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Submission to Australian Commission on Safety and Quality in Health Care: March 2019

AUSTRALIAN CLINICAL TRIALS GOVERNANCE FRAMEWORK

The Australasian College for Emergency Medicine (ACEM, the College) welcomes the opportunity to provide feedback to Australian Commission on Safety and Quality in Health Care (the Commission) on the Australian Clinical Trials Governance Framework (the Framework).

ACEM is the not-for-profit organisation in Australia and New Zealand responsible for the training and education of emergency physicians and advancement of professional standards in emergency medicine. As the peak professional organisation for emergency medicine, ACEM has a vital interest in ensuring the highest standards of emergency medical care are maintained for all patients.

It is understood by ACEM that the Commission has been contracted by the COAG Health Council to develop the Framework as a first step towards a nationally consistent accreditation process for health services undertaking clinical trials. The College notes further that accreditation to conduct clinical trials under the Framework will be based on site compliance with the NSQHS Clinical Governance Standard and the Partnering with Consumers Standard.

The application of standardisation to the currently labyrinthine system of local research governance requirements and regulations is a laudable aim, and implemented prudently could lead to real efficiency gains, particularly in running multi-site, multi-jurisdictional studies.

However there is a real risk that, if adopted in the suggested format, the associated onerous regulatory requirements would only be viable within the research infrastructure of major teaching hospitals. For instance, the introduction of a requirement that anyone involved in caring for a patient in a clinical trial is Good Clinical Practice compliant, including junior doctors and nurses providing study interventions at the bedside, may have the unintended consequence of restricting research to major referral centres. Even within major tertiary hospitals, it is not practical for every junior doctor to undergo CGP training to enrol a patient in a low risk observational trial. It can also be argued that GCP training, whilst laudable, is not required for junior clinical staff enrolling patients in low risk and negligible risk trials. The incentive to host research in smaller centres is already slight, without the expectation that managers accept responsibility for risks they cannot control with absolute certainty, and within budget.

The restriction of research to major referral centres would, in terms of emergency medicine in Australia, effectively limit research to the 43 emergency departments with 24 month accreditation from the College. For many interventions delivered in emergency departments, this would seriously damage the ability to recruit large enough cohorts to provide the external validity and an adequate statistical power to run an effective clinical trial.

It is vital that research continues to be undertaken by non-commercial entities, and the failure of this to occur would be a harmful outcome for the Australian community.

In emergency medicine most research is investigator-initiated-and-led comparative effectiveness studies involving established treatments, and is often poorly funded (if at all). Research activities, in particular data collection and analysis, is undertaken with the in-kind support and goodwill of dedicated investigators and staff, either during working hours or after hours. Analysis of all NHMRC grants funded between 2000 and 2014 shows that only 40 (0.2%) were in the field of emergency medicine.[1] Industry funding inevitably flows towards long-term pharmaceutical interventions for chronic conditions.

A high proportion of well-established interventions in emergency medicine are not evidence based, and require systematic evaluation to maximise effectiveness and prevent patient harm. Addressing such questions as the right dose of oxygen to provide post cardiac arrest, fluids or vasopressors for septic shock, use of analgesics or anti-emetics, or the effect of allied health interventions, all represent no greater risk to the participant than if they were not enrolled in a trial.

However, the current regulatory burden to acquire approval, even for a negligible risk observational study, is a substantial disincentive, and is preventing important questions affecting the care of patients treated in emergency departments from being addressed.

The participation of consumers at every level throughout the research governance process is vital, as are systems of oversight that ensure patient safety. However, such controls must be proportionate to the level of risk associated with the research being undertaken. If all the research being undertaken at a hospital is low or negligible risk, the level of oversight arrangements should reflect that circumstance. If a hospital accredited for low risk research wants to participate in a higher risk multi-centre trial then oversight could be provided from an external source, accrediting the hospital for that particular trial. The cost of oversight could then be factored into the grant application.

Through the ACEM Clinical Trials Network (CTN), the College is supporting the building of research capacity in our discipline, by harnessing the collective strength of individual researchers undertaking investigator-led studies in emergency departments across Australia (and New Zealand). Members of the CTN adhere to the 'grand bargain', which is that researchers enrol into each other's trials, thereby increasing the number of sites and participants, and realising sample sizes that provide confidence in our conclusions on the clinical effectiveness of interventions. The only requirement for site participation is the treatment of patients who are suitable for inclusion.

ACEM believes that the delivery of high quality patient care includes research as a fundamental component of ED activity. It is the fundamental right of patients to participate in emergency research regardless of the size of the hospital to which they present. Reflective practice involves constant evaluation of treatment and processes and is an integral part of clinical care. All practitioners have an obligation to facilitate and engage with research activity.

The College furthermore believes that the imposition of blanket accreditation arrangements, which lack situational nuance, could be detrimental to clinical trial based research in Australia, and specifically to clinical research in the majority of Australian emergency departments.

Thank you for the opportunity to provide feedback to the Commission on the proposed Australian Clinical Trials Governance Framework. Should you require clarification or further information, please do not hesitate

[1] Taylor DM, Cohen DR, Epstein J. Development of a productive research culture in emergency medicine: report of the outcomes of a research forum. Emerg Med Australas. 2016 28: 113–118.

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Yours sincerely,

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