

Critical Care Statistical Analysis Plans

Michael J O'Leary

TO THE EDITOR: I am writing in the hope of offsetting any potential push to rename our journal *Critical Care Statistical Analysis Plans*, as it appears that this type of paper is rapidly becoming the most common publication in the journal. In the past two issues, six original articles from a total of 21 fell into such a category or similar.¹⁻⁶ While I understand the rationale for publishing these plans (although I could be unkind and suggest the principal aim is to fatten the authors' CVs), I am far from convinced they should take up space in a scientific journal. I cannot see how they lend themselves to true peer review, and I would be most surprised if any more than a very few readers even glance over them! Furthermore, they probably do little to advance a journal's impact factor, given that they are likely to only be cited in the final original paper resulting from the study. I think that at best these papers could be published in electronic format only on the journal's website with free public access. While I admit to being a bit of a climate change sceptic, I would really like to avoid further trees being cut down to get this sort of stuff into print.

Michael J O'Leary, Senior Staff Specialist

Intensive Care Service, Royal Prince Alfred Hospital, Sydney, NSW, Australia.

Correspondence: laoire@mac.com

- 1 Delaney AP, Peake SL, Bellomo R, et al. The Australasian Resuscitation in Sepsis Evaluation (ARISE) trial statistical analysis plan. *Crit Care Resusc* 2013; 15: 162-71.
- 2 Dulhunty JM, Roberts JA, Davis JS, et al. A protocol for a multicentre randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients with severe sepsis: the BLING II study. *Crit Care Resusc* 2013; 15: 179-85.
- 3 Al-Khafaji A, Murugan R, Wahed AS, et al. Monitoring Organ Donors to Improve Transplantation Results (MONITOR) trial methodology. *Crit Care Resusc* 2013; 15: 234-40.
- 4 Young PJ, Weatherall M, Saxena MK, et al. Statistical analysis plan for the HEAT trial: a multicentre randomised placebo-controlled trial of intravenous paracetamol in intensive care unit patients with fever and infection. *Crit Care Resusc* 2013; 15: 279-86.
- 5 Pike F, Yealy DM, Kellum JA, et al. Protocolized Care for Early Septic Shock (ProCESS) statistical analysis plan. *Crit Care Resusc* 2013; 15: 301-10.
- 6 Power GS, Harrison DA, Mouncey PR, et al. The Protocolised Management in Sepsis (ProMISE) trial statistical analysis plan. *Crit Care Resusc* 2013; 15: 311-7. □

Paul J Young, Anthony P Delaney, Joel M Dulhunty and Bala Venkatesh

IN REPLY: We are grateful for the opportunity to fatten our CVs by responding to O'Leary's letter. O'Leary argues that statistical analysis plans (SAPs) should not be published in *Critical Care and Resuscitation* (CCR) and points out the potential environmental impact of publishing them in print. With this in mind, he suggests that such manuscripts should only be available in electronic format (if at all). Making all CCR manuscripts freely available online is a great idea. If free online links to the full text of particularly important manuscripts, such as SAPs, were available on PubMed, it is likely that CCR's impact factor would increase and that the number of print subscriptions would rise.

Despite O'Leary's concern, many SAPs for major studies are cited frequently. For example, the Normoglycaemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation (NICE-SUGAR) Study SAP¹ and the Crystalloid Versus Hydroxyethyl Starch Trial (CHEST) SAP² have been cited 31 times and 16 times, respectively.^{3,4} Prepublication of

study protocols and SAPs is now the gold standard for large-scale intensive care trials. This standard has been established by Australian and New Zealand investigators⁵ and its importance is now clearly recognised by international investigators as well.^{6,7} Prepublication of a SAP is also an ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guideline. SAPs are now being advocated even for observational research.⁸ The publication of a SAP encourages good planning, enhances transparency, reduces the risk of biases emerging through altering analyses as the results of a study emerge, and promotes intellectual honesty. SAPs are important for all studies but are particularly important for trials that are likely to dictate future clinical practice.^{6,7,9,10} Manuscripts outlining trial designs and analysis plans have educational value. They often contain a wealth of information about trial design and statistical methods. These kinds of manuscripts are likely to be of even greater value in the future as clinical

trial designs in intensive care continue to evolve.¹¹ For these reasons, we believe that it is vitally important that SAPs continue to be published in *CCR*.

