

## Editorial

# Research ethics in the intensive care unit: current and future challenges

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*Critical Care* is launching a new section to the website Critical Care Forum in which several articles relating to a specific theme will be pulled together under the title Theme series.

With this new section we aim to produce a series of articles that will provide substantial coverage of several topics relating to important themes within the intensive care environment. We are hoping this will raise awareness of the topics covered and provide a platform for discussion related to each theme.

Research ethics is an important, even central, theme in this series. Since the recognition of critical care medicine 40 years ago, concentrated research efforts have enabled us to save lives we would have otherwise lost and to improve the quality of these lives saved. At the crossroads of medical and surgical fields, at the forefront of technology, with its capacity for extensive haemodynamic and clinical monitoring, the intensive care unit (ICU) remains an ideal place to explore the effects of novel therapeutics and innovative technologies.

While research has provided important guidance and breakthroughs, ICU teams still confront many unknowns when caring for critically ill patients. In order to function effectively, ICU teams have had to achieve a level of comfort in facing these unknowns. As a consequence, they have also achieved a level of comfort regarding the risk/benefit ratios of various research endeavours and they welcome research to improve morbidity, mortality and the quality of care provided.

Research in the ICU does pose considerable ethical challenges. Ethical dilemmas may be difficult to anticipate in this setting and indeed may arise *de novo* as understanding of the potential and capabilities of new technologies grows. These previously inconceivable dilemmas present new

challenges to ethical principles originally developed to guide us through the practicalities of living moral lives – for ethical principles were not originally devised to be applied to the research setting, nor were they conceived to meet the unique challenges we face in the ICU. Now, we are asking that the ethical principles be stretched to encompass the uncertainty, the risks, the benefits and the burdens of research protocols. Fundamental questions arise: Are our current ethical principles and theories sufficient to help us navigate the issues arising from such research? How do they guide us, as investigators, as members of the healthcare community, and as members of a wider society, in achieving balance between potential benefits and harms?

Research in the ICU not only tests current ethical theories, it also places specific and unique demands on researchers. It requires a level of critical thinking, and a knowledge of ethics and the law that must be maintained. Addressing ethical issues in a research project can be a source of stress and of frustration as investigators attempt to meet the requirements of research ethics boards (REBs). This is especially so in the setting of multi-centred trials where different REBs impose different and, sometimes even conflicting, requirements prior to protocol approval. Even after such approval is obtained, basic questions still remain for researchers and REBs alike: Can substitute decision-makers legitimately consent to research on behalf of a critically ill patient? Do they have the capacity to do so when confronted with the reality of a critically ill loved one? Should a higher standard of disclosure than required for clinical decision-making prevail? Should research participation become part of advance care planning? What happens when the patient regains capacity? Is he/she obliged to continue in the research project if such continuation is crucial in order to answer the research question? In other words, can/should a Ulysses type of contract exist?

REBs are currently asked to ensure that research protocols they approve are ethically conducted. The logistics and practicalities of this mandate, ways to minimize intrusiveness and to maximize effectiveness, have not been clearly elucidated. At the same time, issues of accountability and even liability in cases of harm are starting to arise for researchers, REBs and substitute decision-makers: What happens if harms do result? Who is accountable if the now capable patient says he/she would never have given consent to participate in the first place? What does risk mean when the stakes are so high to begin with?

The main source of funding for research into innovative therapeutics and most technological advances is industry. Yet our relationship with industry is not an easy one. Issues of conflict of interest, of appropriate expectations regarding the obligations of researchers and those of a for-profit player (to each other, to the participants and to the wider society) abound. How these conflicting views, values and beliefs are weighed and balanced is a source of ongoing debate. While recent high-profile cases, sensationalized by the media, have increased our awareness of some of these issues, they have also generated distrust. Such distrust may lead to decreased enrolment in research trials and ultimately hinder our abilities to improve the morbidity and mortality of critical illness.

Finally, once completed, research must be published to be of any value to the wider ICU community. We have only recently begun to acknowledge the ethical conflicts that arise in the publication stage. How do journals increase their readership impact score? What obligations do they have to the broader ICU community to ensure the quality of research or the quality of the critiques/commentaries they publish? Can the publishers be held accountable or even liable for the impact of the articles they publish?

Researchers in critical care have in the past few years had to tackle many new ethical dilemmas. We have for too long had to figure out how to deal with these issues alone as individual researchers. We have seen prominent researchers publicly reproached and reprimanded when largely unavoidable harms have occurred. It is time to explore what we have learned, to discuss the dilemmas we continue to face and to discover together how to resolve them. In the upcoming *Critical Care* theme issue on research ethics, we shall examine some of the common challenging ethical and legal issues that plague us within the ICU community, provide guidance in avoiding common pitfalls, and discuss an approach to think through as yet unresolved dilemmas.