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for Emergency Medicine

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Submission to the Government of Western Australia Department of Justice on the Statutory Review of Part 9E Guardianship and Administration Act 1990 (WA)

Introduction

The Australasian College for Emergency Medicine (ACEM, the College) welcomes the opportunity to provide comment on the operation and effectiveness of the Part 9E (Medical Research) Amendments to the Western Australian Guardianship and Administration Act (the Amendments).

1. Background

ACEM is responsible for the training of emergency physicians and the advancement of professional standards, including the study, research and development of the science and practice of Emergency Medicine in Australia and Aotearoa New Zealand.

The practice of emergency medicine is concerned with the prevention, diagnosis, and management of acute and urgent aspects of illness and injury among patients of all ages who present to emergency departments with a spectrum of undifferentiated physical and behavioural disorders.

As the peak professional organisation for emergency medicine, ACEM has a vital interest in ensuring the highest standards of medical care are provided for all patients presenting to emergency departments (EDs).

The College's submission is informed by several guiding principles. These are set out in the College's Position Statement on Consent for Research (attached). In brief, these are:

1. Many patients present to emergency departments with serious and time-critical illnesses such as cardiac arrest, major trauma, or shock where the ability of the patient to provide informed consent is impaired.
2. Many routine standard treatments in emergency care are *not supported by high level evidence* but are based upon consensus. Consequently, the effectiveness of these routinely administered treatments is uncertain; some may in fact even be harmful.
3. Resolving treatment uncertainty can only be addressed by well-designed and ethically approved clinical research. Rather than protecting patients, unnecessary barriers to research participation means patients continue to be exposed to unproven treatments. In the context of Emergency Medicine, this can mean the sickest and most vulnerable patients may not be receiving optimal care. *Excluding such patients from approved research designed to produce better outcomes for their condition is in fact unethical.*
4. Clinical Research is highly regulated. All research involving patients must be approved by an independent Human Research Ethics Committee (HREC) and research studies are subject to regular reporting and audit. In addition, clinical trials require to have an independent data safety monitoring committee. Patients who are enrolled in research studies typically have better clinical outcomes due to the close monitoring of their condition. This includes those enrolled in the 'control' or usual care arms of clinical trials.

5. A large proportion of research in Emergency Medicine is observational research (*for example* investigating how well a new diagnostic test works), or clinical trials comparing two or more routinely used treatments to determine which is better. In these cases, the patient receives treatment no different to that if they were not enrolled in the research. Therefore, there is *no additional clinical risk* to the patient by participating in the research.
6. Internationally agreed principles informed by the Declaration of Helsinki allow for the participation in research by people who are unable to provide consent. In Australia, these are set out in the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research. This is the guiding document on which all HRECs in Australia base their decisions. No research will be approved that does not meet the conditions set out in the National Statement.

2. Overview of the submission

The College broadly supports the Amendments as providing a pathway for the participation in research by patients with serious and time-critical conditions presenting to Emergency Departments in Western Australia.

However, the College through its WA based members has identified several problems that will impact on both the effectiveness and operationalisation of the Amendments. Further amendments are required to ensure the fair and equitable access to emergency medicine research studies for patients in WA, to deliver the best possible clinical care while protecting the safety and rights or research participants. The College supports an approach consistent with other Australian states and territories and comparable overseas jurisdictions by removing the current impediments to involving acute and critically ill patients in WA in multicentre research studies.

3. Recommendations

The College recommends to the review that the following changes would significantly improve the effectiveness and operation of Part 9E of the Guardianship and Administration Act. These changes would allow for fair and equitable access by emergency patients who cannot consent due to the serious or time-critical nature of their condition to research while retaining appropriate protection for their rights.

1. Independent Medical Practitioner (IMP)
    a. Remove requirement for an IMP determination from section 110ZR
    b. Remove requirement for an IMP determination from low/negligible risk research under 110ZS
    c. Change definition of an IMP to include the treating clinician
    d. A streamlined process for the IMP to document their determination, where required. This could a single page 'checklist' or written entry in the clinical notes
2. Repeal of the sunset clause on section 110ZS
3. Lead researcher definition to be broadened to include non-medical clinicians

4. Response to the amendments

The Amendments are a positive step towards resolving previous legal uncertainty, and therefore enabling acutely ill and injured patients in WA the opportunity to participate in research studies designed to improve clinical outcomes and which are available to their counterparts in other Australian jurisdictions.

4.1 Experience prior to the amendments

The College notes that prior to 2018 many hundreds of patients were enrolled in approved clinical research without prospective consent of the participant i.e., consent was obtained from a research decision-maker (RDM). in Emergency Medicine and acute care research in WA without adverse consequences. This occurred under the previously widely accepted definitions of 'other medical treatment' in the Guardianship and Administration Act 1990 (the Act).

