Correspondence

Organ donation rate

I would like to respond to the editorial by Dr's Opdam and Silvester in which they examine the reasons for Australia's low organ donor rate.[1] The research and experience of the authors in this field over a long period of time is acknowledged, however I am struck by what little progress has been made and why several important questions remain unexplored.

First, patients suffering from a life-threatening brain insult, who are less than 75 years of age and who have a paucity of co-morbidities (making them suitable potential organ donors), why aren't they admitted to a critical care unit (CCU)? Determining the prognosis is a major challenge in these patients that takes time, they need rapid effective resuscitation, diagnosis and observation of response to treatment. How can this be achieved without first being admitted to the CCU? Are they just allowed to die in an emergency department or a standard hospital ward?

The answer appears to be either: 1) triage not to a CCU is an accepted clinical pathway in these patients, or 2) there is extreme pressure on CCU beds that a rapid prognostication process enables a decision to be made so that an alternative critically ill patient, who is more likely to benefit from admission to the CCU, takes precedence.

If 'pressure' on CCU beds is a primary factor, how have hospital managers and critical care specialists allowed such an under-resourcing of critical care units to occur? The management of these patients, including rapid resuscitation, diagnosis, consultation and observation to the response to treatment, engenders trust and faith in the adequacy of patient management in the eyes of the family. This process, in my view, forms the foundation of the relationship between the critical care specialist and the family, allowing them to react favourably to organ donation when otherwise they may not have.

Second, given that over a period of time a general approach to an increasing awareness and education has failed to improve organ donor rates, isn't it time that we more accurately measure an individual hospital's performance, benchmark performance levels between hospitals and better target the allocation of resources to effect change? Change requires acceptance of the existence of a problem and that comes with measurement and bench-marking. There have been several proposed measures of individual hospital performance with respect to organ donor rates. One such casemix controlled organ donor index, which measures individual hospital performance, has been proposed from our institution.[2] No method of benchmarking organ donor rates between hospitals has been used in Australia since, although the method has been investigated by the Canadian Institute for Health Information.

These questions are but a few in the complex debate of how best to increase organ donor rates in Australia. It is now time to effect change and I believe that in the end this will require more resources for the care of critically ill patients.

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Critical care research and ethics

I read with interest the article by Moore *et al*,[1] in the September 2004 issue of the Journal. As the authors point out, their aim was to promote knowledge and debate. They argue cogently the case for incorporating evidence-based practice into the intensive care unit, and the point is well taken that, if such incorporation rests on a 'patient-best-interests' standard, then the standard is fallible.

However, I am not convinced that the proposed alternatives ought to be dismissed on the grounds of having no baseline risk. The 'minimal risk' concept invoked in Section 6.9 of the NHMRC National Statement[1] has, as its baseline risk, "the risk inherent in the patient's condition and alternative methods of treatment". While I would agree that this is a somewhat unclear line in the sand, it is not non-existent, and similar definitions are seen in several other national regulatory documents.[2-5]

Furthermore, if some sort of risk assessment is not made, then one has to set some other standard which indeed is the argument the authors pursue - by which to judge the ethical validity, or otherwise of a proposed study. The concept of clinical equipoise is a potential

solution; it is well explained in the article and the distinction between clinical consensus and evidence base is pertinent. But, as the authors acknowledge, equipoise is also poorly defined at present; and if we are to replace risk assessment on the grounds that it is subjective, then the equipoise concept will need objective definition.

The issue of consent for the incompetent patient remains the most problematic area of debate, and the various approaches to obtaining consent are well explained. The requirement for free and informed consent for research is indeed the ideal; and while it is difficult for researchers in the critical care arena to attain the ideal, it is nevertheless the ideal and we should strive towards it. Investigation of less-than ideal methods are correctly regarded as second-best and driven by pragmatic necessity, and it is against this background that less demanding consent standards should be viewed. I fear that if we, as a specialty, are perceived to be striving for less than the ideal, then the motives of intensive care researchers may be viewed by the community as research-first and patient-second. I would be interested in the comments of the authors on whether they would see this as unnecessary idealism; as it is clear from their article that they too have the patients interests at heart and the case for non consensual research is argued as clearly as I would think possible.

There is no easy solution, and in the absence of a solution, it is critical that the intensive care community engages in productive discussion. The NHMRC are currently revising the National Statement and it is hoped that the difficulties of research in the critically ill will be addressed to some degree in the revised statement. In addition, the Clinical Trials Group of the Australia New Zealand Intensive Care Society is engaged in preparing guidelines for researchers in intensive care which address some of the ethical issues of intensive care research including consent.

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In reply

We welcome and encourage debate on critical care research ethics, and thank David Blythe for his comments. We agree that it is crucial to reach a consensus on how to provide safeguards for patients participating in research, and to gain public engagement with and support for whatever approach is taken. We also believe the public may be horrified at the number of deaths that have resulted from failure to conduct sufficient research to validate our treatments, and may think continuing with that approach is unethical.

Our paper[1] gave recent examples of unvalidated treatments, used over many years in critical care, that have resulted in hundreds of thousands of deaths. Since our manuscript was submitted, the MRC CRASH trial[2] has also revealed that the unvalidated use of steroids to treat head injury over more than fifty years has almost certainly resulted in very large numbers of further deaths. In our view, it is unethical to continue to use such unvalidated treatments outside the context of systematic research.

Free, informed, and prospective consent from each patient is the general ideal for research participation. This is also the particular ideal in post-operative critical care research after elective services. A central focus of our paper, however, was on the particular ideal where critical care admission is unanticipated, and free, informed, and prospective patient consent is unattainable. We reject the idea that research in such settings is “less than ideal”. It is instead the failure to validate treatments here through appropriate trials that is less than ideal for patients, if not frankly dangerous. For example, though this was hard to predict in advance, the risk to a patient of being randomised into the CRASH trial (without consent) was lower that of being treated by a proponent of steroids.

Important research often involves treatments that are well established in clinical practice but poorly establish-

ed in clinical evidence. Such research can be unsettling for clinicians, and is not always attractive to business interests. This generates failure to do the research, the opposite of what is needed. Where critical care admission is unanticipated, there is the further issue that the general ideal of free and informed consent typically cannot be met. The best response is to do the research, meeting the highest ethical ideals that can be attained in this setting. Critical care physicians owe these things to patients, and to the wider public.

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Strong ion gap or net unmeasured ions?

In my recent article in the journal on "strong ion calculator - a practical bedside application of modern quantitative acid-base physiology",[1] I failed to give credit to John Kellum, who coined the term Strong Ion Gap in 1995[2,3]. My apologies to him for this oversight.

In subsequent correspondence, John Kellum stated he now regrets the term, because it could cause someone to assume that any gap in the total measured cations minus the total measured anions must be filled by unmeasured strong anions. While this is often the case, it is not inevitably so. For example, after major resuscitation with an artificial colloid, it is quite possible that some of the unmeasured anions in plasma will be weak acid anions belonging to the artificial colloid. For this reason, after some discussion, we agreed that we should rename the parameter discussed as Strong Ion Gap in the article with the descriptive term Net Unmeasured Ions, or NUI.

Finally owing to events beyond my control, the Strong Ion Calculator and supplementary material is now at : http://homepage.mac.com/peterlloyd1/File Sharing8.html. I apologize for any inconvenience.

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