AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

# Australian Framework for National Clinical Quality Registries 2024

August 2024

Published by the Australian Commission on Safety and Quality in Health Care

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ISBN: 978-1-922880-87-1



The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care. *Australian Framework for National Clinical Quality Registries 2024*. Sydney; ACSQHC, 2024.

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# Contents

# Foreword

**Australia's national Clinical Quality Registries (CQRs) make a unique contribution to the Australian health system. They collect, analyse and report information about the care and outcomes being delivered by health service organisations, and serve as a fundamental driver of ongoing improvements in the safety and quality of the care provided to Australian consumers.**

To fulfil this purpose, CQRs must have sound governance arrangements in place, including data governance arrangements. They must maintain effective and meaningful processes for the collection and analysis of data, and for the dissemination of information about identified instances of healthcare variation and outlier performances.

Working with an Advisory Group, including CQR experts and representatives from all states and territories, the Australian Commission on Safety and Quality in Health Care (the Commission) has revised the *Framework for Australian Clinical Quality Registries 2014* to produce the *Australian Framework for National Clinical Quality Registries 2024* (the Framework). The Framework has also been informed by a national consultation process with a broad range of stakeholders.

The Framework is a principles-based document that aims to provide support and guidance for CQRs as they work towards achieving their purpose and providing maximum value to the Australian health system. It is intended for use by CQR operators as they make assessments about what their registry is doing well, and plan for improvements over time. CQR operators may include registry data custodians, state and territory health departments, health service organisation administrators, and clinicians. It is also relevant for medical colleges, governments, funders (in the private and public sectors), the community and anyone with an interest in health system improvement, health outcomes, monitoring and reporting on variation in clinical practice.

The Framework underpins the ***National Strategy for Clinical Quality Registries and Virtual Registries 2020–2030*** and with ongoing collaboration and partnership can drive the provision of information that can better support healthcare choices to achieve better patient outcomes across the healthcare system.

**Professor Sandy Middleton**
*Chair, Clinical Quality Registries Framework Review Advisory Group*
*Director, Nursing Research Institute, St Vincent's Health Network*

# About the Framework

**The aim of the *Australian Framework for National Clinical Quality Registries 2024* (the Framework) is to help national Clinical Quality Registries (CQRs) achieve their core purpose. That is:**

***To provide access to clinical information on the appropriateness and effectiveness of health care for the purpose of driving improvements in the safety and quality of the Australian health system.***

The Framework requires national CQRs to have a clear and precisely defined purpose, and to collect epidemiologically sound data in a consistent and systematic way. It aims to ensure that national CQRs provide maximum value to the health system by:

- Collating data within a specific clinical domain, including clinical data; longitudinal health outcome data; and data from patient-reported measures, where suitable
- Analysing this data to generate risk-adjusted reports on the appropriateness and effectiveness of care; and on the safety and efficacy of therapies, devices and procedures
- Making the information in these reports available to health service organisations, jurisdictional health departments, clinicians, patients, consumers, funders, private health insurers, industry, regulators and governments, in a way that meets their needs
- Collaborating on the development of clinical indicators and benchmarks
- Identifying unwarranted variations in healthcare and communicating these to the relevant health service organisation or jurisdictional health department
- Identifying health service organisations or clinicians whose performance deviates significantly from the established benchmarks (outliers) and making these known to the relevant health service organisation or jurisdictional health department
- Providing access to data for research purposes, with the appropriate permissions.

The Framework aims to support the success of national CQRs in an increasingly connected and digitally enabled health system by providing future-focused guidance on establishing and maintaining:

- Appropriate governance arrangements, led by a diverse leadership team that represents a range of skills and experiences
- Effective operational arrangements, designed to deliver a high-quality service in a safe and secure environment
- Technically sound processes for data analysis, risk-adjusted reporting, and identification of healthcare variation and outlier performances
- A robust schedule of fit-for-purpose reports and other communications to meet the needs of all stakeholders, including consumers.

## National alignment

The Framework is aligned with the ***National Strategy for Clinical Quality Registries and Virtual Registries 2020–2030*** (the National Strategy)[1] vision:

***"National clinical quality outcomes data are integrated into Australia's healthcare information systems and systematically drive patient-centred improvements in the quality and value of health care to achieve better patient outcomes across the national healthcare system."***

The Framework supports the Commonwealth, states and territories governments to meet their obligations under the *National Health Reform Agreement (Addendum 2020–2025)*, working in partnership to implement a 'nationally unified and locally controlled health system' which 'improves access to and use of data to support service delivery and improved patient outcomes.'[2]

### National Safety and Quality Health Service Standards

The guidance provided in the Framework enables jurisdictional health departments and national CQRs custodians to support health service organisations to meet the requirements under the ***National Safety and Quality Health Service (NSQHS) Standards***[3] and to meet clinician credentialling obligations.

Health service organisations demonstrating the integration of national CQRs data into clinical quality improvement activities will satisfy, in part, the requirements of the NSQHS Standards Actions as follows:

- Variation in clinical practice and health outcomes (Action 1.28)
- Measurement and quality improvement (Action 1.08 and Action 1.09).

**Information about the *NSQHS Standards* is available on the Commission's website.**

### Other strategic inputs

The Framework is aligned with and informed by the following sources:

- ***Evidence Check: Governance, accreditation, and quality assurance of clinical quality registries***[4]
- ***Legislation and regulation relating to clinical quality registries.***[5]

## Scope of the Framework

The Framework applies to national CQRs and those with the potential to be expanded nationally. It is expected that these will be operating in areas with the greatest burden of disease and cost to the Australian health system, or with the greatest variation in care and outcomes.

The Framework is a principles-based document that aims to provide support and guidance for CQRs as they work towards achieving their purpose and providing maximum value to the Australian health system. It is intended for use by CQR operators as they make assessments about what their registry is doing well, and plan for improvements over time. CQR operators may include registry data custodians, state and territory health departments, health service organisation administrators, and clinicians. The Framework is also relevant for medical colleges, governments, funders (in the private and public sector), the community and anyone with an interest in health system improvement, health outcomes, monitoring and reporting on variation in clinical practice.

The Framework does not preclude those clinical registries operating under specific legislation, such as registries of notifiable diseases (for example, cancer) and notifiable processes (for example, immunisation), or Declared Quality Assurance Activities (QAA) or clinician-led research initiatives, or those clinical registries that are not or will not be national prioritised clinical registries, to apply the guidance in the Framework, where appropriate.

# About Clinical Quality Registries (CQRs)

## What is a clinical registry?

Clinical registries are databases that operate within an overall governance and management structure to systematically collect health-related information on individuals who are:

- Treated with a particular surgical procedure, device or drug, for example, joint replacement
- Diagnosed with a particular illness, for example, stroke, or
- Managed via a specific healthcare resource, for example, treated in an intensive care unit.[6]

Clinical registries are observational in nature and observe practice in the real world without dictating the care to be given.

## What is a CQR?

A CQR is a specific type of clinical registry that systematically monitors and provides feedback on the appropriateness and effectiveness of health care, within specific clinical domains, for the purpose of driving ongoing improvements in safety and quality in the Australian health system.

## Overview of CQR attributes

The Framework sets out the requirements for CQRs operating in Australia that collect, analyse and report on health information on a national basis. CQRs are expected to:

1. Have a clear and precisely defined purpose aimed at improving the safety and quality of health care
2. Have governance arrangements that oversee the registry operation and ensure accountability to meet the needs and objectives of the CQR
3. Provide maximum value to the health system by focusing their core epidemiological data collection on the essential elements required to serve their main purpose
4. Seek to ensure there is complete data collected from the entire eligible population
5. Generate risk-adjusted reports and provide these reports in a usable format and timely manner to relevant stakeholders who use the information to implement change and improve health outcomes.

### Governance

The governance function is central to the CQR as it oversees registry operation and resource application, ensures accountability, establishes the dataset required to meet the needs and objectives of the CQR, and establishes key policies around, for example, the identification and management of outliers.[7]

### Community accountability

CQRs should be designed in partnership with consumers, including Aboriginal and Torres Strait Islander people, culturally and linguistically diverse communities, and other historically disadvantaged or under-represented groups to:

- Ensure that each component of the collected data contributes to our understanding of the benefit and cost-effectiveness of treatment and care, from the perspectives of these groups
- Ensure these groups receive information in a way that is appropriate for them.



## Overview of CQR functions

The key functions of a CQR are represented in Figure 1. Governance arrangements and registry operations are illustrated in relation to sustaining the CQR (including funding), and ensuring the CQR is working to meet the requirements of the Framework including data custodian obligations, provider enrolment and approach to data collection, data quality management and data analysis and reporting.

> **For more information, refer to the *Detailed requirements traceability matrix* in Appendix A of *Attachment 1: Australian CQR Logical Design and Infrastructure Guideline*.**

### Operating models

The Framework provides future-focused, best-practice guidance to enable national CQRs to meet their aims, regardless of their operational model.

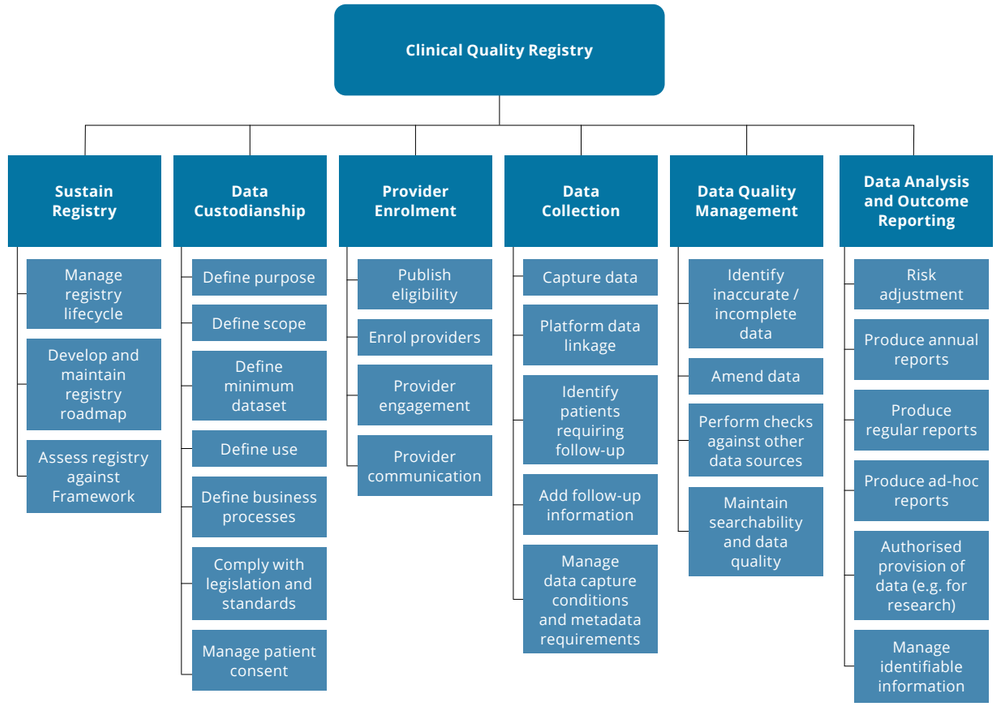
Operating models include:

- CQRs operating either at a national level, or within a state or territory health department
- CQRs developed and operating as standalone CQRs where the CQR has a data platform that is:
  - managed locally and maintained within existing health service organisation/ jurisdiction information systems
  - managed externally through a third-party service provider, such as a university or another vendor.

## CQRs in a learning health system

A defining feature of CQRs is that they provide clinicians and healthcare systems with feedback on their clinical results. The mechanisms and operational details of the feedback process vary depending on factors such as the nature of the information collected, the preferences of participants, and the maturity of the CQR. Ideally, feedback should be timely and sufficiently detailed that the causes of variation and outlying performance can be understood, enabling clinicians to recognise best practice or correct sub-optimal practices where appropriate.[8]

**Figure 1:** Functional overview of Australian national Clinical Quality Registries



This process drives a feedback loop that supports ongoing improvements in the safety and quality of health care, underpins shared decision-making between patients and healthcare providers, and informs approaches to personalised medicine (see Figure 2).

