



Progress in centralised ethics review processes: Implications for multi-site health evaluations



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ABSTRACT

Increasingly, public sector programmes respond to complex social problems that intersect specific fields and individual disciplines. Such responses result in multi-site initiatives that can span nations, jurisdictions, sectors and organisations. The rigorous evaluation of public sector programmes is now a baseline expectation. For evaluations of large and complex multi-site programme initiatives, the processes of ethics review can present a significant challenge. However in recent years, there have been new developments in centralised ethics review processes in many nations. This paper provides the case study of an evaluation of a national, inter-jurisdictional, cross-sector, aged care health initiative and its encounters with Australian centralised ethics review processes. Specifically, the paper considers progress against the key themes of a previous five-year, five nation study (Fitzgerald and Phillips, 2006), which found that centralised ethics review processes would save time, money and effort, as well as contribute to more equitable workloads for researchers and evaluators. The paper concludes with insights for those charged with refining centralised ethics review processes, as well as recommendations for future evaluators of complex multi-site programme initiatives.

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1. Introduction

Historically in western nations, ethics approval processes for medical and health studies have been localised, unregulated and not conducive to large projects (Gold and Dewa, 2012; Snooks et al., 2012). The recent growth in multi-site studies within health research and evaluation has reinforced that previous arrangements were inadequate (Hicks, James, Wong, Tebbutt, & Wilson, 2009; Nowak et al., 2006; Studdert et al., 2010). As Gold and Dewa (2012) explain, local ethics review mechanisms, when used with multi-site studies, can jeopardise the integrity of methodological approaches. Meanwhile, requests for the ethics review of non-medical studies also grew dramatically throughout the 1990s. This was due to both the expansion of evidence-based practices and an explosion in applications from the humanities and the social sciences (Fitzgerald & Phillips, 2006). Hence, a growing awareness of the inadequacy of ethics review processes led to greater

advocacy for the streamlining of ethics approval for all research, including evaluations of health initiatives.

International studies point to the significant advantages from centralised ethics review processes. For instance, Canadian research in the field of oncology found that centralised processes sped up approvals, reduced duplication and resulted in higher quality reviews (Chaddah, 2008). Meanwhile, research from the United States highlighted the potential for centralised systems to result in faster approvals for multi-site projects (Wagner, Murray, Goldberg, Adler, & Abrams, 2010), and better targeting of expertise in the context of increasingly complex proposals (McWilliams, Hebden, & Gilpin, 2006). Tellingly, Fitzgerald and Phillip's (2006) five-year study of multi-site projects in Australia, Canada, New Zealand, the USA and the UK, found that centralised ethics review would save time, money and effort, as well as contribute to more equitable workload and a stronger focus on issues of ethics (rather than administration). The idea of a coordinated and centralised ethics approval system soon took hold in the United States (Nowak et al., 2006), the United Kingdom (Snooks et al., 2012) and Australia (Studdert et al., 2010).

The case study that is considered in this paper is located within the Australian context. The Australian Health Ministers' Advisory Council agreed in October 2006 to implement a national system

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facilitating the recognition of a single ethical review process within and across all Australian jurisdictions (National Health and Medical Research Council [NH&MRC], 2013), it was named the *Harmonisation of Multi-centre Ethical Review* (HoMER). It is now over seven years since the establishment of this agreement and the publication of the findings of the Fitzgerald and Phillip’s study. Hence, we contend that it is timely to consider the progress that has been made in centralised ethics review processes in Australia, particularly in relation to the challenges faced by multi-site health evaluations. Specifically, this paper provides a case study of experiences with the HoMER process between 2011 and 2012 for a national evaluation of diverse Nurse Practitioner models of aged care that spanned Australian jurisdictions, sectors and organisations. As one case it is constrained in its scope, however, it is indicative of potential areas for further examination, it provides insights on which those charged with the process might reflect, and where its insights aligns with existing literature (see Section 4), it reaffirms the need for continued effort in these areas.

