AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Framework for Australian clinical quality registries

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Glossary

Clinical quality registry (CQR)	An organisation which systematically monitors the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify outcome benchmarks, significant outcome variance, and inform improvements in healthcare quality.

1 Introduction

In Australia there is limited capacity to measure and monitor the degree to which health care benefits the patient and how closely that care aligns with evidence-based practice. Currently, only a small number of data collections capture and report process and outcomes data for specific clinical conditions or interventions. This results in significant gaps in current Australian health information regarding the appropriateness and effectiveness of specific healthcare interventions. The development of national clinical quality registries is a cost-effective way of addressing these gaps.[1]

National arrangements for CQRs are a mechanism by which jurisdictions can authorise and secure record-level data, within high-priority clinical domains, to measure, monitor and report on the appropriateness and effectiveness of health care. The information can be used to inform improvements in healthcare quality and safety within those domains. In addition to improved patient outcomes, the use of CQRs significantly improves compliance with evidence-based guidelines and standards and informs the development of new guidelines and standards.[2]

In November 2010, Health Ministers noted that the Commission would draft national arrangements for CQRs.

1.1 Purpose

The purpose of this document is to describe the elements of *a Framework for Australian clinical quality registries* (henceforth referred to as the *Framework*).

The *Framework*:

- is guided by the *Strategic principles for clinical quality registries* (endorsed by Health Ministers in 2010);
- recommends national operating practices in accordance with the *Operating principles for clinical quality registries* (endorsed by Health Ministers in 2010);
- specifies *National health information arrangements for clinical quality registries* (endorsed by the National Health Information and Performance Principal Committee (15 November 2012) and Commission Board (29 November 2012);
- provides a *National infrastructure model* for the efficient design, build, development, operation and security of CQRs under national arrangements;
- details principles, guidelines and standards for best-practice design, build, development, operation and security of CQRs under national arrangements;
- identifies a set of *Prioritisation criteria for Australian clinical quality registries* to support the *Strategic principles* for a national approach to the development of CQRs.

[1] For example, see Larsson S et al, Use Of 13 Disease Registries In 5 Countries Demonstrates The Potential To Use Outcome Data To Improve Health Care's Value, Health Affairs, 31, no.1 (2012):220-227

[2] Ibid.

1.2 Background

In September 2007, AHMAC endorsed the Commission paper recommending that the Commission establish and validate national operating and technical standards for clinical quality registries.

In November 2010, Health Ministers endorsed *Strategic Principles* and *Operating Principles for Australian Clinical Quality Registries*[3] developed by the Commission. Additionally, Health Ministers noted that the Commission would:

> *"draft national arrangements, including data and clinical governance, for Australian clinical quality registries, and prepare a costed infrastructure plan".*

Two work streams (AHMAC deliverables) flowed from those commitments:

AHMAC deliverable 1: National health information arrangements for clinical quality registries

AHMAC deliverable 2: Costed infrastructure model for clinical quality registries

The Commission has worked with jurisdictions, the National Health Information and Performance Principal Committee, the National E-Health Transition Authority and CQR experts to develop those deliverables.

1.3 Rationale

Clinical quality registries offer a better model of measuring quality of care than the historical approach of obtaining smaller datasets through research processes. However, peak clinical groups who operate registries are often prevented from achieving comprehensive national reporting, analysis and outlier management by the burden associated with:

- Developing indicators and datasets;
- Establishing sound data collection methods;
- Establishing and implementing data governance arrangements, including with States and Territories; and
- Developing and maintaining dedicated information systems.

Particular barriers to national reporting include restrictions on the disclosure, collection, and use of patient-level data, and varying hospital and jurisdictional data governance arrangements. Only a small number of Australian clinical quality registries, including those monitoring the management of hip and knee joint replacements, end-stage renal failure and intensive care, have acceptably high levels of national participation. While other high-quality Australian registries exist, many lack adequate levels of coverage. Examples of high-cost, high-volume clinical domains in which such information is insufficient include cardiology and cardiac surgery, stroke and hip fracture. A data collection with low participation rates suffers from 'selection bias', where the resulting data is insufficiently representative of the eligible population, thereby having little credibility to provide quality assurance or inform improvements in healthcare quality.

