

“Clinical outcome registries- guidance for administrators and ethics committees”

This report provides ethics committees & health administrators with guidance in understanding the purpose and function of clinical outcome registries. These registries provide the most effective and accurate method of providing monitoring and benchmark data to improve healthcare performance. An increasing number of registries are being established in Australia and will increasingly require consideration by Institutional Ethics Committees.

What are clinical outcome registries?

Registries involve the systematic collection and analysis of a core data-set (including outcomes) from cases treated in multiple institutions. The information collected is typically confined to a limited number of simple, objective, and reproducible data-elements. These usually include personal identifying information, clinical information, covariates essential for risk adjustment and a simple outcome measure. The value of the information collected is commonly enhanced value through linkage to other disease and procedure registries or other administrative databases.

Table 1 Examples of different types of registries currently in existence in Australia.

Registry (Type)

Australian Orthopaedic Association Joint Replacement Register
Victorian Cardiac Arrest Register
South Australian Infection Control Surveillance Database
Victorian Infection Control Nosocomial Infection Surveillance System
Centre for Healthcare Related Infection Surveillance and Prevention
Hospital Infection Standardised Surveillance System
Australian and New Zealand Dialysis and Transplantation Register
Melbourne Interventional Group Interventional Cardiology Register
Haemostasis Register
Australian Heart Lung Transplantation Register
Australian and New Zealand Intensive Care Unit Society Adult Patient Database
Mental Health Client Management Interface and Operational Data Store
Melbourne Vascular Surgeons' Association Register

Because of the expense involved it is only feasible to establish registries with a limited number of diseases or procedures, where poor outcomes lead to serious reductions in quality of life or a major increase in cost. An example is renal transplantation where poor outcomes lead to patients to revert to haemodialysis, providing a much inferior quality of life at much greater cost.

The collection, storage and transmission of clinical registry data is required to be in keeping with institutional policies, the Australian Code for the Responsible Conduct of Research, and principles set out in the Architecture Overview document produced by the National E-Health Transition Authority.

Clinical outcome registries are also required to have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected. This requires regular audit of registry data against clinical records within the participating institutions.

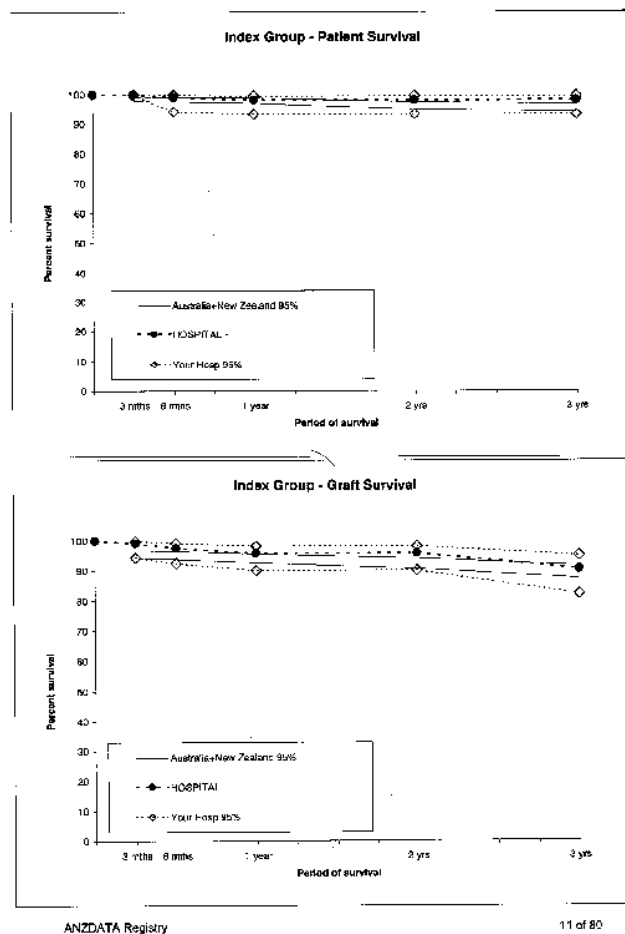
Registries are typically overseen by a Steering Committee comprised of clinicians, data-management staff and representatives of funders and consumers. This is required to ensure accountability and to oversee resource application. This committee is also required to help develop and endorse data access and reporting policies.

Importance of clinical outcome registries to quality improvement in healthcare

An advantage of clinical outcome registries is that they provide information that is epidemiologically sound and therefore credible to clinicians who are increasingly critical of less rigorous approaches to quality measurement. Outcome data provided from registries has provided a strong impetus to improvement, partly by engaging the common desire of clinical teams to compete for excellent results from their clinical programs. They provide the potential for units to learn from those with the best results

and may provide an early warning when quality deteriorates. Without a credible system for measuring and monitoring outcomes there is little opportunity for managers or boards of management to be aware of how their services compare with elsewhere. Enquiries into adverse events have criticised the lack of a system for early detection of error and proactive monitoring of the system.¹

Figure 1: Report from ANZDATA registry provided to individual transplantation hospitals detailing patient and graft survival rates over a three year period with Australian and New Zealand averages



To achieve their goal of improving quality of care registries must collect and collate data about aspects of the health of individual persons.² In most instances this data includes details about the underlying illness, the type of care provided and the outcomes of this care. It is usually necessary to collect information that includes personal identifying information so that a single individual is not counted on more than one occasion and so that individuals treated at more than one institution can be identified. Most importantly it is necessary to enable people to be contacted at the end of their treatment to assess what effect it has had on their illness or quality of life.

