

## Strategic Principles for a National Approach to Australian Clinical Quality Registries

**Principle 1:** Consumers, clinicians, management and governments receive regular reports from Clinical Quality Registries on appropriateness of care (process and compliance with guidelines), and effectiveness of care (patient outcomes) to support ongoing improvement of health care in Australia.

**Principle 2:** Clinical Quality Registries, operating in close coordination with expert national clinical groups, provide an effective mechanism for:

- design of indicators of quality of care
- comprehensive data collection and analysis, and
- outlier management within a sound clinical governance framework.

**Principle 3:** National data governance arrangements and best practice infrastructure provide support for comprehensive reporting, monitoring and management of clinical practice variance.

**Principle 4:** Where existing data flows do not support analyses of quality of care, Australian Clinical Quality Registries are efficient and effective in providing consumers, clinicians, management and government with information for managing and improving delivery of health services.

**Principle 5:** Dedicated investment in Australian Clinical Quality Registries supports infrastructure, data cleansing, reporting and analysis of quality of care, based on succinct datasets captured routinely by clinicians at the point of care.

**Principle 6:** Australian Clinical Quality Registries have sound governance arrangements with strong clinical leadership and a demonstrated framework for quality improvement.

**Principle 7:** Prioritisation of Australian Clinical Quality Registry support is premised on gaps in existing data flows, the significance of the national burden of disease and the cost of interventions, the existence of variation in practice and outcomes, the ability to improve quality of care including reduction in practice variation, availability of national clinical leadership and consideration of existing data, and cost/benefit options.

**Principle 8:** Data governance for the collection, holding and analysis of patient-level, Australian Clinical Quality Registry information is managed as part of the national health information agenda, in a framework that protects patient privacy and complies with regulation. National data governance arrangements are essential to making the data collection, ethics approvals and reporting activities of Australian Clinical Quality Registries more efficient.

**Principle 9:** A secure, future-proof and scalable Australian Clinical Quality Registry design and infrastructure should support and host multiple Registries. Efficiency and best practice are best achieved through the operation of a small number of Australian Clinical Quality Registry systems or centres.

**Principle 10:** Australian Clinical Quality Registries must meet the requirements of national operating principles

## Operating principles for Australian Clinical Quality Registries

### Attributes of Australian Clinical Quality Registries

1. Australian Clinical Quality Registries must be developed with clear and precisely defined purposes aimed at improving the safety and/or quality of health care.
2. For Australian Clinical Quality Registries to provide the maximum value to the health system they must focus their core data collection on the essential elements required to serve their main purposes.
3. Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible, valid (including for risk adjustment) and related to a specific case definition;
4. Methods used to collect data in Australian Clinical Quality Registries must be systematic, with identical approaches used at the different institutions contributing information.
5. Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.
6. In determining the time to outcome assessment, Australian Clinical Quality Registries must consider the burden and cost of data collection together with the likelihood of loss to follow-up.
7. Australian Clinical Quality Registries must ensure that complete registry data are collected from the entire eligible population.

### Data collection

8. The collection of data for an Australian Clinical Quality Registry should maintain an appropriate balance between the time and cost of data collection and the impact on patient care, particularly where clinicians are directly involved in data collection. The collection of data must not be an unreasonable burden on consumers, nor should it incur any cost to consumers.
9. Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors;
10. Data should be uniformly and easily accessible from the primary data source.
11. Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registers and other databases (if approved by relevant ethics committees, etc.).
12. Australian Clinical Quality Registries must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. They need to publish eligibility criteria, metadata, data dictionaries, etc.;
13. To avoid duplicating data capture, Australian Clinical Quality Registries should use data from existing data sources, including administrative data, where they are of a satisfactory quality.

### **Data elements**

14. Australian Clinical Quality Registries should have the capacity to enhance their value through linkage to other disease and procedure registers or other databases.
15. Australian Clinical Quality Registries must collect sufficient patient identifying information to support the registry's stated purpose. Most clinical quality registries would require individually identifiable data, for which use of national Individual Healthcare Identifiers is recommended.
16. Where patterns or processes of care have an established link to outcomes and process measures that are simple, reliable and reproducible, they should be considered for collection by Australian Clinical Quality Registries.
17. Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools.

### **Risk adjustment**

18. Australian Clinical Quality Registries should collect objective, reliable co-variables for risk adjustment to enable factors outside the control of clinicians to be taken into account by the use of appropriate statistical adjustments.

### **Data security**

19. To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems.
20. The collection, storage and transmission of clinical registry data must be in line with relevant legislation, regulation, standards and guidelines.

### **Ensuring data quality**

21. Australian Clinical Quality Registries must report as a quality measure the percentage of eligible patients recruited to the registry.
22. Australian Clinical Quality Registries must have a robust quality assurance plan which allows ongoing monitoring of the completeness and accuracy of the data collected.
23. Australian Clinical Quality Registry data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible.
24. Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks.

## **Organisation and governance**

25. Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry.
26. Australian Clinical Quality Registries must establish policies to manage a range of contingencies arising from the analysis of data from the registry, which includes a formal plan ratified by the Registry Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately.

## **Data custodianship**

27. Custodianship of clinical register data must be made explicit in Contracts and/or Funding Agreements. Australian Clinical Quality Registries should make clear statements of data ownership and data custodianship publicly available.
28. Data access and reporting policies for Australian Clinical Quality Registries must be made available to persons wishing to use register data. Australian Clinical Quality Registries should make data access and reporting policies publicly available.
29. Third parties wishing to access data and publish findings must seek approval from the Registry Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data is sought.

## **Ethics and privacy**

With the exception of instances where data collection has been mandated through legislation or enabled through regulation or legislation:

30. Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry.
31. Registry personnel must be familiar with and abide by the requirements set out in relevant privacy legislation, the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research*.
32. Participants or their next of kin must be made aware of the collection of register data. They must be provided with information about the Australian Clinical Quality Registry, the purpose to which their data will be put and provided with the option to not participate. This must be at no cost to the register participant.
33. Where projects are undertaken using registry data, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity.

### **Information output**

34. Data from Australian Clinical Quality Registries must be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.
35. Australian Clinical Quality Registries must report without delay on risk adjusted outcome analyses to institutions and clinicians.
36. Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings.
37. Clinicians and/or staff at contributing units should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care.
38. Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings.
39. Australian Clinical Quality Registry reports should be produced according to a strict timeline and should demonstrate funding to enable this to occur.
40. Australian Clinical Quality Registries must have documented procedures, including methods employed, for reporting on quality of care, including addressing outliers or unexplained variance.

### **Resources and funds**

41. Australian Clinical Quality Registries should demonstrate sufficient funding is allocated to allow data collection, reporting and the institution of strong quality assurance procedures.