## A clinical 'learning system'

CQRs are one component of the broader clinical 'learning system'. They co-exist with healthcare policy, regulation and guidelines, as well as research and clinical trials, individual clinician preferences, technology and many other factors (see Figure 3).[9]

While CQRs can affect clinical practice on their own, there are synergies between the different components of the clinical system that magnify individual contributions and serve to deliver benefits and reduce costs. In a well-functioning, self-improving system, each of these influence and complement each other (as depicted in Figure 3).[10]

**Figure 2:** CQR feedback loop for ongoing improvements in the safety and quality of healthcare

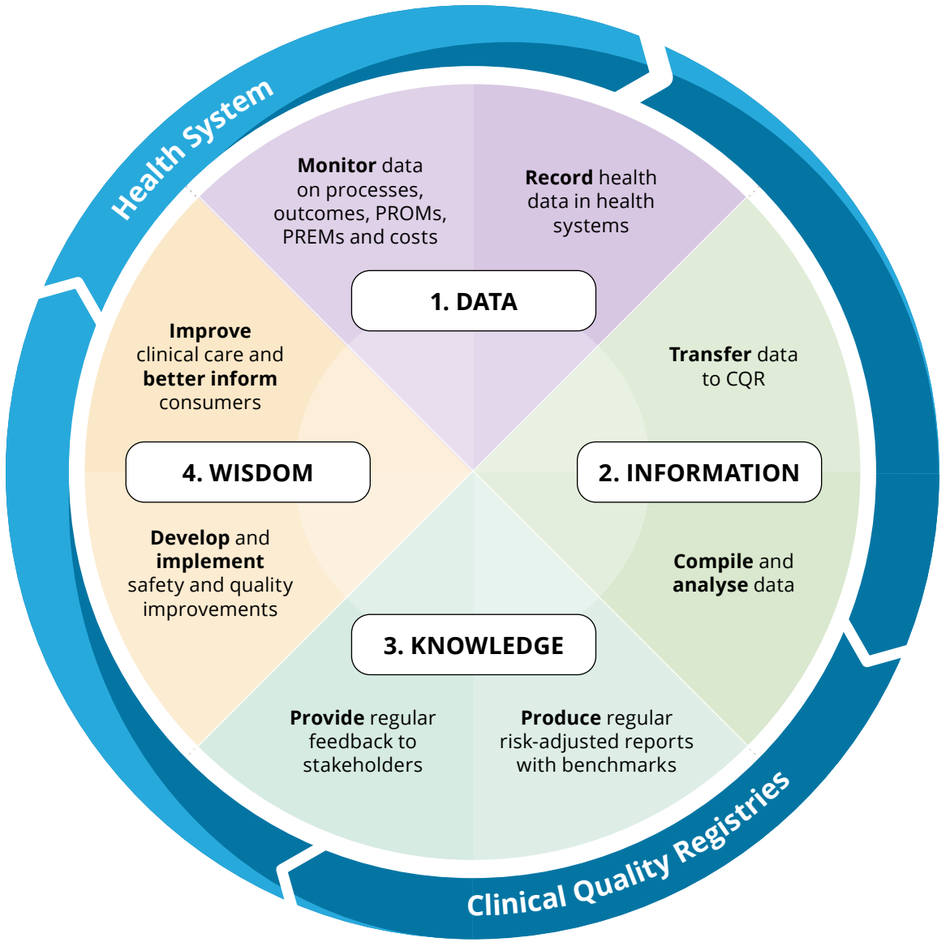
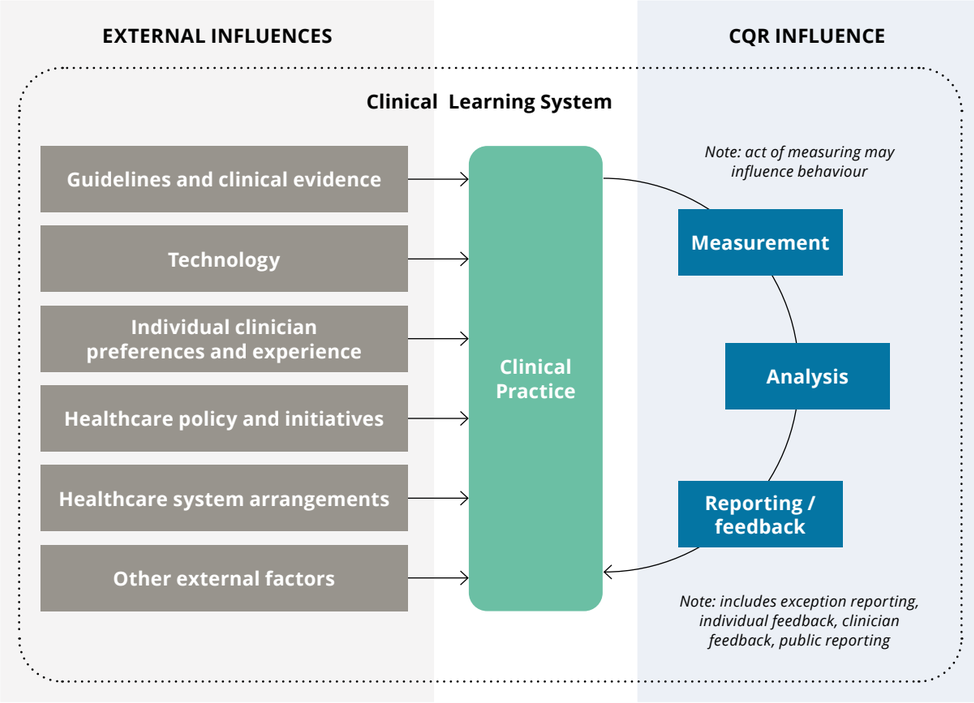



**Figure 3:** The position of CQRs within the broader clinical system[11]




## Ethical approvals for national CQRs

Moving CQRs from a research paradigm to a quality improvement paradigm, with data collected at its source and shared with clinical registries by agreement, is an aspiration favoured by the sector and supported by the Commission. The shift to a quality improvement paradigm is intended to enable and activate local and national quality improvement activities, however it does not preclude CQR data being used to power research activities.

Streamlining CQR approval is a key pillar of the National Strategy. Further work is required to explore options for streamlining health service approval processes for CQRs as quality assurance/improvement activities.

In addition to facilitating quality improvement, national CQRs may also produce reporting for research purposes via agreement. CQRs are advised to refer to the guidance published by the National Health and Medical Research Council (NHMRC) on research as well as ethical considerations in quality assurance and evaluation activities.

Further information can be found in documents published by the NHMRC, specifically:

- ***National statement on ethical conduct in human research 2023***[12]
- ***Ethical considerations in quality assurance and evaluation activities***.[13]

# Context for the Framework

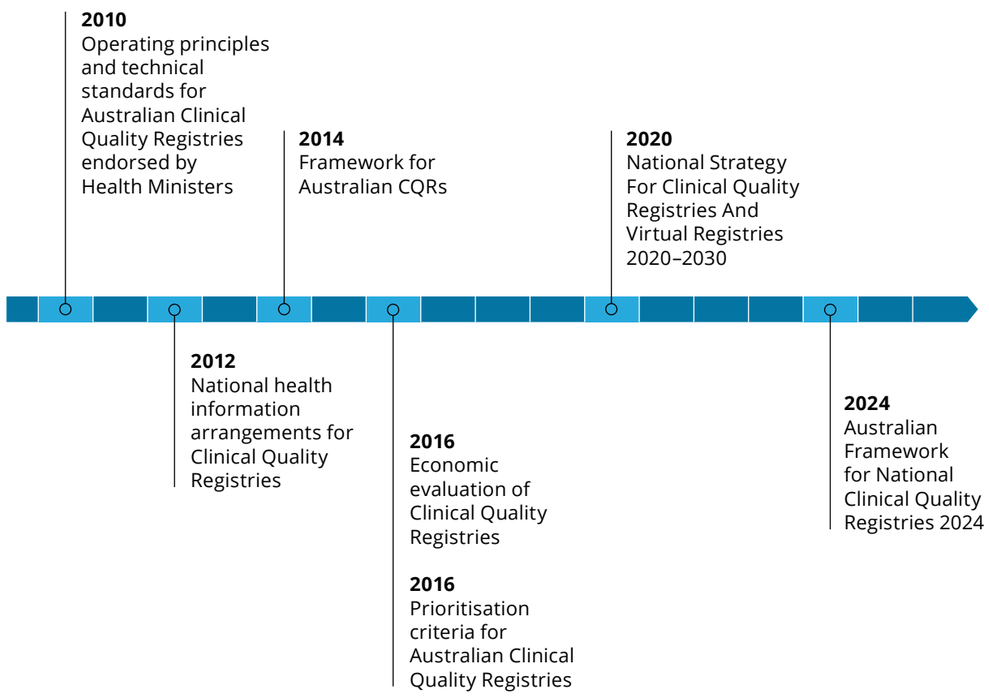
## Background

Many national CQRs are able to achieve their core purpose as drivers of safety and quality improvement. Others face barriers, including the burdens associated with establishing sound data collection methods, establishing and implementing data governance arrangements, and developing and maintaining dedicated information systems.

Additional barriers include the use of clinical registry system architectures, operating systems and data structures that are neither uniform nor standardised in Australia. This creates significant inefficiencies, hampers interoperability with other information systems, and complicates the assessment of CQR system security.

The Framework is part of a national body of work designed to provide national CQRs with support and guidance to help them address these barriers and achieve their core purpose. Figure 4 provides an overview.

**Figure 4:** Timeline of work developed to support and guide for national CQRs






## Emerging opportunities for a digitally enabled health system

International evidence suggests that complete, high-quality CQR data capture at a health-system level is best achieved when data collection fits within existing reporting structures and is facilitated by national digital hosting capability. This includes contemporary database technology and quality assurance processes to facilitate data collection and reporting at the jurisdictional level to reduce the burden on health service organisations.[14]

More recently, greater digitisation and integration of the electronic medical record with other clinical datasets within health service organisations and jurisdictional health departments have enabled access to more uniformly structured data, suitable for monitoring variation in clinical practice in specific populations.

These integration tools and frameworks allow the calculation of clinical process measures to facilitate reporting on adherence to best-practice care recommendations and guidelines. Mature CQRs also support the assessment of longitudinal outcomes using data linkage with other administrative and health data collections and, with expert clinician oversight, ensure the quality and completeness of the data, and the accuracy of the calculated reports.

## National programs of work

Australia's CQRs are at various stages of development in terms of their technical capabilities, and not all are in a position to engage with the opportunities presented by a digitally connected health system. A range of national programs are in place to support their transition into high-functioning, mature CQRs over time.

- ***National Clinical Quality Registry Program***
- ***National Strategy for Clinical Quality Registries and Virtual Registries 2020-2023***
- ***2020–2025 National Health Reform Agreement***
- ***National Healthcare Interoperability Plan 2023–2028***
- ***Intergovernmental Agreement on National Digital Health 2023–2027***
- ***Data Availability and Transparency Act Scheme (DATA Scheme)***.

## Supporting documents

The Framework has been designed as a principles-based document. Supporting documents have been developed to support CQRs that require detailed technical guidance to help them meet the requirements of the Framework. These are available on the Commission's website and include the following:

- ***Attachment 1: Australian CQR Logical Design and Infrastructure Guideline***
- ***Attachment 2: Australian CQR Security Compliance Guideline***.

# Strategic principles

**The strategic principles for CQRs underpin the National Strategy to provide a national strategic approach to CQR development.**

### Strategic Principle 1

CQRs in prioritised clinical domains have a safety and quality focus.

### Strategic Principle 2

In all aspects – including governance, research, design, and the provision of information to the community – CQRs consider the priorities of:

- Consumers
- Aboriginal and Torres Strait Islander people
- Culturally and linguistically diverse communities
- Other historically disadvantaged and under-represented communities.

### Strategic Principle 3

CQRs implement the Framework and operate with sound governance arrangements in close coordination with expert clinical groups and the community.

### Strategic Principle 4

Investment in CQRs enables scalable and future-orientated infrastructure to support improved data management, analysis and reporting on the quality of care.

### Strategic Principle 5

CQRs implement an appropriate data governance framework for the collection, holding and analysis of patient-level data. Information is managed to ensure the protection of patient privacy and adherence to jurisdictional/national legislation.

### Strategic Principle 6

CQRs are efficient and effective in providing the community, clinicians, hospital administrators and governments with regular risk-adjusted reports and information on the appropriateness and effectiveness of care to support ongoing improvements in health care as a recommended strategy to meet the actions under the *NSQHS Standards*.



# Operating principles

**CQRs operate within a variety of external operational and technical environments, and may not have control over some or all of the strategic principles listed above. However, they do have control over their internal operations.**

The following operating principles apply regardless of the CQR operating model, including:

- CQRs operating either at a national level or within a state or territory health department
- CQRs developed and operated as standalone CQRs where the CQR has a data platform that is:
  - managed locally and maintained within existing health service organisation/ jurisdiction information systems
  - managed externally through a third-party service provider, such as a university or another vendor.

### Operating Principle 1: Organisation and governance

- Have in place a governing body that is responsible for the effective governance and management of the CQR, ensuring:
  - clarity on the purpose and intended outcomes of the CQR
  - accountability and transparency for the investment of public funds, where applicable
  - oversight of resource allocation
  - optimal CQR contribution to continual safety and quality improvement.
- Establish policies to manage a range of contingencies arising from the analysis of data to ensure that issues associated with quality of care, including outliers or unexplained variance, are effectively communicated and escalated
- Have an ongoing program of continuous improvement, and a roadmap of improvements planned.

### Operating Principle 2: Data governance

CQRs are accountable for the safety and integrity of the data they handle, and have sound processes in place. CQRs do this by applying the principles outlined below. Data governance (as a component of overall CQR governance) should comply with jurisdictional legislation, data governance standards, policies and procedures for the development and maintenance of health data collections.