Ethical considerations

Applications from clinicians to contribute data to registries have often been considered by Ethics Committees similarly to applications for clinical trials or other research projects. However there are substantial differences involved in the nature of such activities and this pamphlet has been developed to elaborate on these differences and propose a framework under which proposals for providing data to registries should be considered.

With the endorsement of the Ethics Committees of participating institutions registries are able to collect and analyse clinical data in a manner that would otherwise contravene the requirements of the State and Commonwealth Privacy Acts

In accordance with NHMRC guidelines and relevant legislation, Institutional Ethics Committee have the power to approve the provision of clinical data from identified individuals to clinical registries provided a number of strict conditions are met.³ These are outlined in section 14.4 to 14.13 of the National Statement on Ethical Conduct in Research Involving Humans.⁴

Matters to be considered by Institutional Ethics Committees

In operationalising the intent of the NHMRC statement, Ethics Committees must make the following determinations:

- *Does the research address an ‘urgent’ public health issue?*
- *Will the research impinge significantly on the privacy of the individuals involved?*
 - *Will the data be accessible to anyone other than the members of the immediate study team?*
 - *Will the data be held securely?*
 - *Is highly personal or sensitive data involved?*
 - *Is there an appropriate data access and reporting policy that adequately addresses the interests of the institution and its patients?*

An Institutional Ethics Committee may find that the public health benefit outweighs the infringement of privacy if the proposal meets the following criteria:

- A strong case is made for the importance of the registry and its potential to address an urgent public health issue;
- The registry is housed in an experienced unit with a strong record for the management of large medical databases;
- Robust procedures are in place to maintain the security of data;
- The data contains relatively unobtrusive clinical information;
- The data will be made available under reasonable circumstances in support of quality improvement.

If the proposal meets these criteria an Institutional Ethics Committee might appropriately determine that the transfer of personal identifying data could be transferred to a secure registry without individual consent being sought.

In practice, Institutional Ethics Committees are often reluctant to make this determination for several reasons, including:

- Concern for patient autonomy;
- Uncertainty in interpreting the meaning of ‘urgent’ health problems;

- The absence of any formal guidance for considering the setting in which the data management will take place;
- Differing views about the sensitivity of different forms of health related information.

For this reason most Institutional Ethics Committees currently require consent of the individuals whose data is transmitted to a registry, particularly when the registry procedures require further contact with the individual to ascertain outcome data.

Options for obtaining consent from patients

If consent is required then the options available include

- Opt-in consent: where each patient is approached and consent sought prior to transmission of any data. This is similar to asking for volunteers for a research study;
- Opt-out consent: where consent is assumed unless a patient requests that their data is not included on the registry.

If opt-out consent is employed it is important that patients are presented with a brochure at an early stage explaining the purpose of the registry and the fact that their personal identifying data will be provided to the registry for the purpose of quality improvement. If further contact is planned this should also be mentioned, together with the contact details of the registry office for use in situations where the patient does not wish to participate.

In practice a requirement for opt-in consent will render the registry ineffective. Typically only a relatively small percentage of patients will actively volunteer to be involved, a figure confirmed in literature reports. The likelihood that those volunteering would be representative of the total patient group is so low that the inclusion of such patients might invalidate the remainder of the data-set and negate the value of any attempt at benchmarking.

For these reasons the most feasible approaches to data collection for clinical outcome registries is via an opt-out consent process, supported by an effective means of providing information to all registry participants and allowing those opposed to participation to avoid having their data included.

Summary

Registries are increasingly recognised as one of the most important approaches to monitoring and improving the healthcare provided to the Australian population. However, they typically require the transfer of identifiable patient data to a central data-management unit for collation, analysis and benchmarking. This requires the approval of Institutional Ethics Committees from participating institutions to avoid contravening State and/or Commonwealth Privacy legislation.

Ethics committees will appropriately require patient consent for the transfer of identifiable information. However it is well recognised that relatively few individuals are likely to actively volunteer their information for inclusion in a registry. Substantially incomplete information from participating units renders the data unreliable for purposes of quality improvement and benchmarking and would not be accepted by most registries for fear of biasing their database. Recently published data from Canada has demonstrated the large bias resulting from opt-in recruitment to a clinical registry in that country.⁵

Opt-out consent, coupled with an effective information dissemination process, is an alternative which generally allows sufficiently complete recruitment for robust conclusions to be drawn about quality issues. This is because few individuals typically refuse to participate.

This form of consent is appropriate provided the proposal meets criteria essential for a high quality registry, viz:

- A strong case is made for the importance of the registry and it's potential to address an urgent public health issue;

- The registry is housed in an experienced unit with a strong record for the management of large medical databases;
- Robust procedures are in place to maintain the security of data;
- The data contains relatively unobtrusive clinical information;
- The data will be made available under reasonable circumstances in support of quality improvement.

Reference List

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