2. Context: nurse practitioner aged care services in Australia

Australia, like many other industrialised countries, faces unprecedented challenges in the provision of health care and the prevention of disease for an ageing population. Attempts to respond to these challenges have resulted in changing models of health care and shifting professional role boundaries, including the development of advanced practice roles for nursing. One such advance practice role is that of nurse practitioners, which are now well established in the United States and the United Kingdom. In Australia, a Nurse Practitioner (NP) is a registered nurse who has additional training, expertise and endorsement to provide specialised health care services (Australian Nursing and Midwifery Council 2012). This training enables them to take on roles that support healthier communities, including the management of medication and disease symptoms. This provides the potential for them to play a valuable role with aged care in a range of health care

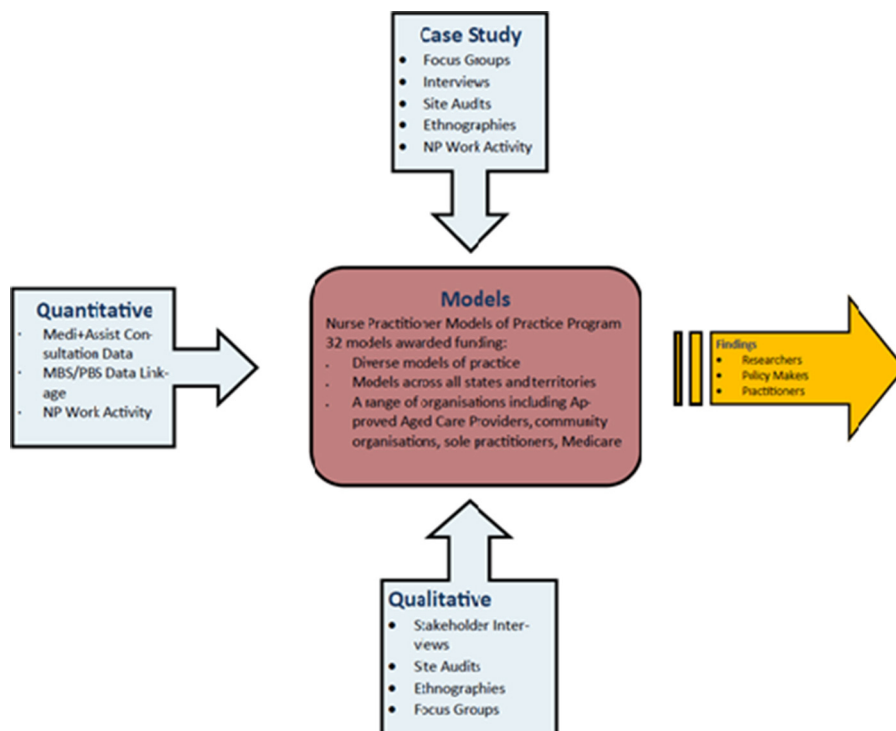
settings. In recognition of these developments, the Australian Government provided \$18 m (between 2011 and 2014) to support the *Nurse Practitioner – Aged Care Models of Practice Program* (the NP Program).

The NP Program aims to establish the role of NP as a key provider of aged care services across Australia. Thirty-two models were selected by the Australian Government to provide a diverse representation of jurisdictions, locations, service delivery settings, aged care service needs and different cultural groups. The Australian Government also provided funding for an independent evaluation of the effectiveness, efficiency and financial sustainability of each of the models. The evaluation of the NP Program was selected as a case for this paper because the authors were chief investigators within this evaluation and, hence, had first-hand access to all information relating to the centralised ethics approval process.

The specific objectives and methods of the national evaluation of the NP Program have been documented previously in this journal (Prosser, Clark, Davey & Parker, 2013). However, they can be briefly summarised as a mixed method evaluation approach (see Box 1), which includes quantitative data on access to health services and the economic viability of delivery models, as well as qualitative data on the critical factors in the effectiveness of these models and different accounts of stakeholder experiences. The final evaluation report is due to be submitted to the Australian Government in early 2015.

3. Case study: centralised ethics review of the nurse practitioner evaluation

Since 2006, the centralised ethics approval process in Australia has been similar to that of the United Kingdom, where global approval is gained prior to seeking local governance approval (Snooks et al., 2012). The NP Evaluation applied for global ethics approval from the University of Canberra Human Research Ethics Committee (the global HREC) in late November 2011. This application consisted of a covering letter, a National Ethics Application Form (NEAF), and copies of data collection tools,



Box 1. Methodological flowchart.

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