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NSW Institute of Trauma and Injury Management,
NSW Agency for Clinical Innovation

Submission to the NSW Law Reform Commission review on Guardianship Act 1997

EXECUTIVE SUMMARY

The New South Wales Institute of Trauma and Injury Management makes this submission to the NSW Law Reform Commission review of the NSW Guardianship Act to draw attention to the following issues in relation to critical care and trauma research.

1. New knowledge concerning the optimal treatment and models of care for patients with acute severe conditions such as trauma is essential to ensure these critically ill patients receive the most effective care in a timely manner.
2. New knowledge is obtained through research. Clinical trials are regarded as the highest level of research methodology.
3. High-quality research is currently lacking in trauma and critical care medicine, resulting in clinical uncertainty, potentially compromising patient care.
4. Clinical trials normally require consenting patients to be allocated to specific treatment groups and their outcomes compared.
5. Prior informed consent is frequently impossible in studies involving critical care and trauma patients.
6. There are other consent models for ethical research in these patient populations that have been working effectively in other Australian jurisdictions such as Victoria for 30 years.
7. Some of these consent processes are unavailable in NSW due to limitations with the current Guardianship Act.
8. Correcting this would enable more severely injured and critical care patients to participate in research designed to improve their survival and outcomes and those of future patients.

1. Introduction

New South Wales Institute of Trauma and Injury Management (NSW ITIM) welcomes the opportunity to present this submission to the NSW Law Reform Commission review of the NSW Guardianship Act 1997.

We have prepared this submission on behalf of trauma clinicians across NSW, including ambulance paramedics, retrieval services, critical care and trauma doctors and nurses working in trauma hospitals. In making this submission, the following definitions are made:

1. Major trauma – severe anatomical injury or injuries resulting in death, urgent surgery and or admission to an Intensive Care Unit. The terms “major trauma” and “severe injury” and “critically injured” are used interchangeably.
2. Critical Care – an area of medical practice encompassing intensive care, anaesthetics, emergency medicine, prehospital and retrieval Medicine.

1.1 Scope of NSW Institute of Trauma and Injury Management

NSW ITIM represents the peak clinical advisory body for trauma care within NSW Health. It is responsible for coordinating and supporting clinical services and provides clinical oversight with respect to the NSW Trauma Plan (2009), as well as governance over the NSW Trauma System. It operates as one of several clinical network groups within the NSW Agency for Clinical Innovation, a central clinical pillar within the NSW Ministry of Health. One of the core functions of NSW ITIM is the clinical review, oversight and coordination of State-wide trauma research projects. This occurs independently and in addition to existing Human Research Ethics Committee approvals that investigators must seek in order for the study to proceed in NSW.

1.2 Major trauma and role of informed consent in clinical practice

The health care burden of major trauma is substantial and remains the single largest cause of death in people under the age of forty (NSW Healthstats 2016). Major trauma occurs dramatically and on the whole, unexpectedly. It affects all populations, particularly vulnerable ones. Morbidity and mortality from major trauma results from several pathological conditions that can evolve within minutes of impact: airway obstruction, severe head injury, shock due to bleeding and respiratory failure (inability to breathe due to injury). Trauma care covers the entire spectrum of health sector response to an injurious event, from Ambulance and Retrieval Services through to Emergency Departments, Intensive Care Units, Operating Theatres and in-patient Ward and Rehabilitation care. Trauma care also includes the education, research and preventive strategies for the benefit of the injured patient. In the acute stage of an injury, decisions made by clinicians regarding care are made urgently. Treatments and expeditious life-saving interventions such as emergency anaesthesia, life-saving surgery or blood transfusions are time critical and underpinned by the principle of beneficence, to ensure survival and optimal outcomes. Informed patient consent for procedures is often not feasible due to the severity of the injury and lack of decision-making capacity (e.g. unconscious from a head injury). Such interventions, delivered in a timely manner at the scene and at trauma facilities can avert death and improve long-term outcomes after major trauma.

