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HoMER

An opportunity or threat to general practice research?

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The National Health and Medical Research Council (NHMRC) Harmonisation of Multicentre Ethical Review (HoMER) project aims to implement a 'single ethical review', where the outcome of an ethical and scientific review by a single recognised Human Research Ethics Committee (HREC) will enable multiple institutions to decide whether or not to participate in a given study.¹ The desired process will include agreement on timeframes, authority of the reviewing HREC, respect among the jurisdictions, verification by independent organisations, and compliance with the national statement and relevant statutory and administrative frameworks. However, there appears to be little discourse on the implications for general practice research in the research community.

It is not known how many of the 200+ institutional HRECs currently have general practice representation or formal requirements for general practice input when needed. However, anecdotal experience of The Royal Australian College of General Practitioners National Research and Evaluation Ethics Committee, including reviewing proposals that have been approved by institutional HRECs, suggests an apparent lack of insight into ethical general practice research. Obvious examples include expecting to recruit patients from general practice with no written participation information statement/

consent forms or inadequate privacy protection. However, more subtle implications encountered are reasons for this discussion of possible impacts of the proposed 'single ethical review' concept.

General practice is a small business. It provides first contact, comprehensive, continuous and personalised care to patients with a high degree of diagnostic uncertainty and contextual complexity covering biopsychosocial elements. It has three key interfaces:

- self care
- secondary care, and
- between care tailored to individuals and populations.²

The general practice research agenda is underpinned by these core values – universal access, patient centred and population based care over time, efficient organisation and advocacy. General practice research questions can be preventive, diagnostic, prognostic, interventional, behavioural or phenomenological. Sustainable general practice research requires a balance of ethical practice, methodological rigour and clinical pragmatics with influences from financial and personal factors.

A central ethical consideration is continuity of care and patient engagement within an ongoing patient-doctor relationship. Informed consent is essential but may be compromised by time constraints and an unequal power relationship between providers and receivers of care. Indistinct boundaries between quality assurance, audit, evaluation and research activities, and limited awareness of, and access to, HRECs are barriers to formal assessment of potential ethical problems inherent in 'research'

in general practice.

Clinicians are generally wary of blinding, random allocation and intention to treat analyses. Sample sizes and power of studies often require multicentre studies, raising issues of clustering. If routinely collected clinical data are used, there are problems with data quality or semantic interoperability among different data sources. Poor response and high attrition rates among GPs who participate in research are growing but understandable issues, given the small business nature of general practice.

Pragmatic clinical challenges that determine the feasibility and sustainability of general practice research projects are universal³ and include time, workload and workflow factors associated with time-consuming informed consent processes. Practice organisation and staff training to embed ethical research and ethical practice are important fundamentals. The distinction between the information in research databases and patient medical records in terms of privacy requirements and information quality attributes, such as correctness and completeness, must be recognised and managed.

Research in and about general practice is growing, but despite a range of Federal Government initiatives³ the general practice research community is relatively immature. Compared to hospital specialists (5%), significantly less general practitioners (<0.5%) are clinical academics/researchers in the United Kingdom² or Australia⁴ or publish research papers.⁵

The question is whether HoMER will close or increase the gap between general practice research and hospital based and specialty research. If HoMER can satisfactorily clarify the roles and responsibilities of the researcher, institution, HRECs and key stakeholders in the

ethical conduct of multicentre research that spans primary and secondary care settings, it will be a good thing. This explicitness, transparency and consistency with the requirements of the National Statement on Ethical Conduct in Human Research will standardise the review process. However, HoMER accredited HRECs should include members who understand general practice research or have a process to obtain research input into the review process.

This is not about lowering 'ethical research standards'. It is recognising the subtleties of general practice research and a fledgling community that is promoting rigorous and ethical research. This community and culture may be lost if HoMER promotes a research funding culture that does not recognise that a rigorous evidence base for cost effective primary and integrated care is essential for safe and effective healthcare within and beyond the confines of general practice.

General practice research is not just about recruiting patients from general practice or evaluating clinical guidelines that may work in general practice. It is about building the evidence for general practice as a central component and driver of safe and cost effective care over the life cycle across the settings of care. The general practice research community must engage with the public discourse on HoMER.

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Conflict of interest: Professor Liaw is Chair of the RACGP National Research Evaluation and Ethics Committee. However, the views in this paper are his personal views.

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