- **Data Governance Guiding Principles:** These principles were developed by the Data Governance Institute to help stakeholders resolve data-related conflicts.
  - **Integrity:** Data governance participants will practise integrity with their dealings with each other; they will be truthful and forthcoming when discussing drivers, constraints, options and impacts for data-related decisions
  - **Transparency:** Data governance and stewardship processes will exhibit transparency; it should be clear to all participants and auditors how and when data-related decisions and controls were introduced into the processes
  - **Auditability:** Data-related decisions, processes, and controls subject to data governance will be auditable; they will be accompanied by documentation to support compliance-based and operational auditing requirements
  - **Accountability:** Data governance will define accountabilities for cross-functional data-related decisions, processes, and controls
  - **Stewardship:** Data governance will define accountabilities for stewardship activities that are

the responsibilities of individual contributors, as well as accountabilities for groups of data stewards
    - **Checks-and-balances:** Data governance will define accountabilities in a manner that introduces checks-and-balances between business and technology teams as well as between those who create/collect information, those who manage it, those who use it, and those who introduce standards and compliance requirements
    - **Standardisation:** Data governance will introduce and support standardisation of enterprise data
    - **Change management:** Data governance will support proactive and reactive change management activities for reference data values and the structure/use of master data and metadata.

- **Five Safes Framework:** This is an internationally recognised approach to disclosing risks associated with data sharing or release. Under the Five Safes Framework, CQRs should consider five dimensions:
    - Project – is the use of data appropriate?
    - People – can the users be trusted to use it in an appropriate manner?
    - Data – is there a disclosure risk in the data itself?
    - Settings – does the access facility prevent unauthorised use?
    - Output – are the statistical results non-disclosive?

**More information about the Five Safes Framework is available on the Australian Institute of Health and Welfare website.**

- **Indigenous Data Governance:** In 2018, the Indigenous Data Sovereignty Summit was held by the Maiam nayri Wingara Indigenous Data Sovereignty Collective and the Australian Indigenous Governance Institute. Its aim was to progress Indigenous Data Sovereignty and Indigenous Data Governance through developing shared understandings and initiating an Australian set of Indigenous Data Governance protocols and principles. The **Maiam nayri Wingara Indigenous Data Sovereignty Principles**[15] state that, in Australia, Indigenous peoples have the right to:
    1. Exercise control of the data ecosystem including creation, development, stewardship, analysis, dissemination and infrastructure
    2. Data that are contextual and disaggregated (available and accessible at individual, community and First Nations levels)
    3. Data that are relevant and empowers sustainable self-determination and effective self-governance
    4. Data structures that are accountable to Indigenous peoples and First Nations
    5. Data that are protective and respects our individual and collective interests

**For more information about Indigenous Data Sovereignty and Governance, see the Maiam nayri Wingara website.**[16]

- **CARE Principles for Indigenous Data Governance:** The CARE Principles for Indigenous Data Governance are people-oriented and purpose-oriented, reflecting the crucial role of data in advancing Indigenous innovation and self-determination. These principles complement the existing **FAIR data principles**[17] (that is, that all data should be findable, accessible, interoperable and reusable) encouraging open and other data movements to consider both people and purpose in their advocacy and pursuits. They are outlined below.
    - **Collective benefit:** Data ecosystems shall be designed and function in ways that enable Indigenous Peoples to derive benefit from the data.
    - **Authority to control:** Indigenous Peoples' rights and interests in Indigenous data must be recognised and their authority to control such data be empowered. Indigenous data governance enables Indigenous Peoples and governing bodies to determine how Indigenous Peoples, as well as Indigenous lands, territories, resources, knowledges and geographical indicators, are represented and identified within data.
    - **Responsibility:** Those working with Indigenous data have a responsibility to share how those data are used to support Indigenous Peoples' self-determination and collective benefit. Accountability requires easily available and meaningful evidence of these efforts and the benefits accruing to Indigenous Peoples.
    - **Ethics:** Indigenous Peoples' rights and wellbeing should be the primary concern at all stages of the data life cycle and across the data ecosystem.

**For more information about the FAIR and CARE principles, see the Australian Research Data Commons website.**

## Operating Principle 3: Data collection

- Collaborate with the public and private sectors to maximise the value of public data in alignment with the National Strategy
- Source data directly from clinical information systems where possible and, as appropriate, work in partnership with jurisdictional health departments, clinical leaders, patients, their families and carers to collect data which is not routinely collected
- Use data dictionaries to ensure a systematic and identical approach to data collection and data entry; review data dictionaries and definitions of data items regularly in consultation with contributing jurisdictional health departments; and leverage standardised/common data dictionaries where possible, such as national agreed data definitions **(METEOR)**, clinical coding terminologies and standards
- Use standard definitions, terminology and specifications to enable meaningful data linkage with other disease and procedure CQRs, and national and jurisdictional information systems
- Maximise the automation of data collection from clinical information systems to avoid or reduce manual collection methods, and duplication of data capture.

**For more information about data collection, see *Data and quality systems* below.**

## Operating Principle 4: Data elements

- Collect data items which are epidemiologically sound, using data collection methods that are systematic and consistent
- Collect sufficient patient-identifying information to support the CQR's stated purpose
- Collect patterns or processes of care with an established link to outcomes and process measures that are simple, reliable and reproducible
- Where possible, collect the indicators identified in relevant **Clinical Care Standards**[18] produced by the Australian Commission on Safety and Quality in Health Care
- Where possible, assess outcomes using objective measures
- Undertake outcome determination at a time when the patient's clinical condition has stabilised to the point that outcome information can be accurately ascertained, or when an event, such as death, has occurred and the outcome can therefore be reasonably ascertained
- Collect and analyse patient-reported measures where these data provide useful information for quality improvement and data collection is feasible.

**For more information on the selection, use and implementation of PROMs, see *PROMs for implementers* on the Commission's website.**

**For more information about data elements, see *Data and quality systems* below.**

## Operating Principle 5: Risk adjustment

- Collect objective, reliable covariates for risk adjustment to enable factors outside the control of clinicians to be taken into account by appropriate statistical adjustments
- When reporting on risk-adjusted outcomes, provide details of the way in which data have been risk adjusted, including the assumptions that underpin the risk adjustment.

**For more information about risk adjustment, see *Data and quality systems* below.**

## Operating Principle 6: Data security

- Comply with ***Australian CQR Security Compliance Guideline (Attachment 2)***, or equivalent as required by the CQR's legal entity
- Comply with the relevant legislation, regulation, principles, standards

and policies of the health service organisation or jurisdiction in which clinical health data are being held.

### Operating Principle 7: Ensuring data quality

- Report, as a quality measure, the percentage of eligible patient, provider and health service data captured in the CQR, as applicable to the CQR's operations
- Have a robust quality assurance plan for ongoing monitoring of the completeness and accuracy of the data collected
- Undertake audits of sample data to assess data quality, including the completeness and accuracy of data, and remedy issues as soon as possible
- Incorporate in-built data validation processes, including data range and validity checks, and share validation specifications with jurisdictional health departments to enable validation in their own data collection systems.

### Operating Principle 8: Data custodianship

- Make clear and explicit statements about the custodianship of CQR data in contracts and/or funding agreements, and ensure these statements are publicly accessible
- Have mechanisms in place to ensure the priorities of Aboriginal and/or Torres Strait Islander people, people from culturally and linguistically diverse communities, and people from historically disadvantaged or under-represented groups are considered by data custodians
- Ensure that third parties wishing to access data for secondary purposes seek approval from the data custodian and obtain relevant Institutional Ethics and/or Human Research Ethics Committee (HREC) endorsement where identifiable, potentially identifiable or re-identifiable data are sought
- Make data-access policies and reporting policies publicly available, including to persons wishing to use CQR data for research purposes
- Return data and/or report back to organisations that have provided data to the CQR, to enable the organisation to undertake quality improvement
- Apply the Five Safes Framework, the **Maiam nayri Wingara Indigenous Data Sovereignty Principles**[19] and the **CARE Principles for Indigenous Data Governance**,[20, 21] as appropriate.

> **More information on the Five Safes Framework, the Maiam nayri Wingara Indigenous Data Sovereignty Principles and the CARE Principles for Indigenous Data Governance is contained in *Operating Principle 2*, above.**

### Operating Principle 9: Privacy

- Comply with overarching principles for the collation, reporting and dissemination of health data as set out in the Australia Privacy Principles of the ***Privacy Act 1988*** (Cth), and any state-based equivalent privacy principles and legislation, including the provision of information to third parties for secondary use of data.

### Operating Principle 10: Information output

- Use CQR data to highlight best practice, promote optimal care and showcase improvements in safety
- Use CQR data to evaluate quality of care by identifying gaps in best practice and benchmarking performance including outlier performance
- Generate and disseminate reports on risk-adjusted outcome analyses to all CQR stakeholders without delay, once a representative proportion of data has been collated
- Verify findings from data using a formalised peer-review process with key clinical leaders before the publication of findings. If issues are identified, the CQR should undertake a process to verify the data in line with *Operating Principle 7: Ensuring data quality*
- Ensure that clinicians and/or staff at contributing health service organisations have the ability to undertake ad-hoc analyses of the data they contribute to the CQR
- Work towards producing regular, publicly accessible reports, in line with *Strategic Principle 6*
- Have a documented policy and procedure in place for reporting on quality of care, and effectively communicating instances of outlier performance or unexplained variance.



# Quality Standard for CQRs

**The Quality Standard for CQRs is designed to mitigate risk relating to the collection and management of data, and to promote the reporting of health information for safety and quality improvement.**

The Quality Standard for CQRs aligns with the *NSQHS Standards* and includes the following components:

- Governance
- Data and quality systems
- Feedback and reporting
- Measuring and identifying outliers.

Additional guidance is provided by two attachments:

- ***Attachment 1: Australian CQR Logical Design and Infrastructure Guideline*** guidance on CQR business functions, logical design and infrastructure, and technology standards
- ***Attachment 2: Australian CQR Security Compliance Guideline*** contains guidance on security standards and techniques.

## How should the Quality Standard be applied?

The Quality Standard for CQRs is voluntary. There is recognition that the way in which a CQR operator implements the Quality Standard will be dependent on the type of CQR operating model and the risks and complexity associated with its operations. However, the Quality Standard ensures a nationally consistent standard that can be used by all CQRs committed to improving the safety and quality of health care.

The Quality Standard contains self-assessment checklists to help CQRs align their current capabilities with the best-practice national guidance provided in the Framework. At all times, a CQR must adhere to regulatory requirements as prescribed in relevant Commonwealth, state and territory legislation.

# Governance

**Effective governance ensures clinical, technical, operational, administrative and risk-management arrangements are in place to meet the requirements of the Framework and information needs of the community. This guidance is to be applied in a way that best suits the context of the CQR.**

CQRs should have competent governance arrangements in place with a focus on leadership that brings stakeholders such as clinicians, data custodians, government representatives, funders, consumers, academics, and administrative staff together as partners to:

- Design and provide oversight of CQRs
- Guide decision-making related to funding, operations and dissemination of information.

## Governing body function

The governing body has ultimate responsibility for the governance of the CQR. It derives its authority from the enabling legislation, and from the organisation's constitutional documents, where applicable.

The governing body must be a legal public entity such as a jurisdiction, health department, health service organisation, university or institute, association, medical college, not-for-profit entity, or a purpose-created registry board. A governing body may have responsibility for more than one CQR. CQR governance may operate within the context of other organisational governance structures.

The governing body sets the strategic direction for the CQR and clearly defines its purpose and intended outcomes. It also oversees operations and is accountable for the work undertaken by the operational staff in delivering effective organisational systems and processes.

The governing body ensures that funding and contractual arrangements made with funders and providers are open and transparent where possible, and that they align with the core purpose and outcomes of the CQR.

In addition to its fiduciary and other corporate duties, the governing body acts in good faith and with integrity. It identifies and complies with laws, regulations, and national and jurisdictional guidelines and policies relating to undertaking a CQR.

### Designation and delegation of roles and responsibilities

The governing body ensures there is appropriate designation of responsibility and accountability, with documented roles and functions that are agreed by all parties. It oversees operational decision-making processes and communication between all those involved in the CQR organisation, with clear and consistent practices in terms of what is communicated to whom, how, when and why.

While the governing body retains responsibility for oversight of strategic decision-making, it delegates implementation to individuals and groups within the CQR. The governing body has a responsibility to ensure that action is taken to remedy operational issues and poor performance within the CQR if and when these are identified (Figure 5). These could include clinical, technical, financial and operational issues, and issues related to privacy and security.

In addition, the governing body may choose to empower certain delegated authorities to make decisions in specialised areas of CQR operations. For example, it may nominate an individual or a group to act as the delegated authority in relation to decisions about data sharing, or data breaches.

The governing body is committed to continuous improvement by regularly assessing its performance and that of its members in upholding its governance responsibilities.