In modern clinical practice, informed consent occurs when a capable and rational person, having been provided with an explanation of the risks and benefits of various therapeutic options, voluntarily agrees to undergo a particular treatment. Such conditions rarely exist in the context of acute severe injury. People involved in major trauma are impaired, at least temporarily, due to a combination of acute severe pain, psychological distress, lack of blood supply, low oxygen levels and reduced level of consciousness. The same distress can also render family members and next of kin incapable of making such decisions at the scene or in the acute care setting. Often these same family members have also been involved in the accident that leads to their loved one being critically injured. For critically injured patients, paramedics are expected to urgently initiate treatment without delay. Emergency treatment administered in this context to save a life or prevent serious harm to an individual without consent is covered under Common Law principles and the Guardianship Act.

2. Consent in trauma and critical care research

2.1 Summary of core issue

The inability to make informed choices about healthcare decisions during the acute stages of severe injury, and the need to make time critical therapeutic decisions in the patient's best interest, lies at the heart of ethical dilemmas around critical care and trauma related research.

2.2 Role of research in trauma and critical care

Research remains the cornerstone of evaluating and improving modern clinical care. It ensures that practices and treatments delivered to patients have a scientific and evidentiary basis, rigorously tested through studies and peer review. Clinical trials test treatments by randomly allocating patients to a group that receives an intervention being studied or one that does not receive that intervention. For this reason, clinical trials are considered the most reliable way of determining the true efficacy a treatment, free from the potential effects of bias and confounding.

2.3 Lack of high-quality clinical trials in trauma and critical care

Unfortunately, there remain far too few clinical trials in the field of trauma care (Holcomb et al. 2011). The reasons for this include the inherently uncontrolled environments of critically injured patients and difficulties in relation to obtaining informed consent in this context. The process of obtaining prior consent in trauma and critical care research profoundly affects the feasibility of a given study. The requirement to obtain consent from the patient at the scene, or seeking permission from an external tribunal at the time of the incident is impractical and not feasible in clinical trials of interventions delivered at the scene or during the acute phase of trauma management. It is impractical, degrades the validity of trial results and places lives in danger by impeding the resuscitation process.

The lack of high-level scientific evidence affects both clinical decisions on individual patients and the ability to establish firm evidence-based guidelines that can be applied with confidence to improve trauma management and outcomes. Uncertainty and deficiencies in clinical evidence

impacts overall patient care - mortality for major trauma has remained stagnant in NSW for the past fifteen years.

2.4 Overview of issues relating to consent in trauma and critical care research

Addressing the issues around consent as they pertain to trauma and critical care research would go a long way to addressing some of the major barriers to conducting high-quality clinical trials in NSW for trauma and critical care patients.

Several trials have in the past required prolonged legal deliberations regarding clinical trial consent processes. These include the PATCH study (Pre-hospital Anti-fibrinolytics for Traumatic Coagulopathy & Haemorrhage study) investigating a readily available and inexpensive treatment to reduce the risk of death from haemorrhage. Another example is SPICE III, a randomised controlled trial of early goal-directed sedation compared with standard care in mechanically ventilated intensive care patients. Other studies have been stymied or aborted in NSW due to the requirement for investigators to obtain Guardianship Tribunal authorisation for each instance of patient enrolment. These include CRASH – 3 investigating the use of an anti-fibrinolytic agent (the same agent investigated in the PATCH study) for severe head injury.

With respect to trauma and critical care trials in NSW, the requirement for voluntary consent from a patient, next of kin or a statutory authority representing the patient rests largely on the definition clinical trial under the Guardianship Act 1987. In the case of Shehabi v Attorney General (NSW) in relation to the SPICE III trial, it was determined that a clinical trial was one that investigated a new treatment that “had not gained the support of a substantial number of medical practitioners specialising in the area of practice concerned”. The decision of Civil and Administrative Tribunal clarified what types of studies could be deemed a clinical trial under the Guardianship Act (1987), thereby mandating consent processes to be followed for such trials. The implication of this finding was that studies comparing treatments that were already in use and accepted by medical practitioners in that field of practice, do not constitute a clinical trial under the Act. Such studies can apply for limited consent, consent to continue (deferred consent) or waiver of consent from a Human Research Ethics Committee under current Australian National Health and Medical Research Council (NHMRC) national statement on ethical conduct in Human Research 2007.

With respect to trials that still fall under the definition of a clinical trial according to the Guardianship Act (1987), clarity is required regarding the optimal consent process, particularly in relation to trauma and critical care trials. The NHMRC national statement of ethical conduct in Human Research 2007 section 4.4.14 stipulates that in situations where it is not practical to obtain a priori informed consent from the patient, next of kin or representative due to incapacity or medical dependence (such as loss of consciousness) and where there is reasonable possibility of benefit from the intervention, no reasonable grounds to assume a patient would not consent, risks associated with the intervention are minimised, and any risks justified by this benefit, that consent can be deferred and should be obtained as soon as reasonably possible after inclusion into the study.

