scandal

Rinaldo Bellomo

On 28 October 2010, *Anesthesia and Analgesia* retracted<sup>1</sup> the report of a randomised controlled trial evaluating 6% HES (hydroxyethyl starch) 130/0.4 as a priming fluid for cardiopulmonary bypass circuits by Joachim Boldt and colleagues.<sup>2</sup> Subsequent investigation by Boldt's institution and state medical authority confirmed fears that the study results may have been fabricated. Further investigations into the veracity and ethical conduct of Boldt's studies have resulted in the retraction of a further 88 reports to date.<sup>2-4</sup>

In response to the developing controversy surrounding the retraction of Boldt's publications, we at *Critical Care and Resuscitation* (CCR) felt that we should institute a key measure to minimise the risk of such an event happening to our journal. Thus, the editor sought written approval from the College of Intensive Care Medicine of Australia and New Zealand to institute a change to the submission process that would require all studies submitted for publication to report their human research ethics committee (HREC) approval number. This requirement is in addition to every human or animal interventional trial having to report its trial registration number.

We acknowledge that such measures cannot entirely prevent academic fraud. However, we feel that requiring the submission of the HREC approval number will provide the journal and its readers with another simple, verifiable

line of defence against the submission of studies that have not been approved and may be fabricated. These changes will be incorporated in a revised version of the CCR instructions for authors (see page 133) and will become "active" as of 1 July 2011.

## Author details

Rinaldo Bellomo, Editor-in-Chief,<sup>1</sup> and Director of Research<sup>2</sup>

1 *Critical Care and Resuscitation*, Sydney, NSW, Australia.

2 Department of Intensive Care, Austin Health, Melbourne, VIC, Australia.

**Correspondence:** rinaldo.bellomo@austin.org.au

## References

- 1 Shafer SL. Notice of retraction. *Anesth Analg* 2010; 111: 1567.
- 2 Boldt J, Suttner S, Brosch C, et al. Cardiopulmonary bypass priming using a high dose of a balanced hydroxyethyl starch versus an albumin-based priming strategy. *Anesth Analg* 2009; 109: 1752-62.
- 3 Rasmussen LS, Yentis SM, Schüttler J, et al. Editors-in-chief statement regarding IRB approval of clinical trials by Joachim Boldt. <http://www.aaeditor.org/EICJointStatement.pdf> (accessed Feb 2011).
- 4 Shafer SL. 25 February 2011 notice. <http://www.anesthesia-analgia.org/site/misc/25.February.2011.Notice.pdf> (accessed Mar 2011). □



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