



Clinical quality registries: A guide for Institutional Ethics Committees

The purpose of this brochure is to assist Ethics Committee members and health administrators in understanding the role of clinical quality registries. It is hoped that it will be of assistance when considering applications from clinicians to develop or participate in new or established clinical registries. This document has been developed as an adjunct to the *Operating Principles and Technical Standards for Australian Clinical Quality Registries*.¹

What is a clinical quality registry?

Clinical quality registries gather and analyse information so as to monitor and enhance the quality of care patients received. A clinical quality registry collects a standardised set of information from all patients treated for specific illness or undergoing specific procedures in participating hospitals. The data are used to monitor patterns of care and compare those patterns with the outcomes and with best practice guidelines. The data is pooled at a central location, typically in a government, academic or research institute, and analysed to provide information about quality of care. Feedback is provided to participating hospitals and clinicians to enable them to benchmark their results (after risk adjustment) to other Australian and international units.

Features of a clinical quality registry include:

- 1) Data is typically restricted to a minimum number of essential data elements.
- 2) Data relating to other illnesses (co-morbidities) is collected to allow risk adjustment.
- 3) Outcome data is sought by questionnaire, record review or data-linkage.
- 4) Data management is undertaken in a centre independent from providers.
- 5) Rigorous quality control procedures are in place to allow high levels of data accuracy.
- 6) Involvement of peak clinical groups in governance, analysis and report.

Purpose of clinical quality registries

Benchmarking information provided by clinical quality registries provides a strong impetus for units to reach their maximum potential in providing high quality care.

Other important information provided by registries may include information about:

- Safety and quality of care.
- Long-term safety of drugs and devices.
- Levels of compliance with clinical guidelines.
- Access to care in different locations or amongst different groups of patients.
- Suitability of units to provide training for junior clinicians.
- Trends in clinical care, allowing the planning of new services.

Identifying information

Clinical quality registries need to be able to collect individually identifiable or re-identifiable information on individuals in order to:

- track individuals whose treatment may span several institutions
- allow follow-up after hospital discharge to ascertain outcomes.

When longer term outcomes are important it may be necessary to collect names and addresses of a next of kin or a treating clinician to assist with follow-up.

Data security

The collection of personal identifying information imposes strict obligations on the organisation acting as registry custodian. Data must be held by the clinical quality registry in accordance with the Australian Code for the Responsible Conduct of Research,² the National Statement on Ethical Conduct in Human Research³ and with any relevant legislative requirements or regulations which



govern collection and storage of health-related data. Because of the complexities in ensuring data security, registries must be housed in an environment with extensive experience in handling confidential medical data. Data must be held under strict security arrangements and with strict procedures in place to ensure that access to data is restricted and released only in an aggregated fashion. Procedures must be in place to separate identifying information from other clinical information by using codes in all working files.

Consent

Clinicians seeking to provide data to a clinical quality registry should seek approval from their Institutional Ethics Committee. Current NHMRC guidelines provide Ethics committees with an option to approve collection of registry data as a quality assurance activity without consent.⁴ However, the guidelines impose various limitations on the use of the data that makes this approach undesirable in most circumstances.

Opt-in consent, whereby each individual patient is approached and asked to provide consent for their data to be transmitted to the clinical quality registry, has been thought the ideal. However it has been repeatedly shown that this approach leads to a 30–50 percent response rate.⁵ When the participation rate to a clinical quality registry is low there is a strong likelihood that the resultant participants will be unrepresentative and the data therefore unsuited for quality improvement or benchmarking.

Thus, opt-out consent is the preferred consent model for clinical quality registries. Eligible registry participants must be provided with information describing the purpose and procedures of the clinical quality registry. Possible participants must be informed that their participation or otherwise has no bearing on their clinical care. Possible participants must be offered simple means to obtain additional information and/or request that their personal identifying information is removed from the registry.

As of 2009, opt-out consent is used by 74% of clinical registries in Australia.⁶ There is evidence from those using this approach that few people do opt out; the Victorian Trauma Registry which holds details on more than 15,000 patients and routinely follows up all patients at six months following discharge has a less than 0.5% patient withdrawal rate, with even lower rates recorded by the National Joint Replacement Registry.

For Institutional Ethics Committees to approve opt-out consent they must be satisfied that:

- Data custodians are experienced in the handling of large clinical data-sets and have the infrastructure and expertise to maintain a high level of data security.
- Data being collected are confined to a minimum and are not of a highly sensitive nature (e.g. HIV status).
- The registry has been established by an appropriately authorised group and complies with the *Operating Principles and Technical Standards for Australian Clinical Quality Registries*.¹
- All eligible participants are provided with an Explanatory Statement.

Governance

Clinical quality registries must be established under the auspices of an appropriate legal entity. They require formal processes to manage access to and reporting of data and any actions that may be necessary as a result of findings arising from the analysis of their data. They should ideally be established in an environment that is clearly independent of the major clinical providers. If this is not possible, it is important that data collectors and data entry clerks are at arms length from clinical practice; that data items including outcome measures are objective; and that data quality checks are



performed by an independent person. A Steering Committee should be formed with representation from both practicing clinicians and the funding bodies, and other relevant stakeholders.

A list of Australian clinical registries and their attributes can be found at the NHMRC Centre of Research Excellence in Patient Safety website: <http://www.crepatientsafety.org.au/registries/> Work is currently underway to establish a web portal detailing attributes of registries, as has been done in the United Kingdom.⁷

Reference List

1. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries [Web Page]. November 2008; Available at http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-08_CQRegistries. (Accessed 24 July 2009).
2. National Health and Medical Research Council, Australian Research Council, Universities Australia . Australian Code for Responsible Conduct of Research. Canberra: Australian Government, 2007.
3. National Health and Medical Research Council (NHMRC). National Statement on Ethical Conduct in Research Involving Humans Part 1 - Principles of Ethical Conduct [Web Page]. Available at <http://www.nhmrc.gov.au/publications/humans/part1.htm>. (Accessed 24 July 2009).
4. National Health and Medical Research Council. When does quality assurance in health care require independent ethical review? Canberra: Australian Government, 2003.
5. Gershon AS, Tu JV. The effect of privacy legislation on observational research. CMAJ 2008; 178(7):871-3.
6. Evans S, Bohensky M, Cameron P, McNeil J. A survey of Australian clinical registries: can quality of care be measured? IntMedJ 2009.
7. National Health System (NHS) Information Centre . Information Catalogue: Directory of Clinical Databases [Web Page]. Available at <http://www.icapp.nhs.uk/docdat/DatabaseList.aspx> (Accessed 24 July 2009).

Checklist

Ethics committees should assess the following issues when determining whether to support the contribution of data to a clinical quality registry.

- 1. Does the proposed clinical quality registry fit the criteria of a Clinical Quality Registry?
- 2. Does the proposed registry meet all requirements of clinical quality registries outlined in the *Operating Principles and Technical Standards for Australian Clinical Quality Registries*?
- 3. Are clinical data collected by the clinical quality registry confined to a minimum and not of a highly sensitive nature?
- 4. Is the clinical quality registry central administering organisation (the registry custodian) a legal entity?