## Governing body structure

The governing body structure depends on the size, maturity and complexity of the CQR. Typically, the structure includes:

- A leadership group representing the governing body (sometimes described as the board, or the executive)
- One or more advisory groups
- An optional management group
- An operational group, alternatively described as the CQR workforce.

It is understood that the work of the CQR, and its contribution to quality improvement in the Australian healthcare system, benefits from the range of perspectives and experiences that diversity brings. It is important that the composition of the governing body reflects a diversity of skills, ages, genders, backgrounds, cultures, and ethnicities, including those from historically disadvantaged or under-represented groups.

### Leadership group

In the CQR, the work of the governing body, including defining the purpose and intended outcomes of the CQR, and overseeing its operations, is undertaken by the leadership group. Where the CQR does not nominate a leadership group, the responsibilities described are undertaken by the governing body.

The leadership group generally comprises a small number of individuals with a diverse skill set, led by a chairperson. Importantly, it includes a balance of individuals and expertise designed to support the functions of a CQR. It may include clinical experts, jurisdictional representatives (appointed on a rotating basis), representatives from relevant medical colleges, academic experts, independent representatives (with appropriate skills), representatives from relevant not-for-profit groups, and key stakeholders. It should also include consumer representatives.

### Advisory groups

The role of an advisory group is to provide current knowledge, critical thinking and analysis to increase the confidence of the decision-makers who represent the CQR. It may help the CQR gain new insights, and advance the progress of the CQR through leadership, innovation and expertise. The advisory group may be made up of internal governing body members, external advisors such as representatives from the Therapeutic Goods Administration (TGA) or from industry, clinician experts, consumers and an independent chairperson.

### Management group

Depending on its size and resources, a CQR may nominate a management group. The management group is responsible for implementing the strategic direction set

**Figure 5:** CQR governance model

| ENTITY | ROLE AND RESPONSIBILITIES |
|---|---|
| **Governing Body (legal entity)** | • Ultimate responsibility for CQR governance<br>• Sets the strategic direction for the CQR |
| **Advisory Group/s** | • Provides current knowledge, critical thinking and analysis to support Leadership Group / Governing Body decision-making |
| **Leadership Group** | • Represents the Governing Body<br>• Defines CQR purpose and intended outcomes<br>• Oversees CQR operations |
| **Management Group (optional)** | • Implements the strategic direction set by the Leadership Group / Governing Body |
| **Operational Group** | • Implements the requirements of the Framework<br>• Implements the directions of the Governing Body, Leadership and/or Management Group |

by the governing body. It is responsible for ensuring that the CQR operating principles are met. It is also responsible for ensuring that CQRs have an effective complaints-management system that is used to improve the quality of CQR operations. Complaints from patients and consumers, clinicians, funders and health service organisations should be received, reviewed and resolved in a timely manner, and there should be a mechanism to regularly review the effectiveness of the complaints management system. This mechanism may incorporate and liaise with health service organisations' complaints mechanisms.

Ideally, it should not exceed 15 members and should include clinical specialists, academics, technical experts, and consumers. Consumers are included as they are integral to ongoing quality improvement in CQR operations and outputs. Engaging with consumers and receiving their input helps ensure that datasets and data collection methods are meaningful and acceptable to the relevant communities.

Where the CQR does not nominate a management group, the responsibilities described are undertaken by the leadership group, or the operational group, or a combination of these.

## Operational group

The operational group is supported by the governing body and, if applicable, the management group to implement the Framework. Clinical and non-clinical staff working within the operational group are responsible for their own professional practice as required by their professional codes of conduct. Operational group members may include, but are not limited to:

- Clinician experts
- Academic experts
- Consumer representatives
- Operational managers
- Data managers
- Statistical and epidemiological support
- Registry coordinators
- Administrative and/or technical support, including security and privacy support.

## Commonwealth, state and territory departments of health, and other funders

The CQR benefits from engagement with its jurisdictional funder, such as a Commonwealth, state or territory health department, or other funder. A close working relationship:

- Enables the funder to see, understand and respond to the CQR's activity
- Enables both parties to evaluate and improve on the aims and operations of the CQR, including the metrics on which the CQR reports, to ensure it continues to deliver value over time.

To maintain a strong and productive relationship, the CQR must commit to delivering regular, meaningful reports to the funder, and the funder must commit to reviewing and responding to the contents of these reports.

In cases where the CQR is owned and funded by a jurisdiction, then the relevant Commonwealth, state or territory health department is responsible for ensuring that governance arrangements are in place, that the CQR outputs are reviewed regularly, and communicated to ensure implementation of healthcare safety and quality improvements, where required. This includes implementation of the Framework and the National Strategy.

Where state and territory health departments provide centralised and coordinated oversight of the performance of the CQR, they are encouraged to report on the success of CQRs operating within their jurisdictions.



# Governance checklist

**This checklist can help CQRs to align their current governance arrangements with the best-practice national guidance provided above.**

**Governing body function**

- ☐ Is the governing body a legal entity?
- ☐ Has the governing body defined the purpose of the CQR, and its intended outcomes?
- ☐ Has the governing body identified the relevant laws, regulations and jurisdictional guidelines and policies relating to the work of the CQR?
- ☐ Is it actively ensuring that the CQR complies with these?
- ☐ Does the governing body have clear and consistent practices in terms of what is communicated to whom, how, when and why?

**Governing body structure**

***Leadership group***

- ☐ Does the leadership group comprise a balance of individuals with expertise to support the functions of the CQR?
- ☐ Does it reflect a diversity of skills, ages, genders, backgrounds, cultures, and ethnicities, including groups that are historically disadvantaged or under-represented?

***Advisory group***

- ☐ Does the CQR have one or more advisory groups capable of providing knowledge, critical thinking and analysis to increase the confidence of CQR decision-makers?
- ☐ Is the advisory group made up of internal and external members, including consumers?

***Management group***

- ☐ If there is a management group, does it include a balance of clinical experts, technical experts and consumer representatives?
- ☐ Does it oversee an effective complaints-management system?

***Commonwealth, state and territory departments of health, and other funders***

- ☐ Are there mechanisms in place to enable a productive working relationship between the CQR and its funder?
- ☐ Are there processes in place to use the CQR outputs to inform healthcare safety and quality initiatives within the jurisdiction (regardless of the CQR funding source)?

# Data and quality systems

**Data governance is a component of overall CQR governance and relates to the decision-making roles, responsibilities and processes that cover the life-cycle management of the health data held in the CQR. Data governance arrangements should comply with jurisdictional legislation, data governance standards, policies and procedures for the development and maintenance of health data collections.**

## Data governance roles and responsibilities

The CQR must have designated roles to ensure good governance of the data it holds, and to ensure that it meets its requirements as a data custodian. The number and scope of these roles will depend on the size and nature of the CQR, and the jurisdiction in which it is operating. However, it is essential that all CQRs identify a data owner and a data custodian, in line with the definitions provided below.

### Data owner

In Australia, the owner of the data contained in a medical record is the doctor, hospital or other health professional who created and maintains the record. Patients have a right to access the data in their medical records.

The ownership of aggregated data is a more complex consideration and is likely to be determined by the contracts, partnerships and/or funding models in place. It is the responsibility of the CQR to understand the data ownership issues relevant to them, in the context of the agreements under which they are operating.

### Data custodian

The data custodian is the organisation or agency responsible for the safe and appropriate collection, management and release of data. The data custodian has legal and ethical obligations to maintain the confidentiality of the data entrusted to them. The data custodian is also responsible for:

- Approving access to the data collections
- Approving use of the data collections
- Ensuring data collections are protected from unauthorised access, alteration or loss
- Providing advice to users of the data, including any caveats on the use of the data.

## Data elements

### Patient-identifying information

The CQR captures sufficient patient-identifying information to support its stated purpose. This includes individually identifiable data, which may require the use of national Individual Healthcare Identifiers (IHIs). The CQR may also need to collect and maintain up-to-date participant contact details to support longitudinal data collection and collection of patient-reported measures. Nevertheless, the CQR should minimise the identifiers collected, and the length of time they are stored in the CQR database.

> **More information on Individual Healthcare Identifiers (IHIs) can be found on the Services Australia website.**[22]

### Measurement for improvement

The CQR collects data to calculate indicators that are useful for quality improvement. CQR indicators measure patterns or processes of care (process indicators) and outcomes of care (outcome indicators). It is recommended that CQRs collect indicators related to both efficacy (effectiveness) and safety.

- Efficacy indicators are usually applicable to the whole CQR population and provide information about how well the patient management/intervention improved patient wellbeing, clinical outcomes and/or function.
- Safety indicators, such as measures of complications and adverse events, usually have a low incidence and occur in a much smaller population. While important, they may not provide information relevant to the whole CQR population.

Patient-reported measures provide valuable insights into outcomes and experiences from the patients' perspective and should be considered for inclusion in the dataset.

Clinicians should be involved in selecting clinical indicators, based on the importance and feasibility of the data to be collected. Where possible, the CQR should implement indicators that:

- Have been published in the Clinical Care Standards produced by the Australian Commission for Safety and Quality in Health Care for the relevant condition or procedure
- Align with the indicators used in similar databases internationally.

Clinical outcomes should be assessed using objective measures where this is possible.

> **More information on patient-reported measures is provided in *Appendix A: Patient-reported measures*.**

### Minimum clinical datasets

CQR minimum clinical datasets should be built around the key process and outcome measures or from a published publicly facing data dictionary, such as **METEOR**.

### Variables for risk-adjustment

The CQR must collect objective, reliable variables to support risk adjustment of factors outside the control of clinicians when benchmarking. These covariates should be clinically identified as the patient-related and/or disease-related variables that have the most significant impact on patient outcomes that are unlikely to be influenced by clinical care.

Where a CQR reports outcomes that are risk-adjusted, the reporting provides details of the way in which the data have been risk-adjusted, including the assumptions that underpin the risk adjustment. Models for risk adjustment should be transparent and made available to stakeholders upon request. When risk-adjusted results are provided to clinicians and health service organisations, it should be accompanied by un-adjusted or crude results as contextual information. This provision of crude results provides a level of transparency by allowing the health service organisation and/or clinicians to understand the basis of the adjusted results.

## Data collection

CQRs should collaborate with the public and private sectors to maximise the value of clinical quality outcomes data, aligning with the National Strategy to achieve better patient outcomes across the healthcare system.[23]

### Patient participation and informed consent

Health service organisations and/or individual health providers that routinely operate or contribute to the CQR should follow relevant legislative requirements, such as the *Australian Privacy Act* and *Australian Privacy Principles* where applicable. This includes applying privacy and data security standards for the collection and use of personal information for purposes beyond which it was originally collected (known as 'secondary use'). Where reasonable, health services or individual health providers should make patients aware of the CQR and provide them with sufficient information to make an informed decision about their involvement, following relevant ethical review processes where required.

### Routinely collected data

Where possible, the CQR sources data directly from clinical information systems which are routinely updated through the course of patient care. It is recognised, however, that not all health service organisations produce electronic medical records (EMRs) and, further, that some CQR data items are not currently captured within EMRs. Data may alternatively be gathered from medical records by data collectors; from direct entry by clinicians or their staff; from data linkage; from data extraction from data systems; or from consumers themselves.

## Data items not collected as a matter of routine

The collection of outcome data, such as patient reported measures, and other data that is not routinely collected should be facilitated in partnership with jurisdictional health departments and clinical leaders, academics, patients, their families and carers. Collecting such data must not be an unreasonable burden nor incur any cost to patients. Where possible, the CQR should undertake to align or coordinate with existing outcome data collections, such as from jurisdictional health departments.

## Data dictionaries

CQRs must use data dictionaries when the CQR is established to ensure that a systematic and identical approach is taken to data collection and data entry.

The CQR must leverage common/standardised data dictionaries such as national agreed data definitions (**METEOR**), clinical coding terminologies and standards, where possible. The CQR should regularly review data dictionaries and definitions of data items in consultation with contributing jurisdictional health departments. Such consultations are an opportunity to discuss and clarify any ambiguity concerns.

An updated and accessible data dictionary should be available to facilitate accurate data collection. The CQR must publish all relevant details including eligibility criteria, metadata, and data dictionaries.

## Data linkage

The CQR has the capacity to enhance its value through linkage to other disease and procedure CQRs, and other national and jurisdictional information systems. Standard definitions, terminology and specifications must be used to enable meaningful comparisons and allow maximum benefit to be gained.

## Automation of data collection

To avoid duplicating data capture, CQRs should maximise the automation of data collection from clinical information systems, using contemporary data integration approaches. Similarly, contemporary technologies should be utilised to avoid or reduce manual collection methods.

## Data quality

The CQR should:

- Regularly monitor its data capture and completion rates
- Ensure it has efficient and effective methods for cleaning and assuring the quality of its data.

Examples of ensuring data quality include:

- Undertaking sample or regular audits of CQR data against medical records or other source documents
- Education and training of data collectors
- Communities of practice
- Triangulation of data.

These measures should be regularly reported publicly so an assessment can be made of the utility of the CQR data and analyses.