[3] http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Strategic-and-Operating-Principles-for-Australian-Clinical-Quality-Registries-AHMC-endorsed-Nov-2010.pdf

To overcome these barriers, the Commission and the National Health Information and Performance Principal Committee (NHIPPC) have developed *National health information arrangements* for clinical quality registries (Section 3). Under these arrangements, Australian healthcare organisations and clinical quality registries will, in partnership with jurisdictions, routinely disclose, collect, analyse and report patient-level data, to monitor and report on the appropriateness and effectiveness of specific healthcare interventions.

Additional barriers to effective national reporting include CQR architectures, operating systems and data structures which are neither uniform nor standardised in Australia. This creates significant inefficiencies, hampers interoperability with other information systems, and complicates the assessment of CQR security.

To address the development, maintenance and operation of dedicated CQR information systems, the Commission has developed the *Infrastructure model* (Section 4) for best-practice design, development, operation and security of Australian CQRs under national arrangements.

Well designed clinical quality registries operating under national arrangements, in partnership with jurisdictions, healthcare providers and peak clinical groups, provide a means by which to achieve national reporting on the appropriateness and effectiveness of health care in high-priority clinical domains.

1.4 Clinical quality registries

CQRs are organisations that systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify benchmarks, significant outcome variance, and inform improvements in healthcare quality.

The aims of national CQRs are to:

1. collect longitudinal health outcome data for the entire eligible population of the clinical domain, and

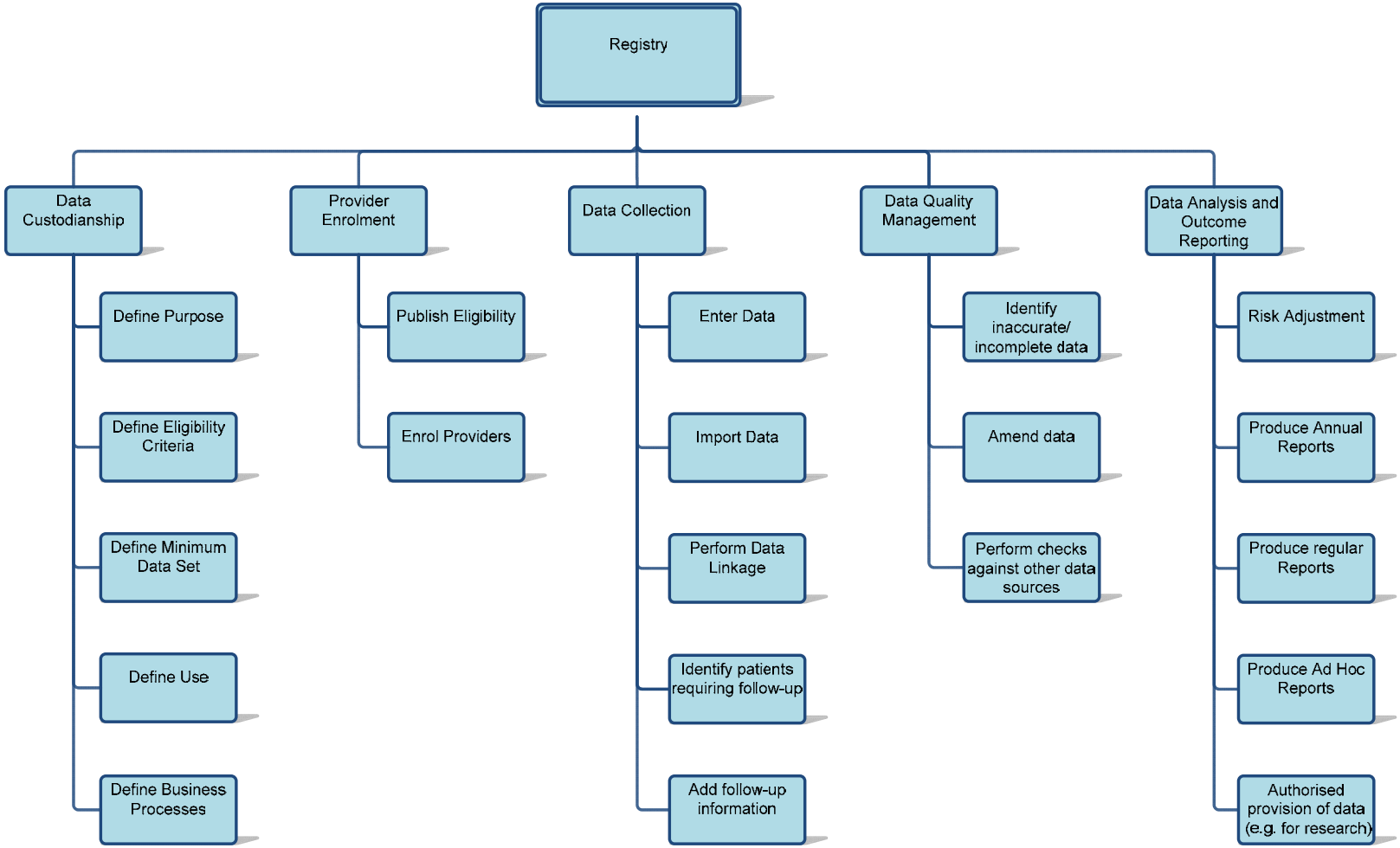
2. generate risk-adjusted reports on the appropriateness and effectiveness of health care. Within the data governance framework, reports are provided to jurisdictions, healthcare providers, funders, clinical colleges and researchers, to identify significant variance and to benchmark nationally and internationally.

