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Rural and regional engagement in Australia: Guidance for anaesthesia research departments

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Purpose of document:

This guidance document outlines the ANZCA Clinical Trials Network (CTN)'s commitment to expanding the reach, relevance, and impact of investigator-led clinical research into rural and regional hospitals across Australia. Building on the learnings from the Preoperative Administration of Dexamethasone and Infection (PADDI) trial, it aims to provide a framework for overcoming challenges and capitalising on opportunities unique to rural and regional healthcare environments.

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This guidance document outlines the ANZCA Clinical Trials Network (CTN)'s commitment to expanding the reach, relevance, and impact of investigator-led clinical research into rural and regional hospitals across Australia. Building on the learnings from the Preoperative Administration of Dexamethasone and Infection (PADDI) trial, it aims to provide a framework for overcoming challenges and capitalising on opportunities unique to rural and regional healthcare environments.

2. Case study: The PADDI trial

The PADDI trial was a landmark multicentre, stratified, randomised, placebo-controlled trial that investigated whether a single intraoperative dose of dexamethasone (8mg) altered the rate of surgical site infections (SSI) in adult patients.

2.1 Key findings

Published in *New England Journal of Medicine*, 2021:

- SSI rate: 8.1% in the dexamethasone group vs 9.1% in the placebo group.
- The trial achieved statistical significance for non-inferiority ($p<0.001$).

2.2 Rural participation

- Over 931 patients (10% of total cohort) were recruited from rural and regional sites.
- Multiple regional centres, including Ballarat Base Hospital (now Grampians Health), demonstrated capacity for high-volume recruitment.

2.3 Key takeaway

The PADDI trial provided a powerful proof-of-concept that large-scale, high-quality clinical trials can be successfully conducted in non-metropolitan hospitals when supported by the right frameworks and resources.

3. The case for rural and regional engagement

3.1 Why involve rural sites?

- Over 30% of the Australian population resides in rural and regional areas.
- An estimated 10% of these individuals undergo surgery each year.
- To ensure equitable representation in clinical research, regional participation must be actively facilitated.

3.2 Patient benefits

- Enhanced postoperative monitoring and complication management.
- Greater engagement in care and improved patient satisfaction.
- Broader access to new interventions and treatments.

3.3 Hospital benefits

- Development of a culture of inquiry and continuous improvement.
- Recruitment and retention of highly skilled clinical and research staff.

- Improved data capture on clinical outcomes, caseload complexity, and cost-of-care metrics.
- Contribution to high analytical research trials.

3.4 Clinician benefits

- Professional development through trial participation.
- Stronger alignment with national and global healthcare trends.
- Evidence to advocate for clinical resources and research infrastructure.

3.5 System-level benefits

- Tangible economic returns on investment: A 2017 joint report by Australian Clinical Trials Alliance (ACTA) and the Australian Commission on Safety and Quality in Health Care found that implementing results from 25 major trials could save $2 billion annually, with a $5.80 return per $1 invested.

4. Lessons learned from PADDI

4.1 Critical success factors

- A straightforward intervention that could be implemented across multiple levels of care.
- The presence of motivated principal investigators (PIs) and research co-ordinators.
- Early engagement with hospital executives to establish buy-in.
- Utilisation of CTN resources, including training, templates, and communications support.

4.2 Overcoming initial barriers

- Some sites contributed only small numbers but demonstrated feasibility.
- Initial set-up requires considerable effort but yields long-term capacity.
- Recognition and sustained support for pioneering sites is essential.

5. Understanding and addressing challenges

5.1 Common barriers

- Lack of dedicated research staff, such as co-ordinators.
- Limited exposure to clinical trials and Good Clinical Practice (GCP).
- Minimal institutional processes for ethics and governance.
- Limited effective digital infrastructure in rural and regional organisations. (Redevelopment of rural health services needs to include the integration of digital infrastructure to ensure success of “virtual” hospitals or remote monitoring).

5.2 Enabling strategies:

- Design low-burden protocols suited to available clinical capacity.
- Start with observational studies or simple interventional trials.
- Offer seed funding, mentoring, and access to trial templates.
- Encourage local champions to advocate within their health service.

6. Technology-enabled future for rural trials

The following are a number of futuristic feasible approaches to running clinical trials in rural and regional Australia.

6.1 Remote monitoring and virtual hospitals

- The HIVE (Hospital in a Virtual Environment) program at Royal Perth Hospital demonstrates the power of telemonitoring.
- Real-time data transmission and video consultations between central command centres and rural wards are now feasible.
- High-resolution cameras allow remote wound assessment, device inspection, and patient interaction.

6.2 Wearables and longitudinal monitoring

- Upcoming wearable sensors will allow 24/7 remote monitoring of blood pressure, oxygen saturation, heart rate, and respiratory rate.
- These devices reduce the need for on-site staffing while improving data quality and safety.
- Wearables can also support long-term follow-up in pragmatic and registry-based trials.

6.3 Integration with Electronic Medical Records (EMRs)

- Future integration of trial protocols with EMRs will reduce duplication, streamline recruitment, and allow automated data capture.

7. Building capacity: CTN's commitment to rural and regional engagement

7.1 Immediate actions

- Conduct a national needs assessment of rural and regional research capacity.
- Identify and connect local research champions.
- Provide access to standardised business case templates.
- Distribute trial feasibility checklists and readiness tools.

7.2 Funding and support structures

- Offer pilot funding through the ANZCA Foundation and external sources.
- Facilitate CTN-endorsed seed grants for start-up support.
- Collaborate with Anaesthesia Research Co-ordinator Network (ARCN) to support new research co-ordinators.

7.3 Community and network engagement

- Establish regular forums for regional site leads.
- Promote success stories through newsletters and conference presentations.
- Include regional perspectives in CTN planning and governance.

8. Conclusion

The PADDI trial proved that clinical trials can be implemented successfully in rural and regional hospitals. The ANZCA CTN sees these centres not only as contributors but as future leaders in a decentralised, digitally supported research ecosystem. By leveraging existing technologies, tailoring trial designs, and fostering institutional readiness, we can close the rural research gap and ensure better outcomes for all Australians.