

A call for a pragmatic approach to data collection

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TO THE EDITOR: Despite significant improvements in critical care electronic data capture, information technology infrastructure and staff familiarity with such technology, it has come to our attention that the data collection process for many studies in intensive care is still a needlessly laborious task. Current approaches to data collection and study inclusion criteria incur excessive time and labour costs and result in limited patient recruitment. This substantially increases the overall financial burden of trials and means that the results of published studies, even multicentre trials, may not be applicable to wider populations.

Recently we piloted a case report form (CRF) for a prospective observational study involving 23 participants. Each CRF required obtaining data from multiple sources; necessitated the calculation of cumulative intravenous fluid volumes, medications and ventilation hours; and took about 2 hours to complete. In response, we developed a "simplified" CRF with three sections: (1) patient information and entry criteria; (2) daily data; and (3) outcome data. Where possible, outcome options were made binary. As a result, CRF complexity and length were reduced and subsequent data collection was swift.

Recent studies by the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group of robust methodology and high clinical utility, using a pragmatic approach to patient inclusion and data collection with a simplified CRF, have been published in major journals.^{1,2} Thus, we urge future investigators to be cognisant of the data collection process and strive to obtain data in the simplest, most efficient manner.

Where possible, ANZICS Centre for Outcome and Resource Evaluation³ data could be used for baseline information, hospital computer information systems for daily data, and death registries for 90-day follow-up. In addition, efforts should be made to create daily data forms that capture patient-centred data in a contemporaneous fashion. Such an approach would reduce the burden of data collection and simplify data analysis and interpretation.

Only when we move to pragmatic study methodology and data collection will it be possible to conduct studies of tens of thousands of patients in hundreds of centres and truly move closer to evidence-based critical care.

We welcome debate and discussion in this area.

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- 2 ANZIC Influenza Investigators; Webb SA, Pettilä V, Seppelt I, et al. Critical care services and 2009 H1N1 influenza in Australia and New Zealand. *N Engl J Med* 2009; 361: 1925-34.
- 3 Australian and New Zealand Intensive care Society Centre for Outcome and Resource Evaluation. 2008 Annual report. Melbourne: ANZICS, 2008. <http://www.anzics.com.au/core/reports> (accessed Dec 2010). □