Anaesthesia Research Coordinator pandemic guide

The Australian and New Zealand College of Anaesthetists Clinical Trials Network is a large collaboration of investigators throughout Australia and New Zealand, committed to improving the safety and quality of anaesthesia, pain and periperaoperative care.

In 2016, the Clinical Trials Network (CTN) Executive formalised a sub-committee of the ANZCA Clinical Trials Network Executive, named the Anaesthesia Research Coordinators Network (ARCN) Sub-committee. This sub-committee is comprised of eight research coordinators/ trial managers working across Australia and New Zealand. It also includes the immediate past chair, the Chair of the CTN Executive and the CTN Manager or representative. This committee represents approximately 150 research coordinators who facilitate anaesthesia research. Research coordinators have developed specialised knowledge and expertise in the overall conduct of high-quality research. The ARCN sub-committee works to develop strategies to support and mentor research coordinators in their roles and help build and maintain a sustainable CTN workforce.

The emergence of COVID-19 (SARS-CoV-2) pandemic and its impact on global society will have significant influence on perioperative and anaesthetic care services. This document has been produced in an effort to provide guidance for CTN members navigating research programs during this pandemic.

Research coordinators and principal investigators should use the themes and ideas discussed in this document as a reference for further discussions within their own working environments in collaboration with their colleagues. Within the context of government legislation and local health district mandates, all research departments should ensure appropriate contingency plans are put in place to ensure the safety and wellbeing of trial participants during this time as well as supporting pandemic research and research staff. Links to additional resources have been provided at the end of this document.

Working environment and clinical capacity support

Many of our anaesthesia research coordinators (RCs) have clinical nursing experience across many areas within the anaesthetic and perioperative discipline, as well as related disciplines such as critical care. As surge demand for the current pandemic escalates, it is anticipated that on a service-wide level, hospital management will seek clinical staffing support outside the current pool of perioperative nurses and many RCs may be required to assist in a direct clinical role. Priorities will therefore transition to direct patient level care and ongoing service provision.

It is important that any research effort by the CTN into COVID-19 research is meaningful to the global research effort with high level collaboration among key groups, for example, ANZICS, and minimize research waste and impact on site resources.

ANZICS position as outlined in their ANZICS COVID-19 Guidelines V1 dated 23rd March 2020, states on page 31 that “...research involving therapies for COVID-19 remains a high priority. Wherever possible research staff engaged in COVID-19 related research should be protected from redeployment”.

Managing Research Activity

If individual organisations have issued a directive regarding research activity, RCs should adhere to these guidelines. RCs should hold discussions with appropriate anaesthesia consultants and investigators about research priorities and capacity. Consider which current trials will be suspended, continued and commenced. Current models of clinical patient care, particularly intensive care, will need to be adapted as surge demand exceeds critical care capacity. For example, ICU patients may be ventilated via anaesthetic machines in operating theatres, and patients may be cared for in recovery rooms, catheter lab facilities, or other hospital environments outside of ICU. Monitoring and documentation may have to be adapted and patients may be cared for by staff not as familiar with these environments. Documentation for any research and data collection purposes will vary depending on circumstances.

Research equipment and supplies may be repurposed to cope with the pandemic. For example, clinical trial medication fridges may need to be utilised to house extra pharmacy medication. Shelving units storing research trial kits or equipment or resources may need to be repurposed. Consider removing research stock from clinical areas to reduce contamination from aerosolised procedures and patients, and to free up space for other urgent equipment.

Advice for Chief Principal Investigators and trial managers

It is imperative that at individual trial levels, each trial project team provides clear communiciqué to sites. Advice and guidance should be provided around recruitment of new patients, follow up of existing recruited patients and reporting of protocol deviations or breaches directly related to the pandemic and its clinical impact.
On-site, in-person planned monitoring visits should be suspended. If necessary, remote monitoring visits could be considered. Trial managers should understand that maintenance of site investigator files and obligations for regulatory requirements may not be prioritised by RCs. Data lock timelines may not be able to be met by sites. Patient follow-ups may have to be delayed or conducted via another telecommunication means if approved. Trial managers could communicate with ethics/research governance offices on sites behalf if they have capacity to support sites in this manner. Additionally, any support from trial coordinating project teams would be greatly appreciated by RCs.

Advice for Research Coordinators

Obligations for safety should remain an important aspect of all research conduct. If data entry capacity is reduced, priority should be given to safety reporting. Communicate with trial project teams about reporting individual non-serious safety breaches and consider submitting a post COVID-19 deviation report after the pandemic situation has subsided, including summary details of number of participants impacted, changes to medication dosing due to supply/dispensing issues, protocol breaches due to unforeseen events, and missing or delayed data.

Data lock timelines may not be able to be met. Communicate with trial project teams about plans to conduct patient follow-ups, as follow-ups may have to be delayed or conducted via another telecommunication means if approved. Seek support from admin staff to assist with administrative duties (printing, photocopying, faxing etc).