Paul J Young, Intensivist,¹ and Director of the Critical Care Research Programme²

Anthony P Delaney, Intensivist,³ and Senior Lecturer⁴

Joel M Dulhunty, Research Fellow^{5,6}

Bala Venkatesh, Professor of Intensive Care,⁷ and Honorary Professorial Fellow⁸

Correspondence: Paul.Young@ccdhb.org.nz

1 Intensive Care Unit, Wellington Hospital, Wellington, New Zealand.

2 Medical Research Institute of New Zealand, Wellington, New Zealand.

3 Malcolm Fisher Intensive Care Unit, Royal North Shore Hospital, Sydney, NSW, Australia.

4 Northern Clinical School, Sydney Medical School, University of Sydney, Sydney, NSW, Australia.

5 Department of Intensive Care Medicine, Royal Brisbane and Women's Hospital, Brisbane, QLD, Australia.

6 Burns, Trauma and Critical Care Research Centre, University of Queensland, Brisbane, QLD, Australia.

7 Princess Alexandra Hospital and Wesley Hospital, University of Queensland, Brisbane, QLD, Australia.

8 Division of Critical Care and Trauma, George Institute for Global Health, Sydney, NSW, Australia.

1 Finfer S, Heritier S. The NICE-SUGAR (Normoglycaemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation) Study: statistical analysis plan. *Crit Care Resusc* 2009; 11: 46-57.

2 Myburgh J, Li Q, Heritier S, et al. Statistical analysis plan for the Crystalloid Versus Hydroxyethyl Starch Trial (CHEST). *Crit Care Resusc* 2012; 14: 44-52.

3 Google Scholar Citations. The NICE-SUGAR (normoglycaemia in intensive care evaluation and survival using glucose algorithm regulation) study: statistical analysis plan. http://scholar.google.co.nz/scholar?cites=16050265129721315477&as_sdt=2005&sciodt=0,5&hl=en (accessed Jan 2014).

4 Google Scholar Citations. Statistical analysis plan for the crystalloid versus hydroxyethyl starch trial (CHEST). http://scholar.google.co.nz/scholar?cites=2855730816104179692&as_sdt=2005&sciodt=0,5&hl=en (accessed Jan 2014).

5 Finfer S, Bellomo R. Why publish statistical analysis plans? *Crit Care Resusc* 2009; 11: 5-6.

6 Pike F, Yealy DM, Kellum JA, et al. Protocolized Care for Early Septic Shock (ProCESS) statistical analysis plan. *Crit Care Resusc* 2013; 15: 301-10.

7 Power GS, Harrison DA, Mouncey PR, et al. The Protocolised Management in Sepsis (ProMISe) trial statistical analysis plan. *Crit Care Resusc* 2013; 15: 311-7.

8 Thomas L, Peterson ED. The value of statistical analysis plans in observational research: defining high-quality research from the start. *JAMA* 2012; 308: 773-4.

9 Delaney AP, Peake SL, Bellomo R, et al. The Australasian Resuscitation in Sepsis Evaluation (ARISE) trial statistical analysis plan. *Crit Care Resusc* 2013; 15: 162-71.

10 Venkatesh B, Myburgh J, Finfer S, et al. The ADRENAL study protocol: ADjunctive corticosteroid tREatment iN critically ill patients with septic shock. *Crit Care Resusc* 2013; 15: 83-8.

11 Bellomo R, Forbes A, Akram M, et al. Why we must cluster and cross over. *Crit Care Resusc* 2013; 15: 155-7. □

Rinaldo Bellomo

IN REPLY: O'Leary's letter is gratefully received. The case for publishing statistical analysis plans (SAPs) has been made before.¹ If all *Critical Care and Resuscitation* (*CCR*) articles were cited as frequently as its SAPs,²⁻⁶ *CCR* would be even higher up the impact factor ladder and would receive more high-quality submissions. The fact that *CCR* has now secured the publication of the SAPs of the three defining sepsis trials of the decade is an editorial hat-trick of unprecedented significance for a boutique journal like *CCR*. It's like a local label signing up Naomi Campbell, Megan Gale and Cindy Crawford to wear its fashions exclusively and for free! It is only a matter of time before the *Kmarts* of intensive care journals wake up to all this and start copying our "haute couture" and perhaps drive us out of business. O'Leary might then have to write letters to them as well, accusing them of intellectual property theft.

Competing interests: The task of the Editor of *CCR* is to grow its educational value, its reputation, its worldwide profile and its bibliometrics. I plead guilty to pursuing these goals by all legal means possible.

Rinaldo Bellomo, Editor,¹ and Codirector²

1 *Critical Care and Resuscitation*.

2 Australian and New Zealand Intensive Care Research Centre, Monash University, Melbourne, VIC, Australia.

Correspondence: Rinaldo.bellomo@austin.org.au

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