CQRs typically focus on conditions and procedures where:

a. there are serious consequences to the patient associated with poor quality of care,
b. unwanted variation in outcomes can be identified and addressed,
c. an evidence-based sequence of care improves patient care, (or there is a need to capture national data to develop an evidence base for care),
d. there is a significant cost burden associated with the condition / procedure / device (although low-volume registries also exist, for example Cystic Fibrosis),
e. the clinical condition/event is able to be systematically recognised, and
f. where the information requirements for a successful CQR can be met.

The functions of clinical quality registries are depicted in Figure 2.

Figure 2: Functional overview of Australian clinical quality registries



2 Strategic Principles

Strategic Principles for clinical quality registries were endorsed by Health Ministers in 2010. The *Strategic Principles* (detailed below) provide a national strategic approach to development of CQRs.

Principle 1: Consumers, clinicians, management and governments receive regular reports from clinical quality registries on appropriateness of care (process and compliance with guidelines), or 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 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 CQR 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 CQR 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 CQR 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 CQR systems or centres.

Principle 10: Australian clinical quality registries must meet the requirements of national Operating Principles for Clinical Quality Registries.

3 National health information arrangements

3.1 Introduction to health information arrangements for CQRs

In 2010, Health Ministers noted that the Commission would draft national health information arrangements for clinical quality registries. This section describes those arrangements.

National health information arrangements for clinical quality registries were developed by a time-limited working group of the National Health Information and Performance Principal Committee (NHIPPC), a standing committee of the Australian Health Minister's Advisory Committee (AHMAC). The proposed *Health information arrangements for CQRs* were endorsed by the National Health Information and Performance Principal Committee (15 November 2012) and Commission Board (29 November 2012).

Health information arrangements specify minimum data custodianship requirements that are incumbent on organisations and staff participating in accredited CQR activity under national arrangements. Minimum data custodianship requirements include:

- the development and use of standardised national data sets
- compliance with specified minimum reporting requirements
- security certification of CQR business operations and data hosting services
- transparent accreditation or compliance assessment process

The purpose of *Health information arrangements for CQRs* is to:

1. facilitate national monitoring and reporting of the effectiveness and appropriateness of health care for the purpose of informing improvements in healthcare quality and safety,
2. complement existing health information arrangements including legislation, regulation and policies,
3. augment the National Health Information Agreement, and
4. provide assurance to participating stakeholders that minimum requirements regarding CQR information custodianship, security and accreditation are specified in official arrangements.

3.2 Elements of national health information arrangements

The elements of N*ational health information arrangements for clinical quality registries* are specified below:

3.2.1 Strategic information environment

National health information arrangements for CQRs are constituted within a strategic information environment which provides a foundation for a national approach to CQR purpose, development, direction, governance, data custodianship, operation and accreditation. The strategic information environment encompasses three elements described below.

a) *Strategic Principles for clinical quality registries*

The first element of the strategic information environment for CQR is the *Strategic Principles* for a national approach to CQRs, endorsed by Health Ministers in 2010. The *Strategic Principles* are described Section 2 of the *Framework*.

b) *Existing health information arrangements*

Under national health information arrangements for CQRs, CQR data will be collected from a variety of sources and flow via a range of information channels. The strategic information environment for CQR therefore recognises existing health information arrangements, incorporated in existing legislative and administrative settings.