2.5 Experience in other Australian jurisdictions

Guardianship and Administration Acts in other Australian jurisdictions have supported research in trauma and critical care research without any major incidents. For example, section 42A the Victorian Guardianship and Administration Act 1986 states that:

A registered practitioner may carry out, or supervise the carrying out of, a special procedure, a medical research procedure or medical or dental treatment on a patient without consent under this Part or authorisation under section 42T if the practitioner believes on reasonable grounds that the procedure or treatment is necessary, as a matter of urgency;

a. to save the patient's life; or
b. to prevent serious damage to the patient's health; or
c. in the case of a medical research procedure or medical or dental treatment, to prevent the patient from suffering or continuing to suffer significant pain or distress.

2.6 Examples of clinical trials approved under Section 42A of Victorian Guardianship and Administration Act

a. Bernard SA, Nguyen V, Cameron P, Masci K, Fitzgerald M, Cooper DJ, Walker T, Myles P, Murray L, David, Taylor, Smith K, Patrick I, Edington J, Bacon A, Rosenfeld JV, Judson R. Prehospital rapid sequence intubation improves functional outcome for patients with severe traumatic brain injury: a randomized controlled trial. Published in Annals of Surgery 2010; 252:959-65 Implication – this NHMRC funded trial changed standard of care for patients with severe head injury in Victoria
b. Bernard SA, Smith K, Cameron P, Masci K, Taylor DM, Cooper DJ, Kelly AM, Silvester W; Rapid Infusion of Cold Hartmanns (RICH) Investigators. Induction of therapeutic hypothermia by paramedics after resuscitation from out-of-hospital ventricular fibrillation cardiac arrest. A randomised controlled trial. Circulation 2010; 122:737-42 Implication – This NHMRC funded trial changed standard of care for patients suffering a cardiac arrest

2.7 Recommendations from NSW ITIM

With respect to research studies that have been reviewed and approved by a lead Research Ethics Committee in NSW, meeting aforementioned National Health and Medical Research Council guidelines, NSW ITIM believes the provision for consent to continue (deferred consent), or waived consent in research into life-saving interventions where a patient’s life is imminently at risk, provides sufficient safeguards to protect the rights and autonomy of severely injured patients and their families. Aligning laws across jurisdictions together with current medical research standards in Australia will provide clarity and certainty for trauma practitioners, researchers and patients alike. Therefore the recommendation from NSW ITIM to this review would be as highlighted below:

Recommendations:

1. Clarify the definition of “clinical trial” under any revised Guardianship Act, in light of recent deliberations
2. For research falling under the definition of a “clinical trial”, allow provision for consent to continue, consistent with current NHMRC standards and other jurisdictions within Australia
3. Allow provision in any revised Guardianship Act under certain conditions for waiver of consent for treatments AND research into life-threatening situations such as cardiac arrest and severe trauma

We thank the Law Reform Commission once again for the opportunity to submit the perspective of trauma and critical care researchers to this important review. Please do not hesitate to contact any of the list authors below if further clarification is required.

3. Appendices

3.1 Contributing Authors

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3.2 References

1. Centre for Epidemiology and Evidence. HealthStats NSW. Sydney: NSW Ministry of Health. Available at: www.healthstats.nsw.gov.au Accessed March 25th 2017.
2. Holcomb JB, Weiskopf R, Champion H, Gould SA, Sauer RM, Brasel K, Bochicchio G, Bulger E, Cotton BA, Davis D, Dutton R, Hauser CJ, Hess JR, Hides GA, Knudson P,

MacKenzie E, McGinnis RL, Michalek J, Moore FA, Omert L, Pollock BH, Tortella B, Sugarman J, Schreiber MA, Wade CE. Challenges to effective research in acute trauma resuscitation: consent and endpoints. Shock. 2011; 35(2):107-13. doi: 10.1097/SHK.0b013e3181f7fd01.

3. National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra
4. Civil and Administrative Tribunal New South Wales. Shehabi v Attorney General (NSW) [2016] NSWCATAP 13