

Appendix 2: Operating Principles for Clinical Quality Registries (CQR) development (from Principles, guidelines and standards for CQR development section), endorsed by Australia's Health Ministers in November 2010

Attributes of clinical quality registries

1. CQRs must be developed with clear and precisely defined purposes aimed at improving the safety and/or quality of health care.
2. For CQRs 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 CQRs must be confined to items that 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 CQRs 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, CQRs must consider the burden and cost of data collection together with the likelihood of loss to follow-up.
7. CQRs should seek to ensure that complete CQR data are collected from the entire eligible population.

Data collection

8. The collection of data for a CQR 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 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 must be used in CQRs to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other CQRs and other databases (if approved by relevant ethics committees, etc.).
12. CQRs must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry.

CQRs must publish their eligibility criteria, metadata, data dictionaries, etc.

13. To avoid duplicating data capture, CQRs should use data from existing data sources, including administrative data, where they are of a satisfactory quality.
14. CQRs should have the capacity to enhance their value through linkage to other disease and procedure CQRs or other databases.

Data elements

15. CQRs must collect sufficient patient identifying information to support the CQR'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 CQRs.
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. CQRs must 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 CQR data, CQRs must use secure access controls and secure electronic transfer and electronic messaging systems.
20. The collection, storage and transmission of clinical CQR data must be in accordance with relevant legislation, regulation, principles, standards and guidelines.

Ensuring data quality

21. CQRs must report as a quality measure the percentage of eligible patients recruited to the CQR.
22. CQRs must have a robust quality assurance plan which allows ongoing monitoring of the completeness and accuracy of the data collected.
23. CQR 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 must be identified by the data centre and remedied as soon as possible.

24. CQRs should incorporate in-built data management processes such as data range and validity checks.

Organisation and governance

25. CQRs must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the CQR.
26. CQRs must establish policies to manage a range of contingencies arising from the analysis of data from the CQR, which includes a formal plan ratified by the CQR 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 CQR data must be made explicit in contracts and/or funding agreements. CQRs should make clear, publicly available statements of data custodianship.
28. Data access and reporting policies for CQRs must be made available to persons wishing to use CQR data. CQRs should make data access and reporting policies publicly available.
29. Third parties wishing to access data and publish findings must seek approval from the CQR 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. Appropriate ethics approval must be obtained to establish and maintain the CQR.
31. CQR 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 CQR data. They must be provided with information about the CQR, 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 CQR participant.
33. Where projects are undertaken using CQR 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 CQRs must be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.
35. CQRs must report without delay on risk-adjusted outcome analyses to all CQR stakeholders in accordance with agreed reporting requirements of the CQR.
36. CQRs 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 the data they contribute to the CQR to enable monitoring of clinical care.
38. CQRs must produce a publicly accessible, annual report detailing aggregated clinical and corporate findings.
39. CQR reports must be produced according to a strict timeline and should demonstrate funding to enable this to occur.
40. CQRs must have documented procedures, including methods employed, for reporting on quality of care, including addressing outliers or unexplained variance.

Resources and funds

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