Existing health information arrangements, within which CQRs are required to operate, include the following legislative Acts and information privacy principles:

National	The Privacy Act 1988 (Section 95) including Information Privacy Principles (applicable to Commonwealth agencies and the ACT, not applicable to other States and Territories)
Private Health Sector	The Privacy Act 1988 (Section 95A) including National Privacy Principles (applicable to all health service providers in the private health sector)
Australian Capital Territory	Privacy Act 1988 Health Records (Privacy and Access) Act 1997
New South Wales	Health Records and Information Privacy Act 2002*
Northern Territory	Information Act 2002
Queensland	Information Privacy Act 2009 Health and Hospitals Network Act 2011 Private Health Facilities Act 1999 Public Health Act 2005
South Australia	Cabinet Administrative Instruction 1/89: Information Privacy Principles 1, 2 & 3; Code of Fair Information Practice

Tasmania	Personal Information Protection Act 2004
Victoria	Health Records Act 2001 Health Services Act 1988 Mental Health Act 1986
Western Australia	Hospital and Health Services Act 1927

* Information is being sought on more recent NSW legislation and regulation in this area

c) National Health Information Agreement

The third element of the strategic information environment for CQRs is the *National Health Information Agreement (NHIA)*[4]*.* National arrangements for CQRs are consistent with the stated purpose and principles of the NHIA. Future iterations of the NHIA could be supplemented by references to health information arrangements for CQRs, for example; within a dedicated CQR schedule to the NHIA.

The scope of the NHIA does not cover the private hospital sector. However, an explicit intention of the *Framework* is to include the private hospital sector within national arrangements for CQRs.

3.2.2 Principles, guidelines and standards

National health information arrangements for CQRs specify principles, guidelines and standards for best practice CQR design, development, operation and security. They include *Operating Principles* and technical guidelines, and are described in Section 5 of the *Framework*.

3.2.3 Requirements for CQR data custodianship

National health information arrangements for CQRs specify explicit requirements for CQR data custodianship. Requirements are drawn from the *Strategic Principles and Operating principles for clinical quality registries,* existing legislative and administrative health information arrangements, and the *NHIA.*

Requirements are incumbent on organisations and staff participating in CQR activity under national arrangements.

a) *Standardised data sets*

CQR data will be collected from a range of healthcare settings. In order that these data can be compared, CQR data sets, elements and metadata specifications must be standardised using data items specified in the National Health Data Dictionary (NHDD).

CQRs operating under national arrangements must use nationally standardised data sets, in the form of Data Set Specifications (DSS) or National Minimum Data Sets (NMDS), in accordance with established national processes described in the NHIA.

[4] http://meteor.aihw.gov.au/content/index.phtml/itemId/182135

b) *Collection*

Record-level data defined by a standardised data set, must be collected in accordance with the legislative and administrative arrangements that apply to the data provider, typically the health service or individual clinician. Data collection for CQRs is performed at the service provider level by healthcare staff, or by routine, authorised, local data extraction processes.

Additionally, data collection activity should be guided by the *Operating Principles for clinical quality registries*.

Data may be collected by CQRs directly from healthcare organisations and clinicians, or via jurisdictional agencies and private health groups.

On receipt of the information CQRs will subject the data to various uses, including correction ('cleaning'), statistical analysis, aggregation/disaggregation, risk-adjustment and reporting.

c) *Transfer of data to the CQR*

CQR data sets will be transferred to accredited CQR data repositories from several settings and sources. Data transfer must be conducted in accordance with the legislative and administrative arrangements of the data provider.

Additionally, data transfer mechanisms should be guided by the technical resource suite:

- *Requirements specification for clinical quality registries*[5] *(*Attachment 7.1*)*
- *Infrastructure and technical standards for clinical quality registries*[6] (Attachment 7.2)
- *Logical architecture and design for clinical quality registries*[7] (Attachment 7.3)

In keeping with data collection activity, information may flow from source organisations directly to CQRs or via jurisdictional agencies and private hospital groups. Whatever the route, transfer of data from source to repository must comply with mechanisms for secure data transfer detailed in the *Security compliance guideline for clinical quality registries*[8] (Attachment 7.4)

d) *Storage and access control*

CQR information will be stored in secure data repositories in accordance with mechanisms for secure data hosting (see S*ecurity compliance guideline*, Attachment 7.4).

Appropriate data access controls will be established and maintained in accordance with signed agreements between participating registries, jurisdictions and health organisations.

e) *Reporting*

CQRs will comply with minimum reporting requirements, consistent with the explicit purpose of the particular CQR.