Ethical and local governance submissions for new trials may be delayed by your human research ethics committee (HREC), however, there may be opportunities to prepare ethics and governance paperwork from home or during any downtime. Some HRECs may prioritise COVID-19 related research. Trial managers should support RCs and sites in administration of these amendments as much as possible.

Communication with colleagues is important. Communicate openly, simplify where possible and remember that everyone is operating under stressful and challenging circumstances.

If RCs are able to continue working in a research role, consider the ability to work remotely and put in place IT requests to facilitate remote IT access. RCs should maintain patient privacy in accordance with Good Clinical Practice (GCP) guidelines when working remotely and should follow organisational guidelines. Additional equipment may be required, such as the purchase of a work mobile phone for patient contact in order to protect the privacy of staff working from home.

Role of Principal Investigators

Many RCs may struggle to negotiate the requirements of their research role if pressure is applied to assist in a clinical capacity. Support from medical colleagues and principal investigators should be sought to advocate that where possible, the RC remains in a research role. However, we recognise that consideration should be given to the most urgent priority whenever needed.

If clinical assistance is required of the RC, consider the following:

1. The RC must be remunerated for clinical shifts from the relevant clinical cost centre where the shift is worked. This will protect research finances, especially in a time of low recruitment due to cancellation of elective surgeries and other perioperative activity.
2. RCs should consider their scope of practice and qualifications if required to assist in clinical duties.
3. If transition to clinical care is required, the RC should actively seek support and training from educators or senior staff to assist with clinical transition. Consider supernumerary shifts to familiarise with the clinical area and required equipment. Consider BLS and ALS reassessment/training & other mandatory assessments.
4. RCs should undertake specific training on personal protective equipment (PPE), donning and doffing procedures.
5. If the RC is unable to undertake clinical duties, they could consider offering non-clinical support.

Consent and good clinical practice

The principles of Good Clinical Practice (GCP) should continue to be applied for informed consent. Consent processes approved by the reviewing HREC for individual trials should still be adhered to. However, pandemic related social distancing will affect the capacity and scope to perform in-person consent. Local research office advice regarding patient recruitment and consent should be followed in a pandemic. Advice may be to stop recruitment to clinical trials due to the health risk to research staff. Breaches relating to GCP protocol and consent should be mitigated as much as possible. Document any approach to consent, particularly detailing difficult circumstances surrounding consent. Ensure clear communication with the coordinating centre/trial sponsor/HREC.

Consider discussions with trial sponsors about how to manage alternative approaches to consent, noting HREC requirements and obligations. Seek support from trial sponsors to consider applying for an amendment to HRECs for rapid approval of alternative methods of consent (such as verbal telephone consent). Trial sponsors should support administrative approach to HREC to facilitate this and relieve the burden from sites. However, it should be noted that HRECs will also be operating under difficult circumstances and may not be able to process amendment requests for alternative consent approaches promptly.

Sustenance of research programs

Financial circumstances to support research will be difficult. Income generation may be severely impacted, and this may

Consider discussions with hospital executives and finance departments about extensions of timelines for RC business case and contract renewals. Please communicate with ARCN and CTN executive about any financial difficulties this pandemic may create as CTN may be able to offer advice and assist in advocating for research funding. It should be noted that healthcare costs to support the pandemic will be substantial. Financial circumstances to support research may be difficult and income generation may be severely impacted. Consider reviewing individual research program portfolios at each site and consider research revenue options.

COVID-19 Research
Your hospital may prioritise research projects directly related to the pandemic. If you have capacity, communicate with RCs from other disciplines and offer assistance to any urgent pandemic related research; particularly in the critical care space if RCs with clinical backgrounds are redeployed.

Please contact the CTN office if your site is participating in COVID-19 research, in particular ANZICS endorsed studies. The CTN office may be able to link you in with people who have offered their assistance for COVID-19 research.

Research coordinator safety and well-being
RCs may be personally impacted by COVID-19 and be unable to continue in research duties. Important research activity during periods of RC absence will need to be prioritised. Consider seeking assistance from RCs in other clinical disciplines who may be able to support any urgent work. Alternatively, consider other workforces that may be able to assist. Note however, that assistance from other staff unfamiliar with research, may require that they have GCP training, are included into delegation logs and CVs provided.

Conclusion
These are unprecedented and challenging times. It is critical that all research staff adhere to local, state and national guidelines regarding pandemic advice. It is anticipated that the current pandemic will last for many months and we would urge members to care for their own mental and physical health and well-being. Consider the impact your role will have on your family. If work commitments become too much, discuss this with your supervisor in the first instance. Support can be accessed from The CTN Executive, ARCN Sub-Committee and other RC colleagues.

Additional resources and references
Australian and New Zealand Intensive Care Society

WCG Clinical Presentation: Clinical trials in the era of covid-19, changes you need to make now

NHMRC Grant Guidelines

FDA: Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic
https://www.fda.gov/media/136238/download

Australian and New Zealand Intensive Care Research Coordinator Interest Group (IRCIG)

MRFF Research Fund

Department of Health COVID-19 Guidance on clinical trials for institutions, HRECs, researchers and sponsors

Medicines Australia Responding to the challenge of COVID-19

Change control register

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