

Medical registry governance and patient privacy

A more efficient system of governance is needed to safeguard individual privacy while allowing registries to operate for the public good

The recent controversy about cancer registries and patient privacy in the United Kingdom highlights the need for more debate about the governance of medical registries.¹ For 40 years, identified data from UK patients with cancer have been transmitted to cancer registries without the patients' express knowledge or consent. Although many benefits have flowed from analysis of these data, societal conventions have now changed, and questions are being asked in the UK and other countries, including Australia, about the privacy issues involved in the governance of medical registries in particular²⁻⁴ and medical research in general.^{5,6}

Medical registries were traditionally established by public health authorities to monitor trends in the incidence of conditions such as infectious diseases and cancer. However, registries have become increasingly important in monitoring outcomes after the implementation of disease-prevention and treatment programs. They are now vital to quality-improvement programs that assess the safety of new drugs and procedures, identify best clinical practice and compare healthcare systems. For example, the Australian Orthopaedic Association National Joint Replacement Register currently monitors the use and survivorship of artificial hip- and knee-replacement prostheses,⁷ while the Victorian State Trauma Registry (VSTR) was established largely to monitor the effects of changes to the state trauma system.⁸

For registries to be effective, they must include all eligible participants so as to avoid biases that would affect the applicability and generalisability of results, and they must collect patient-specific data so as to adjust outcomes for risk and management factors. Further, in the absence of a unique national identification number, registries require name-based identification if participants are to be contacted for follow-up, or if registry data are to be validated against those held in other databases.

The need for identified data raises consent and privacy issues. Registries must be established and governed in compliance with both federal and state legislation on privacy. Current requirements

of this legislation have necessitated the development of consent procedures that maintain the effectiveness of medical registries, while informing patients and protecting their personal medical information. However, obtaining patient consent before participation in broad-based registries is often impractical and results in poor enrolment rates.^{2,4} A more practical approach is to inform participants of their registration but to allow them to opt out of the registry. This approach resulted in the loss of fewer than 0.5% of eligible participants from the VSTR (unpublished data). This both complies with privacy legislation and achieves enrolment levels sufficient to maintain the scientific integrity of registries.

Privacy legislation also sets down the circumstances under which privacy principles may be waived. For example, a human research ethics committee (HREC) may determine that the public benefit in allowing access to identified data substantially outweighs individuals' right to privacy. However, as broad-based registries collect identified data from many sources, they are currently required to seek approval from many individual HRECs. This process is both time consuming and expensive. Further, many local HRECs have insufficient resources or expertise to evaluate the scientific merit of epidemiological research or to interpret privacy legislation,^{4,8,9} and consequently may reject legitimate research proposals.

Registries could be established by legislation that overrides privacy provisions, but this approach lacks flexibility. A more workable system is required for establishing and governing medical registries that both safeguards individual privacy and allows the registries to continue to provide the foundations for quality-improvement programs and epidemiological research.

No general guidelines for establishing and governing registries have been published, either in Australia or overseas. However, the National Health and Medical Research Council (NHMRC) has produced guidelines for genetic registers,¹⁰ which complement the National Privacy Principles¹¹ with respect to the collection, use and disclosure of sensitive information, data quality and security,

and the use of unique identifiers. After further development by the NHMRC in conjunction with federal and state privacy commissions, this model might be applied to other medical registries.

We also propose that the NHMRC acts as an accrediting authority for institutions maintaining medical registries. This would ensure that the institutions comply with privacy legislation, maintain independence from the agencies that directly manage participating patients' healthcare, and have the personnel, facilities and funding to maintain the registry and achieve its purpose. Institutions could be encouraged to seek accreditation by linking it to ongoing funding for registries.

Further, a centralised HREC with scientific, ethical and legal expertise might be better able than local HRECs to ensure that registries can achieve their public health aims while maintaining patient privacy. Such a centralised committee should include patient advocates, as well as experts in epidemiology, ethics and privacy law. It could also provide guidance to local HRECs, if current legislation requires that they make their own determination, to avoid unnecessary duplication of review processes.

Good registry governance involves developing a structure that

- includes stakeholders in management of institutions that analyse personal medical information;
- has a management independent of the institutions that provide healthcare;
- provides a research environment that maximises scientific benefit to patients and the wider community; and
- receives adequate funding to ensure continuity of data collection and quality assurance.

We hope that developing processes to ensure good registry governance will allay public concerns about privacy and allow registries to continue to underpin programs of healthcare quality improvement and epidemiological research.

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