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[5] http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Requirements-Specification-688-KB.pdf

[6] http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Infrastructure-and-Technical-Standards-for-Clinical-Quality-Registries-219-KB.pdf

[7] http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Logical-Design-1.16MB.pdf

[8] http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Security-Certification-Framework-1.33-MB.pdfvc

Attachment 7.5 outlines minimum reports that must be generated and provided to stakeholders by CQRs operating under national arrangements.

Additional reports may be generated, as determined by the CQR governance arrangements.

The primary purpose of CQRs is to monitor and report on the quality of health care. However, third party requests for access to CQR information for purposes other than CQR-related activity - that is, for health research - will be considered for legitimate research groups. Access to CQR information for health research must be compliant with the established legislative, ethical and administrative healthcare research arrangements of the originating data provider.

f) *Security*

Under national arrangements for CQRs, registries must demonstrate certification of the security of their business operations and data hosting services.

The *Security compliance guideline for clinical quality registries* details minimum requirements against which registries can demonstrate compliance under national arrangements.

Where the operational (business) activities and technical (data hosting) activities of a CQR are conducted in distinct jurisdictions operating under different legislation and regulatory arrangements, both organisations are required to demonstrate compliance against the *Security compliance guideline*.

4 National infrastructure model

The Commission has developed an *Infrastructure model* for the best-practice design, development, operation and security of Australian of CQRs under national arrangements. The *Infrastructure model* was developed in collaboration with jurisdictions, the National E-Health Transition Authority and CQR experts.

The *Infrastructure model*:

- supports monitoring and reporting of the appropriateness and effectiveness of health care through *National health information arrangements for clinical quality registries*
- is based on models developed by the Commission, the National E-Health Transition Authority (NEHTA) and CQR experts
- facilitates efficiencies in the development of national CQR infrastructure by specifying and promoting best-practice CQR design, development, operation and security
- features centres (or clusters) as the preferred model for CQR operation
- promotes improved interoperability with existing clinical information systems and the potential for future linkage with the Personally-Controlled Electronic Health Record
- supports the improvement and sustainability of existing CQRs; and encourages and assists with the development and establishment of new CQRs
- provides efficiencies in data collection through, for example, reduced data entry duplication
- optimises levels of information and system security
- allows scalability and future-proofing of CQR design
- improves capabilities for the generation of ad-hoc and routine reports
- facilitates improved statistical analysis and benchmarking with the capacity for sensitive risk-adjustment

