

Streamlining ethics review for multisite quality and safety initiatives: national bariatric surgery registry experience

The current ethics review process is inappropriate for clinical quality registries

Rigorous methods for assessing and improving the quality of health care have proven difficult to develop by traditional research approaches.¹ Clinical quality registries (CQRs) systematically collect an agreed minimum dataset of data across multiple sites on clinically relevant outcome measures. Data are analysed, comparing procedures, providers and institutions.² Feedback to practitioners has been shown to drive performance improvement, especially if the data are perceived to be high quality.³

Because CQRs collect and store health information, protocols require human research ethics committee (HREC) approval to ensure that they comply with the Australian *Privacy Act 1988* (Cwlth). Principle 6 of this Act states that stored personal information must not be used or disclosed for a secondary purpose unless patient consent is obtained or there is a permitted health situation. Section 16B of the Act defines the permitted health situations, which include research relevant to public health or public safety. The use or disclosure of personal information must be conducted under guidelines approved under section 95A of the Act. Current National Health and Medical Research Council guidelines state that ethical review is required at each contributing site for CQRs except where multi-institutional approval is in operation.⁴

Bariatric surgery is burgeoning in Australia. In 2016, it is estimated that there will be over 15 000 such procedures performed in Australia at a direct cost of over \$225 million. Yet there are no evidence-based guidelines directing who should be offered this surgery, nor are there any long-term community data documenting its safety and efficacy in Australia.

The Obesity Surgery Society of Australia and New Zealand (OSSANZ) partnered with Monash University Department of Epidemiology and Preventive Medicine (DEPM) to establish a national registry of all bariatric procedures with the aim of filling these knowledge gaps. The pilot commenced in 2012 and national rollout commenced in May 2014 (with federal government funding).

The Bariatric Surgery Registry (BSR) collects information on each procedure performed, the devices used, changes in patients' weight and diabetes status, and adverse events. Data are collected primarily from surgeons and are validated against hospital International Statistical Classification of Disease and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM) discharge codes. Because the BSR is tracking and storing identifiable sensitive health information longitudinally as

well as cross referencing data points to external data sources, HREC review is required at every site contributing to the BSR.^{4,5}

We believe that there are 164 hospitals undertaking bariatric surgery in Australia. As of 30 April 2015, there were 52 hospitals (31.7%) for which HREC approval for participation in the BSR had been obtained. Private hospitals accounted for 67% of these sites, 29% were public hospitals and an additional approval was received from both the Royal Australasian College of Surgeons and Monash University. Applications for high risk projects were requested from 31.4% of private hospital and 33.3% of public hospital HRECs. Seven sites (13.5%) provided approval through an affiliated site. Fifty sites (96%) had additional governance requirements and, in 76% of cases, this was a separate process. The median time from the first application to final approval was 86 days (range, 17–414 days). The maximum numbers of queries from or changes requested by an HREC was 67.

The process of obtaining ethical approval at these initial hospital sites cost the BSR \$180 698.58 in salaries and \$3474.97 per application. In addition, the BSR has had to pay five sites a total of \$3927.00 for ethics approval application fees.

The number of CQRs in Australia is growing rapidly in response to community demands for better monitoring of health care outcomes.⁶ HREC review of registry processes is one way of ensuring that the rights of individuals participating in registries are protected and complying with the Privacy Act. However, as highlighted by our experience in rolling out the BSR, the lack of a consistent process for obtaining HREC approval across multiple sites for these quality and safety initiatives creates cost and slows implementation.

HRECs are typically set up to review research projects rather than quality and safety initiatives. Unlike clinical trials, which are hypothesis driven and in which patients are given the option of participating, CQRs attempt to ensure quality through benchmarking, and so need to recruit all patients who undergo a given intervention to avoid the risk of bias. Many HRECs are not familiar with these basic and essential differences, and this can lead to confusion and delays, as the processes for clinical trials and CQRs invariably differ.⁷ Based on the cost and time involved in obtaining even 31.7% of the required approvals for the BSR, we call for a bespoke national process for HREC review of CQRs. This would streamline implementation and reduce costs while still protecting patient's privacy. Examples of such a process could be having all sites apply to a single national ethics committee,

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as in New Zealand, or implementing specific federal legislation protecting the transfer of information to and from approved CQRs.

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