# Data and quality systems checklist

**This checklist can help CQRs align their current health data safety and quality system capabilities with the best-practice national guidance provided above.**

**Data governance roles**

- ☐ Does the CQR have designated roles to ensure the good governance of the data held by the CQR?
- ☐ Has the CQR identified the data owner and the data custodian, consistent with the definitions previously provided?

**Data elements**

- ☐ Is the CQR collecting the data it needs to support its core purpose, including personally identifiable data where appropriate?
- ☐ Is the CQR taking action to minimise the identifiers collected, and the length of time they are stored in the CQR database?
- ☐ Is the CQR using indicators that have been clinically identified, and which align with the indicators published in any relevant Clinical Care Standards produced by the Australian Commission on Safety and Quality in Health Care and/or any relevant international registry, where relevant?
- ☐ Are clinical outcomes being assessed using objective measures where possible?
- ☐ Are PROMs being collected?

**Risk adjustments**

- ☐ Is the CQR applying risk adjustments to account for factors outside the clinicians' control?
- ☐ Are those risk adjustments transparent, and explained in detail in CQR reports?

**Data collection**

- ☐ Is the CQR operating in a way that optimises the use and reuse of health data for the benefit of the Australian public, in alignment with the National Strategy?
- ☐ Is the CQR making participants aware of the CQR, and providing them with sufficient information to make a decision about either consenting or opting-out of data collection?
- ☐ Is the CQR using data dictionaries to ensure a systematic approach to data entry?
- ☐ Are data dictionaries regularly reviewed in consultation with contributing jurisdictional health departments?
- ☐ Does the CQR have the capacity to integrate with other information systems?
- ☐ Does the CQR maximise the use of automated data collection systems?

# Feedback and reporting

**Timely data analysis and reporting, accompanied by clinical interpretations, play a critical role in safety and quality improvement and are core functions of a CQR.**

CQRs are required to:

- Generate benchmarked data on the appropriateness and effectiveness of health care, risk-adjusted where appropriate
- Generate longitudinal health outcome data about clinical quality outcomes for the eligible population
- Feed back these data to the participating health service organisation, jurisdictional health department, funders, clinical colleges, and researchers
- Use these data to inform national and international benchmarking and identify significant variation in processes and outcomes.

*Reporting is the most visible output of the CQRs work. These reports identify significant variation and establish benchmarks that inform improvements in safety and quality. Reporting can also help consumers make informed decisions about what care they receive, and where.*

## Quality review

CQR reports undergo a process of review to ensure they are of high quality and suitable for dissemination.

Analysis of data includes clinical interpretations of the findings. CQRs have in place a structured clinical governance process for peer review of statistically significant outliers. In addition, any unwarranted variation is highlighted in the report for the attention of stakeholders.

Where significant outliers and/or unwarranted variation are identified, the CQR makes recommendations that action is taken by the provider to address clinical safety and quality issues and initiate improvements. However, it is acknowledged that these subsequent actions are the responsibility of the relevant stakeholder, and not the CQR.

## Dissemination of reports

CQR reports are disseminated to the participating health service organisation, jurisdictional health departments, funders, clinical colleges, researchers and consumers. A best-practice approach to dissemination would see reports shared with the staff and clinicians directly involved in data collection, however it is acknowledged that this may be decided by the relevant stakeholder, and not by the CQR.

## Timely feedback

Best-practice reporting mechanisms should aim to be as prompt as possible. Tardy or belated reporting of aggregate or summary information is insufficient to meet the needs of safety and quality improvement across the health sector.

Where reporting on long-term outcomes is dependent upon linked data, the availability of linked datasets can affect reporting timelines. The CQR governing body is responsible for monitoring this to help ensure that data linkage occurs in a timely manner.

CQRs should work towards integrating effective technological solutions that enable stakeholders to view a live snapshot of CQR data, on demand. They should also have in place a process and resources to meet stakeholder requests for additional analyses and ad-hoc reports.

Table 1 provides the type and frequency of reports that should be generated and provided by CQRs operating under national arrangements in future.

**Table 1:** Type and frequency of CQR reports

| | 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; good practice would report findings relevant to and consumable by healthcare consumers. | Public |
| 2. | Routine provider reports | As appropriate to the focus and purpose of the CQR | 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 | As appropriate to the focus and purpose of the CQR | CQR | Risk-adjusted granular data limited to the contributing provider unit with comparators at national/ jurisdictional/peer group level | Contributing provider unit – confidential |
| 4. | Routine clinician reports | As appropriate to the focus and purpose of the CQR | CQR | Risk-adjusted granular data limited to the contributing clinician with comparators at national/peer group level (patients identified) | Contributing clinician – confidential |
| 5. | Ad hoc jurisdiction reports | On request | CQR | Risk-adjusted unit-level data limited to the jurisdiction with comparators at national/jurisdictional/ peer group level (clinicians and patients not identified) | Jurisdiction – confidential |
| 6. | Ad hoc unit reports | On request | Authorised unit staff | Risk-adjusted granular data limited to the querying unit | Contributing unit – confidential |

† The term 'unit' may apply to any defined healthcare quality entity including hospitals, hospital departments, local or regional health services or other healthcare organisations.

| | Report | Frequency | Generator | Content | Stakeholder Recipient |
|---|---|---|---|---|---|
| 7. | Ad hoc clinician reports | On request | Authorised clinician | Risk-adjusted granular data limited to the querying clinician (patients identified) | Contributing clinician – confidential |
| 8. | Reporting on device and therapeutics | Annually and on request | CQR | Details of devices and therapeutics | Clinician, health service organisation, TGA, device nd the therapeutic manufacturers – confidential |
| 9. | Public reporting | As appropriate to the focus and purpose of the CQR | CQR | Aggregated clinical and CQR findings; national trends in outcomes and patterns of practice; good practice would report findings relevant to and consumable by healthcare consumers<br><br>Risk-adjusted data by jurisdiction and private hospital ownership group (clinicians and patients not identified) | Public |

## Regular provider reporting

Having good quality data is not, in itself, sufficient to improve quality of care. The CQR must have in place the appropriate processes and personnel to ensure that data are analysed in a timely manner, accompanied by clinical interpretations, and then fed back to relevant individuals and/or entities to ensure that appropriate action occurs (for detailed requirements specifications refer to ***Australian CQR Logical Design and Infrastructure Guideline (Attachment 1)***.

The CQR should aim to provide population-level data regarding the natural history and clinical outcomes of particular diseases and interventions. In routine reports to hospitals and clinicians, the CQR may provide:

- The proportion of eligible patients participating in the registry against a target indicator
- Participant (cohort) information, including comparison of cohort characteristics
- Activity information regarding participant numbers, procedures
- Clinical outcomes (efficacy and adverse events)
- Trends in the above, over time
- Descriptive reporting of variation in process or outcome measures
- Benchmarking
- Patient-reported measures, if collected, and trends over time
- Clinical quality indicators including performance against standards of care/guidelines
- Survival/mortality indicators if appropriate
- Data completeness
- Recommendations for improvement for the participating health service about data quality.

The CQR routinely analyses data and provides timely reports to clinicians and relevant stakeholders. Depending on the capacity and focus of the CQR, analysis and reporting also may include:

- Assessment of outcome data against minimum procedure volume
- Post-market surveillance of devices and of new and existing technologies where relevant
- Cost effectiveness assessment, cost-utility and cost-benefit
- Annual clinical and corporate outcomes.

To support reporting requirements, CQR staff should be able to generate routine standard reports that can be sent to identified institutions and clinicians or made available to authorised users, including CQR and technical staff, through a secure portal or uploaded into the database. In addition, registries may allow authorised users in participating units/institutions and jurisdictions to produce centrally configured reports of their own data.

> **Guidance on specific requirements for the provision of regular provider reports is contained in *Australian CQR Logical Design and Infrastructure Guideline (Attachment 1)*.**

## Regular public reporting

To drive innovation and impact in a self-improving health system, the National Strategy encourages CQRs to contribute to national reporting, including appropriate public reporting.

In addition, CQRs are expected to develop and publish a public-facing Annual Report to increase consumer access to CQR information.

The CQR is encouraged to apply best-practice approaches to preparing public-facing reports, and to consult with consumers and clinicians to determine the most suitable and useful formats for public reports and accompanying communications.

The CQR is required to make reports available and accessible to the public, but it is not the responsibility of the CQR to action the findings from the reports.

## Ad-hoc reports

Access to a contributor's data and associated reports can act as a strong incentive for participation in a registry. In addition, many professional societies have performance review and measuring practice outcomes as part of their Continuing Professional Development (CPD) platforms.

Accordingly, the CQR system should enable participating clinicians, hospitals, health service organisations and jurisdictional health departments to undertake ad hoc analyses of their own data. Authorised users should be able to define parameters, such as date ranges, filter criteria, and sort criteria. Secure access for authorised users to this ad-hoc reporting function should be enabled via a secure web interface.

> **Guidance on specific requirements for the provision of ad-hoc reports is contained in *Australian CQR Logical Design and Infrastructure Guideline (Attachment 1)*.**

## Authorised provision of data

The CQR should be able to export unit record data for approved purposes such as:

- Secondary use of data for research, once the necessary approvals have been obtained
- Use in statistical software packages to support complex data analysis.

The CQR system should be able to record authorisation details when providing identifiable information to external parties and the purpose for which the information is to be used.

Notwithstanding the need to secure approvals for secondary use of data, where relevant, it is acknowledged that the CQR makes its own determinations regarding the release of data

> **Guidance on specific requirements for the authorised provision of data is contained in *Australian CQR Logical Design and Infrastructure Guideline (Attachment 1)*.**

# Reporting checklist

**This checklist can help CQRs align their current reporting capabilities with the best-practice national guidance.**

**Overall**

- ☐ Is reporting carried out in the most timely manner possible?
- ☐ Is the analysis of data accompanied by clinical interpretations of the findings?
- ☐ Does the CQR have in place a structured clinical governance process for peer review of statistically significant outliers and any unwarranted variation?
- ☐ Where significant outliers and/or unwarranted variation are identified, does the CQR make recommendations for the provider?
- ☐ Does the CQR have processes and capacity to provide stakeholders with additional analysis and ad hoc reports, on request, within a reasonable period of time?

**Regular reports**

- ☐ Are CQR staff able to generate routine reports and send them to authorised users through a secure portal, or by uploading to the database?
- ☐ Are participating units/institutions able to generate regular reports of their own data?

**Ad hoc reports**

- ☐ Are participating hospitals, health service organisations and jurisdictional health departments able to generate ad hoc reports of their own data using their own parameters and criteria?

**Authorised provision of data**

- ☐ Is the CQR able to export unit-record data for approved purposes?



# Data-driven healthcare improvements

Reports by CQRs support the development of a continuously improving health system in a number of ways, including:

- Supporting the development and application of benchmarking
- Collecting information about patient outcomes and experience through PRMs
- Tracking trends in clinical care over time
- Identifying variations in processes or outcomes, compared to peers or evidence-based guidelines and standards of care, described as 'healthcare variation'
- Recording the unique details about medical devices (i.e. Unique Device Identification) to more easily and quickly identify device revisions
- Identifying health service organisations or clinicians whose performance deviates from the established benchmark in a significant way, described as 'outliers'.
- Providing feedback on data completeness to highlight gaps in the quality of data.

## Identifying outliers

CQRs should have an effective outlier policy in place that provides opportunities for CQRs to support quality improvement and minimise risks to patients. The policy should state who the policy is for and/or applicable to, and why the policy is needed (the purpose and aim of the policy). It should be developed in consultation with participating clinicians, health service organisations and jurisdictional health departments. It should also identify the processes by which potential outliers will be made known to health service organisations and/or other relevant stakeholders. Oversight of outlier measurement by the CQR's governing body is highly recommended.

The goal of outlier measurement is to rapidly identify situations where patients may be possibly exposed to harm. Each CQR should determine its approach to outlier measurement, as appropriate for its clinical focus and the nature of the data it collects.

> **More on best-practice approaches to outlier measurement is provided in *Appendix B: Approaches to outlier measurement*.**

Responses to the outliers identified by CQRs are managed by the jurisdictional health department or health service organisation, or, where appropriate, peers and medical colleges. Responses to outliers can help drive a self-improving health system in two ways:

- Clinicians or health service organisations identified as having consistently excellent performance can be encouraged to share their best-practice processes so others can learn from them
- Clinicians or health service organisations associated with persistent and significant unwarranted variation can be supported to improve their performance.

It is acknowledged that CQRs can play a role in connecting participating hospitals, health service organisations and jurisdictional health departments for the purpose of shared learning and quality improvement. This accelerates improvements in quality and can advance peer-informed clinical practices. CQRs are strongly encouraged to offer this platform for knowledge exchange and continuous improvement of healthcare delivery.

## Identifying unwarranted variation

The value of monitoring healthcare variation is reflected in the ***NSQHS Standards***.[24] Under the ***NSQHS Clinical Governance Standard: Action 1.28***, variation in clinical practice requires health service organisations to have systems in place that use data to monitor

variation in care to identify unwarranted variation and to regularly review and improve the appropriateness of clinical care.