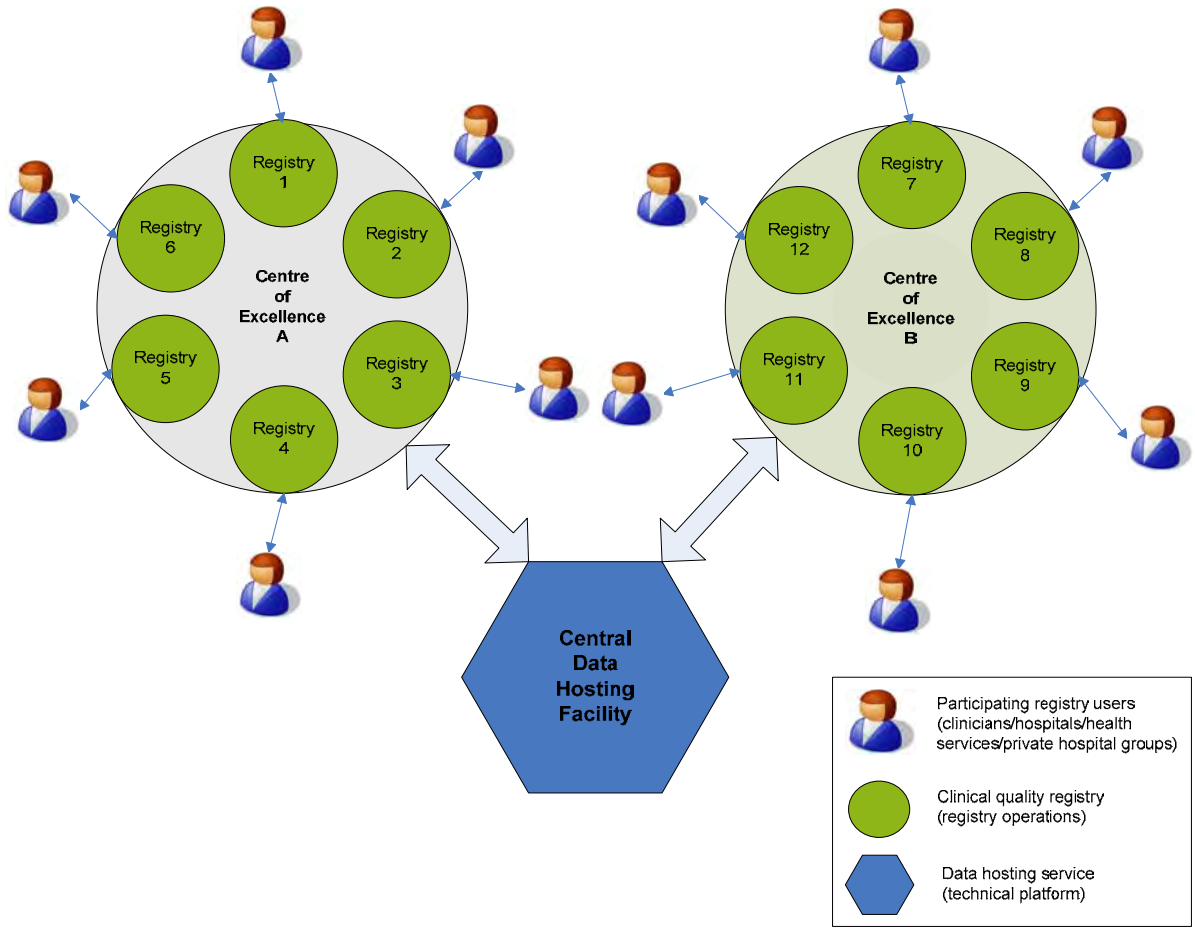
A national approach to standardised, best practice CQR infrastructure will enable peak national clinical groups to focus on reporting, analysis, research and outlier management from national CQR data.

4.1 Infrastructure model

The Commission explored several infrastructure models with jurisdictions, the National E-Health Transition Authority and CQR experts. Options for the configuration and deployment of CQRs under national arrangements included a single, centralised infrastructure, or clusters and stand-alone registries

The infrastructure model recommended by registry and jurisdictional experts comprises expert clusters or centres which operate registries on behalf of peak clinical groups and healthcare providers (see Figure 1 below). Data hosting may be centralised, or operated by each centre.

Figure 1: Centre-based model



In this model, centres each provide infrastructure, management and operational resources for co-located CQRs. While it is possible that Australia will move toward a single national data hosting facility, it is at least several years away. In the near future, centres would each operate their own data hosting services.

4.2 Technical and data hosting services

The following elements comprise the technical and data hosting service components of the *Infrastructure model:*

- Resources - to provide the creation, management and ongoing technical support for national CQRs
- Facilities - provision of accommodation and equipment for resources
- Hosting and infrastructure - to make national CQRs available via a secure browser interface
- Software licensing - the provision of desktop and server-based products required for the creation and ongoing operation of national CQRs

In order to provide expert development guidance and specify best practice registry build and hosting:

- A reference architecture was developed to identify the key considerations and concepts, including core and secondary infrastructure services, required to support a dedicated national infrastructure for CQRs. The reference architecture was based on the *Requirements specification* and is shown in Attachment 7.3, *Logical architecture and design*.
- The system services identified in the reference architecture were then mapped to technologies required to support those services. The reference model is based on the Australian Government Architecture Technical Reference Model (AGATRM)[9].
- A technical reference model hierarchy provides the framework to group standards and technologies that directly support the service area and identified CQR services.
- A logical deployment architecture was then developed to provide an understanding of the major users and their interactions with the CQR system. It is also shown in Attachment 7.3.

[9] http://agict.gov.au/policy-guides-procurement/australian-government-architecture-aga/aga-rm/8-1-intro

4.3 Operational components

The operational components of the *Infrastructure model* principally comprise human resources for staffing CQR operations and management. A minimum level of staffing is required to achieve effective operation of a CQR.

The mix of staff includes:

- a director, often with expertise in the clinical field being monitored by the CQR
- a registry manager, overseeing the day-to-day operations of the CQR
- statistical and epidemiological support
- a data coordinator
- staff to undertake the tasks of data collection, entry and cleaning
- administrative support

Staffing components have been verified by obtaining advice from registry experts in the field, and through two independent analyses.