In 2018 the WA State Solicitor provided advice that the provisions in the Act did *not* apply to consent for clinical research. Consequently, all research involving patients unable to consent in WA ceased, and no new research projects were approved. The participation of WA patients in local, national, and international research studies ceased, and some WA based researchers were required to return grant funding. In at least one instance a NHMRC funded and ethically approved clinical trial was unable to be completed and

consequently important questions of the safety and effectiveness of existing treatments in use remain unresolved.

4.2 Experience since passage of amendments in 2020

Since the passage of the Amendments in April 2020 the number of participants enrolled in research under its provisions is currently only a *small fraction of the number prior to 2018*. This is following a hiatus of over two years from the suspension since it took several months after the passage of the Amendments for WA Health to develop pathways to operationalise them. One low-risk observational research study involving patients with Critical Illnesses presenting to Emergency Departments that was previously recruiting 8-10 patients a month has slowed to 1-2 per month, with eight in total being recruited under the provisions of Part 9E. That study previously enrolled patients across several hospitals but is currently recruiting at only one (Royal Perth Hospital). The reasons relate to the complexity and impracticality of aspects of the Amendments which are detailed below. Recently, Perth Children's Hospital has commenced recruiting patients into an international multicentre comparative effectiveness trial of two routinely used intravenous fluid solutions in children with septic shock. This trial has enrolled 20 patients, with 10 being enrolled under the provisions of section 110ZS because parental distress precluded a discussion about research participation at the time of enrolment. Subsequent consent was obtained from parents without issue emphasising the importance of the urgent research pathway.

The College also notes that prior to 2018 Western Australia had a vibrant and internationally recognised program of research in prehospital care. An example of the outstanding pre-hospital and emergency medicine studies previously published by WA that cannot be carried out in the current operating environment is the study by Jacobs et al. This was effectively terminated in 2018. This has not recommenced due to the restrictions on research (e.g., EXACT trial protocol) undertaken by non-medical clinicians such as paramedics in the Amendments, and the impracticality of obtaining an IMP determination in the pre-hospital setting.

WA based members of the College have described the following specific areas of concern regarding the effectiveness and operationalisation of the Amendments:

4.2.1 Independent Medical Practitioner

a. In the College's view the principle of involving a second practitioner is reasonable in some circumstances under section 110ZS. The College does *not* consider the involvement of an IMP is necessary under 110ZR. College members report that the involvement of an IMP when a research decision-maker (RDM) is present and willing to provide consent is intrusive and confusing for the RDM. In some circumstances, the lack of availability of an IMP can mean that the patient cannot be enrolled in the research even though the RDM agrees that the participant would wish to participate. Good clinical practice allows for recourse to a second opinion should this be thought necessary by the researcher or the RDM, but this should not be a legislative requirement. **The requirement for an IMP in 110ZR should be removed.**

b. The Amendments take no account of the *hierarchy of risk* in research. Much research in Emergency Medicine is low or negligible risk observational or comparative effectiveness research. These criteria are explicitly laid out in the National Statement. The requirement to involve an IMP where the HREC has determined that the research meets these criteria is disproportionate and confers no additional protection for the patient while imposing a significant obstacle to their participation. **The requirement for an IMP determination should be removed from s110ZS where the HREC determines that the research is low or negligible risk.**

c. The definition of an IMP requires that he or she be a) not involved in providing treatment to the potential research candidate and b) not involved or connected to the research. In practice this means a researcher is required to explain not only the details of the patient's condition but also the research project to another doctor who is not familiar with either. This takes substantial time away from patient care and introduces greater risk by removing the decision from the immediate clinical scenario as well as potentially delaying the commencement of treatment. The College contends that the prime role for the IMP should be to satisfy themselves about the suitability of the patient for the research study, and

to determine to the best of their knowledge that the research candidate would not otherwise decline to participate, or that there is no advanced directive which would be contrary to their participation. Consideration of the wishes of the research candidate as stated in 110ZU(1)(a), in so far as they can be ascertained, is the paramount consideration. The treating clinician also has a professional responsibility to act as the patient's advocate in these circumstances which further reinforces their participation in the decision. The best decisions are most likely to be realised when the research decision is reached by *agreement between the treating clinician and a member of the research team*. The prohibition on the treating doctor being the IMP should be removed.

d. The requirement for the IMP to provide written reasoning to satisfy 110ZZC (b-e) is unnecessary as it confers no additional protection to the research candidate. The required four-page document requires specific elements of the legislation be separately addressed, is written in legal language and bears little relationship to clinical norms. In practice, doctors operating as the IMP require considerable guidance to complete this document correctly. To ensure independence is maintained, College members advise that some studies have provided additional written guidance to assist the completion of the form. The process is time-consuming and *is a substantial obstacle to offering research participation to patients and their families*. The College notes that the IMP determination can be made verbally in an urgent clinical scenario, and it is important that this is retained. The process could be substantially improved, in the limited circumstances where the College believes an IMP determination is reasonable (see above), by having a simple checklist that the IMP could sign to confirm they have discharged their responsibilities under the Act. This would not detract from the protections while making the process workable and proportionate as well as improving transparency. The requirement for the IMP to provide written reasons for their decisions in each of the specific domains required by the Amendments should be removed.

e. The definition of the Independent Medical Practitioner does not recognise the research that is undertaken by other AHPRA registered health professionals such as nurses, psychologists, paramedics and other allied health professionals. The terminology for the IMP should be changed to Independent Health Practitioner.