Conducting analyses that identify performance that is significantly different from the average is one way to identify variation in the safety and quality of healthcare.

The role of CQRs is to generate risk-adjusted reports in a timely manner and provide them to health service organisations, clinicians, jurisdictional health departments, funders, clinical colleges, and researchers, to identify significant variance and to benchmark nationally and internationally. It is the role of health service organisations to implement safety and quality improvements.

**More information on monitoring unwarranted variation is provided in the *NSQHS Standards User Guide for the Review of Clinical Variation in Health Care*.**[25]

## Developing a CQR outlier policy

CQRs provide opportunities for data-driven healthcare improvement by enabling health service organisations to regularly review their data completeness and quality; their clinical activity; their clinical practice compared with their peers; their relative performance in relation to quality measures, and performance in relation to standards of care and national clinical targets.

In instances where CQRs monitor high-risk, high-volume activities, the prompt identification of outliers is critical in order to minimise the potential risk to patients. An overview of the key components of a CQR outlier policy is provided below.[26]

- **Governance of outlier identification and management**
  The CQR outlier policy identifies who is involved in the process of outlier analyses and management of a potential outlier. This involves documenting responses to the following questions:
  - Who is responsible for the analysis and reporting of the submitted data for clinical care and outcomes of care?
  - Who is notified when data suggests a health service organisation or clinician is identified as a potential outlier, and that additional analysis may be required?
  - Who is responsible for reviewing the outlier analysis report, including acceptance of findings and finalises the report?
  - Who is provided with the final outlier analysis report?
  - Who is responsible for addressing confirmed outlier issues?
  - Who is responsible for following up that outlier issues have been addressed?
- **Choice of performance indicators**
  The CQR outlier policy identifies the performance indicators that will inform the type of data used for the outlier analyses. These should:
  - Provide a valid measure of a health service organisation's quality of care
  - Be in use or endorsed at a national or jurisdictional level, or by specialist medical colleges and societies, to allow for comparisons across health service organisations
  - Be selected with input from clinicians, consumers, healthcare professionals, medical colleges, policymakers and the public to help ensure relevance for a range of stakeholders
  - Be feasible to collect from a reliable data source
  - Be of sufficient incidence that they can be meaningfully measured with the volume and frequency of data available
  - Be reviewed at least annually by the organisation's management/ steering committee.

Patient-reported measures that capture patients' perspectives on care experiences and health outcomes should also be considered a valuable component of outlier measurement.

**For further information about selecting PROMs, see the list of validated condition-specific PROMs on the Commission's website.**

**For more information on patient-reported indicators and the use of PROMs and PREMs see *Appendix A: Patient-reported measures*.**

- **Defining the expected performance level (target)**
  The CQR outlier policy defines the expected target for an indicator in reference to either:
  - External sources such as Clinical Care Standards and guidelines, performance indicators, research evidence or clinical consensus
  - Internal sources, that is, using data to compare hospitals against peers.
- **Assessment of data quality**
  The CQR outlier policy describes how the data used in the outlier analyses is validated. This includes reporting on the following three aspects of data quality, ideally at both a site level and a national level:
  - Case ascertainment: the number of patients included in the analyses compared to the number eligible
  - Data completeness: presented as a proportion of non-missing values of fields containing information on performance indicator data and data on patient characteristics required for case-mix adjustment
  - Data accuracy: tested internally using consistency and range checks within the available datasets and, if feasible, externally through comparison with another data source or peer review.
- **Risk adjustment (case-mix adjustment)**
  The CQR outlier policy specifies the use of a risk adjustment (case-mix adjustment) model to identify whether differences between health service organisations are due to variations in care, or can be attributed to differences in factors related to the disease, or to the mix of patients seen by different health service organisations. The factors with the highest association with outcomes should be included in the risk adjustment model.
- **Reliability adjustment**
  For small-volume health service organisations and/or health conditions, the CQR outlier policy should also consider establishing a reliability adjustment. Reliability is a measure of imprecision. When sample sizes are small, the observed rates may be due to chance and may be less precise compared with rates based on larger sample sizes.
- **Defining and detecting a potential outlier**
  The CQR outlier policy establishes a definition for an outlier based on statistically derived limits of acceptable performance. These are typically defined as a range of values that are within three standard deviations from the target value.
- **Management of a potential outlier**
  The CQR outlier policy establishes an agreed process, endorsed by the CQR leadership group, that will be followed if a persistent outlier clinician or health service organisation is identified. The process should identify who is notified of a potential outlier and who is involved in the management of the potential outlier. This aims to ensure that the results are made known to the health service organisation, and that they are provided with support in understanding their data as part of investigating the potential cause of the variation.

**See Appendix B: Approaches to outlier measurement for more guidance on outlier measurement and policy development including an example of the stages of managing a potential outlier at the alarm level.**

# Outlier policy development checklist

**It is recommended that CQRs have a specific outlier policy that describes how they operationalise the national outlier guidance (previously summarised), and provided in detail in *Appendix B*. The policy should be approved by the CQR governing body, include a time frame for review and be available publicly (published on the CQR's website). The checklist below is provided to help align the policy with the national guidance.**

**Oversight**

- ☐ Does the policy identify governance arrangements for the process of outlier analyses and management?
- ☐ Does the policy describe the time frames, notification and escalation stages for running the outlier process?

**Performance indicators**

- ☐ Does the policy identify performance indicators that provide a valid measure of the safety and quality of care?
- ☐ Were the performance indicators selected with input from clinicians, consumers, healthcare professionals, medical colleges, policymakers and the community?
- ☐ Will any additional metrics collected be applied to an outlier analysis; if not, has an explanation been provided?

**Performance targets**

- ☐ Does the policy specify performance targets based on valid external or internal sources?

**Data quality**

- ☐ Does the policy describe how the data will be validated in terms of case ascertainment, data completeness and data accuracy?
- ☐ Does the policy describe which specific patient cohort the policy applies to (for example, xx audit round, patients diagnosed from YYYY–YYYY)?
- ☐ Does the policy describe what will happen when issues with data quality or completeness prevent a health service organisation from having a conclusion drawn about its outlier status?

**Risk adjustment**

- ☐ Does the policy apply risk adjustment approaches to account for differences in the mix of patients?

**Reliability adjustment**

- ☐ Does the policy apply reliability adjustment approaches to account for small sample sizes?

**Outlier definition and detection**

- ☐ Does the policy describe the metrics that will be subject to an outlier analysis?

**Outlier management**

- ☐ Does the policy describe the process to be followed in response to a persistent outlier?
- ☐ Does the policy describe where the results of the outlier analysis will be published (for example, the annual report)?
- ☐ Will the terms 'alert' and 'alarm' be adopted?
  - If yes, what metrics does the policy use to define alerts and alarms respectively?
  - If no, does the policy explain how limits of expected performance will be defined and the reasoning for an alternative approach?
- ☐ Does the policy provide recommendations to the outlier on investigating their outlier status?

# Logical architecture and design

**The purpose of the *Australian CQR Logical Design and Infrastructure Guideline (Attachment 1)* is to provide an overview of the functionality and system requirements of a CQR. The document describes the infrastructure that would support CQR information design, and the data model and generic business functions of CQRs.**

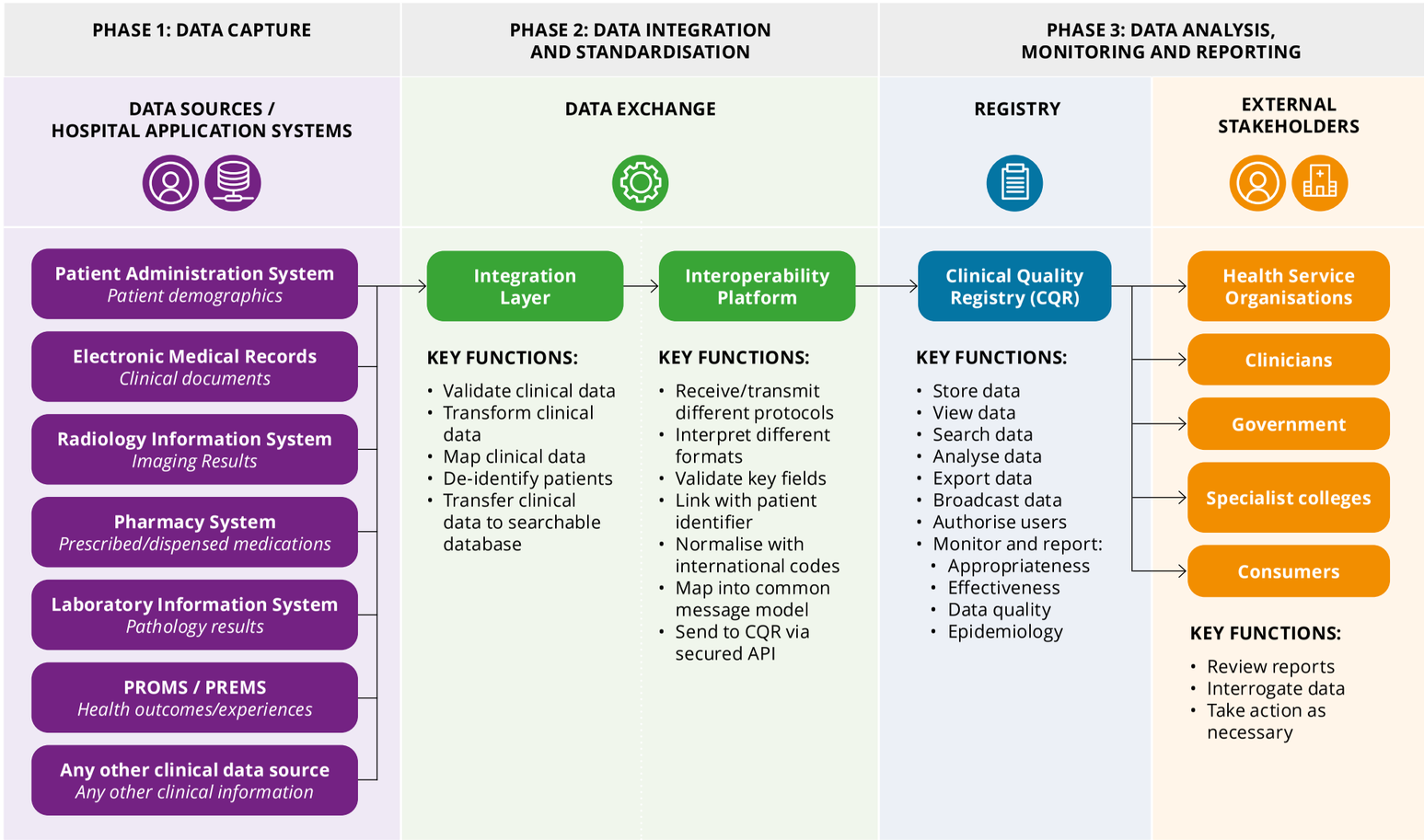
This document presents the logical design for CQRs regardless of operating model:

- *Section 2:* describes the generic business functions of a CQR that are supported by the design
- *Section 3:* considers solution architectures and describes a technology agnostic view of the solution that constitutes a CQR system
- *Section 4:* proposes an information design, providing a data model and data dictionary for common aspects of CQRs and guidelines for how condition-specific aspects can be modelled for consistency
- *Section 5:* provides definitions, acronyms and abbreviations
- *Section 6:* provides the software industry standards, core information model and data dictionary.

Figure 6 illustrates the phases of CQR data capture and reporting at the level of the health service organisation based on the integration of the electronic medical record with other clinical datasets to generate more uniformly structured data for monitoring variation in clinical practice in specific populations.

**For more information see *Australian CQR Logical Design and Infrastructure Guideline (Attachment 1)*.**

**Figure 6:** Phases of CQR data capture and reporting



# Security compliance

**The purpose of the *Australian CQR Security Compliance Guideline (Attachment 2)* is to provide guidelines that aid CQR operators in meeting security requirements. This Guideline is intended to support CQR operators (and third-party hosting organisations on behalf of the CQR operator) to evaluate their adherence to security standards and techniques, current in February 2024. It is intended to serve as a resource for internal review and drive maturity enhancement of CQRs over time.**

The Guideline builds on the work of the Australian Digital Health Agency's ***National eHealth Security and Access Framework – v4.0*** (NESAF) which provides guidance for the Australian healthcare sector and businesses to build and implement secure systems that protect patient data and e-health related assets, while providing the provenance needed to ensure patient safety and privacy:[27]

- *Section 2:* defines the key elements of information security and outlines some of the common threats to CQRs
- *Section 3:* outlines risk profiles for Clinical Quality Registries
- *Section 4:* 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:* provides checklists to help CQRs assess their security practices across a number of key security domains for minimum 'recommended practice' requirements
- *Section 6:* provides guidance from the Office of the Australian Information Commissioner (OAIC) on how to respond to data breaches.