5 Principles, guidelines and standards for CQR development

5.1 Operating principles

Operating principles for clinical quality registries were endorsed by 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 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 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-variates 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.

5.2 Technical guidelines

In collaboration with the National E-Health Transition Authority and CQR experts, the Commission has developed a suite of technical guidelines for clinical quality registries.

The technical guidelines facilitate efficiencies in the development of national CQR infrastructure and promote best-practice CQR design, development, operation and security.

Technical design features include interoperability with existing clinical information systems and the potential for future linkage with the Personally-Controlled Electronic Health Record.

The guidelines include:

- *Requirements specification* (Attachment 7.1)
- *Infrastructure and technical standards* (Attachment 7.2)
- *Logical architecture and design* (Attachment 7.3)
- *Security compliance guideline* (Attachment 7.4)

5.2.1 Requirements specification

The purpose of the *Requirements specification for clinical quality registries* is to provide a baseline of high-level business, data, operational, and technical requirements for the development of best-practice infrastructure for CQRs.

The specification guided the development of architectural options for the *Logical architecture and design* and informed the development of the *Infrastructure model (Framework, S*ection 4).

5.2.2 Infrastructure and technical standards

The *Infrastructure and technical standards for clinical quality registries* (Attachment 7.2) sets out the infrastructure and technical standards that CQRs should consider during their development and operation.

The standards are composed of two sections:

- *Infrastructure Overview* – describes the national infrastructure that is relevant to CQRs. The infrastructure aims to enhance the sustainability, efficiency and interoperability of registries.
- *Standards Map* – describes a listing or mapping of the various technical standards that may be relevant to a CQR. The standards map recognises that there may be varying levels of technical sophistication required, depending on a given CQR's scope and purpose. The standards map identifies standards that may be relevant to CQR in the following areas:
  - Interoperability
  - Clinical communications
  - Unique healthcare identifiers

- Identity management
- Secure messaging
- Supply chain
- Engagement and adoption

5.2.3 Logical architecture and design

The purpose of the *Logical design for CQRs* (Attachment 7.3) is to provide pragmatic guidance to organisations wishing to develop and support a new CQR, or upgrade an existing CQR.

The *Logical design* document proposes a logical application that is intended to provide a standardised starting point for the physical design and implementation of CQR.

The *Logical design* includes the following sections:

Section 3 describes the generic business functions of a CQR that are supported by the design.

Section 4 proposes an information design, providing a data model and data dictionary for common aspects of CQR with guidelines for how CQR-specific aspects can be modelled for consistency.

Section 5 describes a technology-agnostic design of the application components that constitute a CQR system.

Section 6 presents the infrastructure design needed to support the deployment of CQR applications.

Section 7 presents a set of considerations that may apply when the logical design is used to support the development and deployment of multiple CQRs on a common infrastructure platform.

5.2.4 Security compliance guideline

The *Security compliance guideline for clinical quality registries* (Attachment 7.4) details minimum requirements against which registries must demonstrate compliance of the security of their business operations and data hosting services under *National arrangements*.

Purpose

The purpose of the *Security compliance guideline* is to outline a checklist approach for CQRs, operating either as stand-alone entities or co-located with other CQRs in centres or clusters, to be assessed against minimum security standards.

In addition, assessment against the *Security compliance guideline* will ensure best practice CQR security, derived from accepted standards and techniques, including the *National eHealth Security and Access Framework* (NESAF)[10]. Demonstrated compliance with these minimum security standards will provide assurance to jurisdictions that their data is managed and stored within securely operated infrastructure. The *Security compliance guideline* can be used by

[10] http://www.nehta.gov.au/implementation-resources/ehealth-foundations/national-ehealth-security-and-access-framework

individuals and organisations wishing to assess the compliance of a new or established clinical quality CQR against appropriate security standards and techniques.

Key elements of the *Security compliance guideline* are:

Section 1.4 ‘National arrangements for clinical quality registries’ provides context for the development of the *Security compliance guideline* and outlines its importance and use under national arrangements.

Section 2 ‘Considerations in securing clinical quality registries’ defines the key elements of information security and outlines some of the common threats to CQRs.

Section 3 ‘Infrastructure models and risk profiles’ identifies two distinct infrastructure configurations or ‘models’, and risk profiles for CQRs.

Section 4 ‘Security assessment approach’ describes a high-level approach to the assessment of CQR security compliance, including the measures to be taken to address any identified security gaps.