4.2.2 Definition of a lead researcher (110Z0)

The definition of a lead researcher specifies a medical practitioner. Many College members undertake collaborative research which may be led by non-medical personnel such as paramedics, nursing, and allied health professionals. At present, a research study of an allied health intervention is required to have a medical practitioner as the lead researcher even if the project is outside their training and expertise. The College recognises the expertise of other members of the multidisciplinary teams in which its members work. All have their own professional standards regulated by the Australian Health Practitioners Authority. This issue has particularly impacted paramedic-led prehospital research in WA. A lead researcher should be defined as a registered health professional with expertise in the area of the research.

4.2.3 Sunset clause

There is currently a clause within the Amendment which will delete the pathway for urgent research without consent (110ZS) after four years, i.e., in April 2024. As most clinical research trials last several years this is currently an obstacle to commencing new research projects in WA as local researchers cannot guarantee that they will be able to complete the study. The College contends that it is imperative that this sunset clause be repealed.

5. Additional review questions

The College notes the questions which the review will consider and provides the following additional observations in relation to the items relevant to its membership.

5.1 Definition of Medical Research

The College reports no issues identified by its members regarding the definition of medical research in the Amendments which have impacted on their effectiveness or operation.

5.2 Role of the State Administrative Tribunal

The College recognises that a properly constituted HREC which consists of independent clinicians, researchers, lawyers, lay people and pastoral care representatives is best placed to assess the issues of scientific merit and risk for any proposed research involving participants who are unable to consent. The HREC is bound by the terms of the National Statement ensuring consistent application of these principles across Australia, and its members are highly experienced. The HREC is also responsible for the ongoing monitoring of research projects including resolving any issues of compliance or complaints which may arise.

The view of the College is that additional review or approval of projects by the State Administrative Tribunal (SAT) is not appropriate. Unlike a HREC, the SAT does not have the expertise to assess the merits or risks of a clinical research project. Any such requirement would substantially increase the already significant time and cost burden involved in obtaining research approvals, while conferring no additional protection for research participants. For non-commercial, investigator-initiated research (which makes up the vast majority of research in emergency medicine) such an additional requirement could render some important research unviable.

For decisions regarding the participation of an individual patient in a research project, the nature of the research undertaken in emergency medicine requires that a decision needs to be made in within minutes, often outside usual business hours. Any requirement to obtain authorisation from the SAT would be completely impossible to achieve in practice.

5.3 Statutory penalties for researchers

The College does not believe that specific penalties for researchers who fail to comply with their obligations under the Act are required. The emergency physicians and trainee specialists who the College represents are all experienced medical practitioners who are already bound by a professional code of conduct and subject to disciplinary procedures for breaches of conduct. Emergency Medicine is complex and involves professional judgement to be exercised often under pressure of time and with incomplete information. Emergency Physicians are highly qualified medical experts, and the interest of the patient is their primary concern.

Clinical research is a highly regulated enterprise, with a far higher level of scrutiny and oversight than in routine clinical care. Clinical researchers in Australia all are required to undertake specific training in good clinical practice (GCP) related to research. There are already in place robust systems for monitoring of compliance with GCP, including processes for complaints. The College believes that additional specified penalties for breaches related to the Act would serve no additional benefit above those penalties which already exist. It would potentially further disincentivise clinicians from involving their patients in research because of fear of repercussions from a research decision made in good faith. Unnecessary barriers to research participation mean the ultimate losers are patients who are denied access to research designed to achieve the best outcome for their condition, and the community for whom the opportunity to improve care is denied.

6. Conclusion

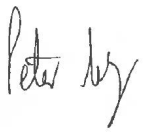
Since the passage of the Amendments in 2020, only a small fraction of the number of patients who are unable to consent have been enrolled in emergency research in WA compared to the period prior to 2018. This is directly due to the difficulties implementing the requirements of the Amendments in practice. Some areas of research which previously thrived in WA such as prehospital research have completely ceased.

In addition, the College believes that the Amendments do not optimally achieve their intent. An IMP who is not involved with either the research or the care of the patient is not best placed to carry out the required functions. An IMP determination provides no additional protection to patients in the setting of low and negligible risk research and unnecessarily complicates the process where there is a RDM present for no additional benefit. The requirement for the IMP to provide written reasons is a substantial obstacle to research participation.

The demonstrated impact of these issues is that many patients are continuing to be denied the benefits from participating in research which was previously available in WA and continues to be available to their counterparts in other States and Territories.

Thank you again for the opportunity to provide this submission. If you require any further information about any of the above issues or if you have any questions about ACEM or our work, please do not hesitate to contact Jesse Dean, General Manager, Policy and Regional Engagement (jesse.dean@acem.org.au; +61 423 251 383).

Yours sincerely,



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