The information held by CQRs is a core health data asset. The protection of this asset in terms of its confidentiality, integrity and availability is the focus of information security. These three key elements of information security are defined below.

> **For more information, see *Australian CQR Security Compliance Guideline (Attachment 2)*.**

**Table 2:** Elements of information security

| Element | Definition |
|---|---|
| Confidentiality | Refers to ensuring that information is only accessible and available to those authorised to have access. |
| Integrity | Refers to being able to store, use, transfer and retrieve information with confidence that the information has not been tampered with or altered, other than through authorised transactions. Information integrity also contributes to the maintenance of confidentiality through the protection of access control data, audit trails and other system data that enable the identification of breaches in confidentiality. |
| Availability | Ensures that information is accessible to authorised individuals when and where it is required. |



# Glossary

**Where appropriate, glossary definitions have been adapted to fit the context of the Framework.**

| Term | Definition |
|---|---|
| **Approving authority** | Approving authorities are public or private legal entities (institutions or organisations) where Clinical Quality Registries are conducted |
| **Australian Charter of Healthcare Rights** | Australian Charter of Healthcare Rights specifies the key rights of patients when seeking or receiving healthcare services. The Charter was endorsed by Health Ministers in 2008 and updated in 2019.[28] |
| **Australian Open Disclosure Framework** | The Australian Open Disclosure Framework was endorsed by Health Ministers in 2013. It provides a framework for health service organisations and clinicians to communicate openly with patients when health care does not go to plan.[29] |
| **Benchmarking** | Benchmarking is **the process of measuring patient care and outcomes against other comparable healthcare organisations or practices.**[30] Risk-adjusted models must be applied to the data. |
| **Clinical governance** | Clinical governance is an integrated component of the corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services. It is the set of relationships and responsibilities established by a health service organisation between its governing body, executive, clinicians, patients and consumers, to deliver safe and quality health care. **Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe and high-quality health care.**[31] |
| **Clinical indicator** | A clinical indicator is a measure which can be used to evaluate the performance of a health service organisation or clinician. It is typically expressed in terms of numbers, rates, or averages and can be used to inform plans and strategies for improvements in safety and quality. |
| **Clinical leaders** | Clinical leaders are clinicians with management or leadership roles in a health service organisation who can use their position or influence to change behaviour, practice or performance. Examples are directors of clinical services, heads of units, clinical supervisors and CQR principal investigators. |

| Term | Definition |
|---|---|
| **Clinical quality outcomes datasets** | Clinical quality outcomes datasets are datasets that include a combination of clinical and patient-derived data for a particular clinical domain. This universal term is inclusive of Clinical Quality Registries (CQRs) and other mechanisms such as virtual registries (i.e. those that draw data from existing platforms, such as state-based Electronic Medical Records (EMRs) or data lakes and data warehouses), which are designed to report timely, actionable and risk-adjusted benchmarked data back to clinicians, health providers and other stakeholders for the purposes of quality improvement.[32] |
| **Clinical Quality Registry (CQR)** | Clinical Quality Registries (CQRs) are a specific type of clinical registry focused on routinely collecting and analysing health outcome data, and generating risk-adjusted reports, for the purpose of driving ongoing improvements in safety and quality. |
| **Clinical Quality Registry – high functioning/mature** | A high-functioning or 'mature' **Clinical Quality Registry** (CQR) is one:<br>▪ With strong governance arrangements in place<br>▪ With a data management system that complies with privacy and security requirements associated with personal health information<br>▪ With a high level of coverage of the relevant patient population<br>▪ That provides regular risk-adjusted, benchmarked feedback to clinicians<br>▪ That publicly reports fit-for-purpose information; and<br>▪ With policies in place to guide the identification and management of outliers and to respond to requests for access to CQR data.[33] |
| **Clinician** | A clinician is a healthcare provider, trained as a health professional, including registered and non-registered practitioners. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialled healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health practitioners, technicians, scientists and other clinicians who provide health care, and students who provide health care under supervision. |
| **Consumer** | A person who has used, or may potentially use, health services, or is a carer for a patient using health services. A healthcare consumer may also act as a **consumer representative**, to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes.[34] |
| **Consumer representative** | A health consumer who has taken up a specific role to provide advice on behalf of consumers, with the overall aim of improving health care. **A consumer representative is often a consumer member of a committee, project or event who voices consumer perspectives and takes part in co-design and/or decision-making on behalf of consumers.**[35] |



| Term | Definition |
|---|---|
| **CQR workforce** | The CQR workforce includes but is not limited to: clinical and non-clinical managers, data managers, statisticians, registry investigators and registry coordinators. The workforce can be members of the CQR organisation or those providing technical support who have assigned roles and responsibilities for care of, administration of, support of, or involvement with, patients in the health service organisation or CQR contributing site. |
| **Data custodian** | The data custodian is the organisation or agency responsible for the safe and appropriate collection, management and release of data. The data custodian has legal and ethical obligations to maintain the confidentiality of the data entrusted to them. |
| **Data lake** | A data lake is a repository that stores large volumes of structured and unstructured data, including unprocessed data, from a variety of sources. Virtual registries commonly make use of repositories such as data lakes (and data warehouses) to maximise the secondary use of data and link together existing datasets to deliver a comprehensive picture of the patient journey. |
| **Data owner** | In Australia, in the context of medical records, the data owner is the hospital, doctor or other health professional who created and maintains the medical record (although patients have a right to access the data in their records). The ownership of aggregated data is a more complex consideration, and is likely to be determined by the contracts, partnerships and/or funding models in place. |
| **Data warehouses** | A data warehouse is a repository that stores large volumes of processed data. Virtual registries commonly make use of repositories such as data warehouses (and data lakes) to maximise the secondary use of data and link together existing datasets to deliver a comprehensive picture of the patient journey. |
| **Electronic Medical Records (EMR)** | Electronic Medical Records (also known as Electronic Health Records) store health information in a secure digital system. They are a digital version of notes that used to be kept in paper form. |
| **Governance** | **Governance is a set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers).** Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal and HR) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of the different participants in the organisation to achieve the organisation's objectives.[36] |

| Term | Definition |
|---|---|
| **Governing body** | The governing body is the legal public entity which has ultimate responsibility for the governance of the CQR. The structure of the governing body depends on the size, maturity and complexity of the CQR. Typically, the structure includes:<br>▪ A leadership group which undertakes the work of the governing body, including defining the purpose and intended outcomes of the CQR, and overseeing its operations<br>▪ One or more advisory groups providing current knowledge, critical thinking and analysis to help the CQR gain new insights, and advance the progress of the CQR through leadership, innovation and expertise<br>▪ An optional management group, responsible for implementing the strategic direction set by the governing body. It is responsible for ensuring that the CQR operating principles are met<br>▪ An operational group of clinical and non-clinical staff, responsible for implementing the Framework and delivering a high-quality service in a safe environment. |
| **Health care** | **Health care** is the prevention, treatment and management of illness and injury, and the preservation of mental and physical wellbeing through the services offered by clinicians, such as medical, nursing and allied health[37] professionals.[38] |
| **Health literacy** | The Australian Commission on Safety and Quality in Health Care separates **health literacy** into two components – individual health literacy and the health literacy environment. The health literacy environment is the infrastructure, policies, processes, materials, people and relationships that make up the health system, which affect the ways in which consumers access, understand, appraise and apply health-related information and services.[39] |
| **Healthcare record** | Healthcare record includes a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care. |
| **Health service organisation** | A separately constituted health service organisation that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. It can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms. |
| **Incident** | An incident (clinical) is an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may also be a near miss. See also *near miss*. |



| Term | Definition |
|---|---|
| **Indigenous** | The term 'Indigenous' refers to Australia's First Peoples, Aboriginal and Torres Strait Islander peoples. |
| **Individual Healthcare Identifier (IHI)** | An Individual Healthcare Identifier (IHI) is a unique 16-digit number used to identify an individual for healthcare purposes. IHIs provide a way for healthcare providers to match the right records to the right person. A healthcare identifier record includes basic information about a person, such as their name, date of birth and gender. It may also include a person's address, Medicare number, Department of Veterans' Affairs file number and, if relevant, aliases. |
| **Interoperability** | Interoperability is the ability to transfer data within and between systems or products without special effort on the part of the user. The main goals of healthcare interoperability are to support safe, secure, efficient, quality care through a connected healthcare system that conveniently and seamlessly shares high-quality data with the right people at the right time. |
| **Jurisdictional requirements** | Jurisdictional requirements are those **systematically developed statements from state and territory governments about appropriate healthcare or service delivery for specific circumstances**. Jurisdictional requirements encompass a number of types of documents from state and territory governments, including legislation, regulations, guidelines, policies, directives and circulars. Terms used for each document may vary by state and territory.[40] |
| **Leadership** | **Leadership** is having a vision of what can be achieved, and then communicating this to others and evolving strategies for realising the vision. Leaders motivate people and can negotiate for resources and other support to achieve goals.[41] |
| **Local community** | The local community are those people living in a defined geographic region or from a specific group who receive services from a health service organisation. |
| **National health information arrangements** | National health information arrangements are the mechanism by which jurisdictions can authorise CQRs to use record-level data for the purpose of measuring, monitoring and reporting on the safety and quality of care within high-priority clinical domains. The intention is to enable CQRs to generate information that can be used to establish benchmarks, identify areas of significant variation in outcomes, and inform improvements in healthcare quality and safety within those domains. |
| **Near miss** | An **incident or potential incident** that was averted and did not cause harm but had the potential to do so.[42] |
| **Organisation-wide** | Organisation-wide is intended for use throughout the health service organisation. |

| Term | Definition |
|---|---|
| **Outcome** | Outcome is the status of an individual, group of people or population that is wholly or partially attributable to an action, agent or circumstance.[43] |
| **Outlier** | An outlier is a health service organisation or clinician whose performance is identified as deviating from the established benchmark in a significant way. It is the CQR's responsibility to measure, monitor and report on outliers. Management of outliers is the responsibility of the CQR's funder and/or the relevant jurisdictional health department. |
| **Partnership** | Partnership is a situation that develops when patients and consumers are treated with dignity and respect, when information is shared with them, and when participation and collaboration in healthcare processes are encouraged and supported to the extent that patients and consumers choose. Partnerships can exist in different ways in a health service organisation, including at the level of individual interactions; at the level of a service, department or program; and at the level of the organisation. They can also exist with consumers and groups in the community. Generally, partnerships at all levels are necessary to ensure that the health service organisation is responsive to patient and consumer input and needs, although the nature of the activities for these different types of partnership will vary depending on the context of the health service organisation. |
| **Participant** | A participant is a CQR subject, patient or consumer who is enrolled to participate in a CQR. |
| **Patient** | A patient is a person who is receiving care from a health service organisation. |
| **Patient Reported Experience Measure (PREMs)** | Instruments used to capture patients' experience of receiving treatment and care. The Beryl institute defines patient experience as 'the sum of all interactions, shaped by an organisation's culture, that influence patient perceptions across the continuum of care'. PREMs provide a systematic way to assess a person's perception of whether something that should happen during their care actually happened or how often it happened. For example, whether their concerns were listened to and whether the staff communicated with each other about their care. People receiving care have a unique perspective on the day-to-day running of a healthcare service and how this affects them. Evidence suggests that good experiences of care are associated with good clinical and quality of life outcomes. Healthcare services can use PREMs to identify specific areas for improvement. |
| **Program** | A program is an initiative or series of initiatives designed to deal with a particular issue, with resources, a time frame, objectives and deliverables allocated to it. |



| Term | Definition |
|---|---|
| **Patient-reported outcome measure (PROM)** | Instruments that are used to measure patient-reported outcomes, most often through self-reported questionnaires. A patient-reported outcome is defined as 'any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else'. PROMs focus on various aspects of health, such as symptoms, daily functioning, and quality of life. PROMs are usually measured on two or more occasions to enable comparisons over time. PROMs facilitate measurement of the impacts of health conditions and treatments. Insights from using PROMs can be used alongside with relevant clinical information to gain a broader understanding of a person's health. |
| **Protocol** | A protocol is a detailed plan that includes the purpose and procedures of the research and who can be part of the research. The protocol provides the rationale, design, methodology for the CQR, population inclusion and exclusion criteria, the data collected, quality indicators, method of analysis, and monitoring of data safety and quality. |
| **Quality improvement** | Quality improvement is the combined efforts of the health workforce and others – including consumers, patients and their families, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care), and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or on a continual basis.[44] |
| **Research** | Research includes investigation undertaken to gain knowledge and understanding or to train researchers.[45] |
| **Risk** | Risk is the chance of something happening that will have a negative or positive impact. Risk is measured by the consequences of an event and its likelihood. |
| **Risk adjustment** | Risk adjustment is a statistical process that accounts for factors beyond the control of the healthcare team. CQRs apply risk-adjustment processes to data in order to generate more accurate comparisons, and to inform the appropriate definition of benchmarks. |
| **Risk assessment** | Risk assessment is the assessment, analysis and management of risks. It involves recognising which events may lead to harm in the future, and minimising their likelihood and consequence.[46] |
| **Risk management** | Risk management is the design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation. |

| Term | Definition |
|---|---|
| **Safety culture** | Safety culture is a commitment to safety that permeates all levels of an organisation, from the clinical workforce to executive management. Features commonly include acknowledgement of the high-risk, error-prone nature of an organisation's activities; a blame-free environment in which individuals are able to report errors or near misses without fear of reprimand or punishment; an expectation of collaboration across all areas and levels of an organisation to seek solutions to vulnerabilities; and a willingness of the organisation to direct resources to deal with safety concerns.[47] |
| **Standard** | A standard represents the agreed attributes and processes designed to ensure that a product, service or method will perform consistently at a designated level.[48] |
| **System** | The system is the resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. A system:<br>▪ Brings together risk management, governance and operational processes and procedures, including education, training and orientation<br>▪ Deploys an active implementation plan; feedback mechanisms include agreed protocols and guidelines, decision support tools and other resource materials<br>▪ Uses several incentives and sanctions to influence behaviours and encourage compliance with policy, protocol, regulation and procedures.<br>The workforce is both a resource in the system and involved in all elements of systems development, implementation, monitoring, improvement and evaluation. |