Section 5 ‘Security compliance checklists for CQR ‘good practice’’ provides the checklists to be used for the assessment of organisations requiring security compliance. Each organisation is assessed across a number of key security domains for minimum ‘good practice’ requirements.

Section 6 ‘Detailed guidance on controls’ provides detailed guidance and explanation on each security control, categorised by security domain. The guidance provided is a blend of detail from relevant security frameworks and specific detail to suit CQR environments. The guidance provided is informed by the National eHealth Security and Access Framework and ISO/IEC 27002.

6 Prioritisation criteria for CQR development and operation

The Commission and CQR experts have developed *Prioritisation criteria for CQRs*. The *Prioritisation criteria* support the *Strategic principles for a national approach to the development of CQRs* and reference the national approach to the development of Australian Clinical Care Standards[11].

The criteria are grouped according to the two principal considerations for prioritisation – the clinical need for the CQR and the feasibility of establishing the CQR. The *Prioritisation criteria for CQR* are:

1 Clinical relevance

1.1 There are serious consequences for the patient associated with poor quality care for the clinical condition or with poor quality of the device or procedure.

1.2 Unwarranted variation from this sequence of care can be identified and addressed.

1.3 An evidence-based, well executed sequence of care improves patient outcomes for the clinical condition.

1.4 The condition, device or procedure of interest is associated with a high cost to the health system.

2 Feasibility

2.1 The clinical condition is suited to CQR data collection:

2.1.1 The relevant clinical population can be captured.

2.1.2 The clinical condition or event is able to be systematically recognised.

2.2 There is clinician support for the CQR (or the proposed CQR).

2.3 The governance requirements for a successful CQR are in place.

2.4 The information requirements for a successful CQR are in place:

2.4.1 An entire population with a chronic condition or disease, or who have undergone an acute event can be captured.

2.4.2 There is a suitable data source.

2.4.3 Clinically meaningful performance indicators can be defined.

2.4.4 There is potential for reliable risk adjustment.

2.5 There are sufficient resources available for the sustainable operation of the CQR.

[11] http://www.safetyandquality.gov.au/our-work/clinical-care-standards-2/

7 Attachments

7.1 *Requirements specification*

http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Requirements-Specification-for-CQR_FINAL-CONSULTATION-DRAFT_October-2011_879KB.pdf

7.2 *Infrastructure and technical standards*

http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Infrastructure-and-Technical-Standards-for-Clinical-Quality-Registries-v1.0-May-2012.pdf

7.3 *Logical architecture and design*

http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Logical-Design-for-CQR_v1.0_FINAL-DRAFT_March-2012_1.58MB.pdf

7.4 *Security compliance guideline*

http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Security-Compliance-Guideline-for-CQR-March-2013-v1.5.pdf

7.5 *Reporting*

ATTACHMENT 7.5: Reports that must be generated and provided by CQRs operating under national arrangements

	Report	Frequency	Generator	Content	Stakeholder Recipient
1.	Routine annual CQR reports	Annually	CQR	Aggregated clinical and CQR findings; national trends in outcomes and patterns of practice	Open to the public
2.	Routine jurisdiction reports	Quarterly	CQR	Risk-adjusted unit level data by jurisdiction and private hospital ownership group (clinicians and patients not identified)	Jurisdiction and private hospital ownership groups
3.	Routine unit* reports	Quarterly	CQR	Risk-adjusted granular data limited to the contributing provider unit with comparators at national / jurisdictional / peer group level	Confidential to the contributing provider unit
4.	Routine clinician reports	Quarterly	CQR	Risk-adjusted granular data limited to the contributing clinician with comparators at national / peer group level (patients identified)	Confidential to the contributing clinician
5.	Ad hoc jurisdiction reports	Ad hoc	CQR	Risk-adjusted unit-level data limited to the jurisdiction with comparators at national/jurisdictional/peer group level (clinicians and patients not identified)	Not for publication
6.	Ad hoc unit reports	Ad hoc	Authorised unit staff	Risk-adjusted granular data limited to the querying unit	Confidential to the contributing unit
7.	Ad hoc clinician reports	Ad hoc	Authorised clinician	Risk-adjusted granular data limited to the querying clinician (patients identified)	Confidential to the contributing clinician

* Unit = The term ‘unit’ may apply to any defined healthcare entity including hospitals, hospital departments, local or regional health services or other healthcare organisations