# Abbreviations

| Abbreviation | Full name |
|---|---|
| DATA | Data Availability and Transparency Act |
| EMR | Electronic Medical Record |
| IHI | Individual Healthcare Identifier |
| LHD/LHN | Local Health District/Local Health Network |
| METEOR | Metadata Online Registry |
| NESAF | National eHealth Security and Access Framework |
| NHDD | National Health Data Dictionary |
| NHIA | National Health Information Agreement |
| NHMRC | National Health and Medical Research Council |
| NHRA | National Health Reform Agreement |
| NMDS | National Minimum Data Sets |
| ONDC | Office of the National Data Commissioner |
| PRMs | Patient-Reported Measures |
| PREMs | Patient-Reported Experience Measures |
| PROMs | Patient-Reported Outcome Measures |
| TGA | Therapeutic Goods Administration |

# Acknowledgements

**Many individuals and organisations have freely given their time and expertise in the development of this document. In particular, the Commission wishes to thank the Clinical Quality Registries Framework Review Advisory Group and other key experts who have given their time and advice. The involvement and willingness of all concerned to share their experience and expertise is greatly appreciated.**

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A number of Commission staff were also involved in the writing and review of this publication. The Commission wishes to acknowledge the following staff members.

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# Appendix A: Patient-reported measures

Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are questionnaires that enable patients to report on outcomes relating to their health and wellbeing, and their healthcare experiences.

- PROMs focus on various aspects of health, such as symptoms, daily functioning, and quality of life. PROMs facilitate measurement of the impacts of health conditions and treatments. Insights from using PROMs can be used alongside with relevant clinical information to gain a broader understanding of a person's health.
- PREMs focus on capturing patients' experience of receiving treatment and care. PREMs provide a systematic way to assess a person's perception of whether something that should happen during their care happened or how often it happened. For example, whether their concerns were listened to and whether the staff communicated with each other about their care.

The use of PROMs in CQRs is an emerging area. Each CQR should determine whether the collection of PROMs is relevant and feasible, in the context of its focus and purpose. PROMs are often culturally contingent and may not be validated for use by culturally and linguistically diverse groups and Aboriginal and Torres Strait Islander people.

Where the CQR has determined that collecting and reporting on PROMs is appropriate, it should seek to align with existing PROM guidelines and tools. It should also seek to integrate and coordinate the collection of PROMs with jurisdictional health departments and other partners, in order to minimise duplication and reduce the burden on patients.

> **For further information about best practice implementation of PROMs, including examples of current implementation, advice on PROMs selection and the list of validated PROMs, see Patient-reported outcome measures on the Commission's website.**

### Collecting and reporting on PROMs

PROMs are usually measured on two or more occasions to enable comparisons to be made over time. They typically have questions that patients respond to using rating scales.

There are three general types of PROMs:

- Generic PROMs that measure aspects of health common to most patients and can be used across a range of conditions and populations
- Condition-specific PROMs that have questions relating to specific health conditions and their associated treatments. These can be used as a complement to generic PROMs
- Population-specific PROMs that apply to specific service sectors or segments of the population. These can be used as a complement to generic PROMs.

### Collecting and reporting on PREMs

Patients have a unique perspective on the day-to-day running of a health service and how this affects them. Finding out what patients experienced during their treatment and care can help hospitals and healthcare providers to improve their services. The information collected from PREMs allows hospitals and healthcare services to identify where they could improve and how they might change.

Measuring patient experience is different to measuring patient satisfaction. Satisfaction is how patients felt about the events, while experience is about the events themselves – what happened and how often. The questionnaire is typically sent to patients after an episode of care has finished.

In Australia, collection of PREMs following an acute care encounter is routine in most public hospitals and private hospitals. There are a range of tools being used to collect patient-experience, including but not limited to the Australian Hospital Patient Experience Question Set developed by the Commission.

The use of PREMs in CQRs is an emerging area. Each CQR should determine whether the collection, or secondary use, of PREMs is relevant and feasible, in the context of its focus and purpose.

**For more information about best practice implementation of PREMs, including information on the Australian Hospital Patient Experience Question Set, see *Australian Hospital Patient Experience Question Set resources* on the Commission's website.**



# Appendix B: Approaches to outlier measurement

This guidance is drawn from the Healthcare Quality Improvement Partnership (UK) ***Outlier management for National Clinical Audits*** which provides a useful overview of the statistical approaches used for identifying potential outlying performance in health care.

The literature identified suggests using an 'alert and alarm system' as an example of defining potential outlier status. In this system, more than:

- Two standard deviations (but less than three standard deviations) from the target is defined as an 'alert'
- Three standard deviations is defined as an 'alarm'.[49]

Funnel plots allow for the size of an organisation to be accounted for when identifying outlier performance, recognising that natural variation will be present in smaller organisations and that it is not automatically a cause for action. Similarly, funnel plots place stricter requirements on larger organisations where natural variation between organisations should be less likely.

While funnel plots allow for the identification of organisations with unusually high or low performance (with respect to their peers) they are limited to a particular time period. Time series control charts may be useful in understanding how an identified organisation's current result compares to previous results.

Once an organisation's performance on a measure is classified as either 'alert' or 'alarm' (i.e. it is at least two standard deviations from the target) then an investigation management process should commence. An example process, based on that proposed in *Outlier management for National Clinical Audits* is summarised in Table 3 and Table 4.

Another example of a review process is provided in the Commission's resource ***Using hospital mortality indictors to improve patient care: A guide for Boards and Chief Executives.***[50] This process outlines an example for reviewing elevated or worsening hospital mortality by local health service organisations.

CQRs have an important responsibility to flag signals of variation in health outcomes. Health service organisations together with the jurisdictional/local health department, as required, lead any action to address outlier concerns.

**Table 3:** Example actions for outliers at the alert level (greater than two standard deviations but within three standard deviations of expected performance).

| Step | Action | Owner |
|---|---|---|
| 1 | The CQR should inform the participating site contact of all outliers at the alert level. However, unlike for alarm level outliers (see Table 4 below), a formal notification and escalation process for alert level beyond notification of the relevant HSO clinical team is not expected. | CQR |
| 2 | The expectation is that the HSO should use 'alert' information as part of their internal quality monitoring process. They should review alerts in a proactive and timely manner, acting accordingly to mitigate the potential risk of care quality deteriorating to the point of becoming an alarm level outlier. | HSO |

**Table 4:** Example actions for outliers at alarm level >3 standard deviations from expected performance

| Step | Action | Owner | Within working days |
|---|---|---|---|
| 1 | Health service organisations (HSO) with a possible performance indicator at alarm level require careful scrutiny of the data handling and analyses performed to determine whether:<br>■ *'Alarm' status not confirmed:*<br>• Data and results revised in CQR records<br>• Details formally recorded, and process closed.<br>■ *'Alarm' status confirmed*<br>• potential 'alarm' status:<br>• proceed to step 2 | CQR | 15 |
| 2 | Participating site contact informed about potential 'alarm' status and asked to identify any data errors or justifiable explanation(s). All relevant data and analyses by the CQR should be made available to the participating site contact. | CQR | 10 |
| 3 | HSO participating site contact to provide written response to CQR. | HSO | 20 |
| 4 | Review of HSO participating site contact response to determine:<br>■ *'Alarm' status not confirmed:*<br>• It is confirmed that the data originally supplied by the HSO contained inaccuracies. Re-analysis of accurate data no longer indicates 'alarm' status.<br>• Data and results should be revised in the HSO and CQR records including details of the healthcare provider's response.<br>• Details formally recorded, and process closed.<br>■ *'Alarm' status confirmed:*<br>• Although it is confirmed that the originally supplied data were inaccurate, analysis still indicates 'alarm' status;<br>or<br>• It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of 'alarm' status.<br>• proceed to step 5 | CQR | 25 |
| 5 | Contact HSO participating site contact of confirmed 'alarm' 3SD outliers and/or non-participation outliers and copied to HSO lead clinician and medical director. For 3SD outliers, all relevant data and statistical analyses, including previous response from the HSO lead clinician should be made available to the HSO lead clinician and medical director.<br>The HSO and Local Health District/Local Health Network (LHD/LHN) should confirm receipt of the notification. | CQR | 10 |
| 6 | The LHD/LHN advise that during their routine local engagement with the HSO, their review will:<br>■ Encourage HSO to identify any learning from their performance and provide the LHD/LHN with assurance that the HSO has used the learning to drive quality improvement<br>■ Ask the HSO how they are monitoring or plan to monitor their performance<br>■ Monitor progress against any action plan if one is provided by the HSO.<br>If an investigation (and subsequent actions) has been conducted at the HSO into an alarm outlier status, it is expected to be communicated to the LHD/LHN and CQR provider | HSO/ LHD/ LHN | 15 |
| | If no acknowledgement received, a reminder letter should be sent to the HSO medical director, copied to the CEO. | CQR | 15 |

| Step | Action | Owner | Within working days |
|---|---|---|---|
| 7 | The actions from their review would be published by the CQR alongside the annual report. If no acknowledgement received within 15 business days, CQR publishes alarm status in their annual reports or data publications online. | CQR | CQR publication report date |

**Table 5:** Non-participation

The following is proposed as the starting point for types of non-participation and how they may be regarded as part of the outlier process.

| Issue | Healthcare provider is responsible for non-participation | Reporting of results | Outlier process applied to metrics where provider is non-participant |
|---|---|---|---|
| HSO is eligible for at least one metric (and had eligible cases in the cohort) but has not participated in the registry data collection at all. (Complete non-participation) | Yes | Included in reporting with results flagged with 'Data not submitted by the HSO. HSO is included in the published non-participant list. | Yes* Provider should be treated as an alarm level outlier for all eligible metrics and followed up via standard processes with a note clarifying that status is due to non-participation. |
| HSO eligible for more than one metric (and had eligible cases in the cohort) but for one or some of these metrics has submitted no data. (Partial non-participation) | Yes | Included in reporting with specific metric results flagged with 'Data not submitted by the HSO'. HSO is not included in the published non-participant list. | Yes* Provider should be treated as an alarm level outlier for all eligible metrics where non-participant, and followed up via standard processes with a note clarifying that status is due to partial non-participation. |

*For non-participation, the Outlier process as outlined in Table 4 will start at step 5 with the HSO lead clinician being notified that their non-participation is to be flagged up to the HSO CEO and Medical Director and the Outlier process followed.



# Appendix C: Checklists for the Quality Standard for CQRs

## Governance checklist

**This checklist can help CQRs to align their current governance arrangements with the best-practice national guidance provided above.**

**Governing body function**

- ☐ Is the governing body a legal entity?
- ☐ Has the governing body defined the purpose of the CQR, and its intended outcomes?
- ☐ Has the governing body identified the relevant laws, regulations and jurisdictional guidelines and policies relating to the work of the CQR?
- ☐ Is it actively ensuring that the CQR complies with these?
- ☐ Does the governing body have clear and consistent practices in terms of what is communicated to whom, how, when and why?

**Governing body structure**

***Leadership group***

- ☐ Does the leadership group comprise a balance of individuals with expertise to support the functions of the CQR?
- ☐ Does it reflect a diversity of skills, ages, genders, backgrounds, cultures, and ethnicities, including groups that are historically disadvantaged or under-represented?

***Advisory group***

- ☐ Does the CQR have one or more advisory groups capable of providing knowledge, critical thinking and analysis to increase the confidence of CQR decision-makers?
- ☐ Is the advisory group made up of internal and external members, including consumers?

***Management group***

- ☐ If there is a management group, does it include a balance of clinical experts, technical experts and consumer representatives?
- ☐ Does it oversee an effective complaints-management system?

***Commonwealth, state and territory departments of health, and other funders***

- ☐ Are there mechanisms in place to enable a productive working relationship between the CQR and its funder?
- ☐ Are there processes in place to use the CQR outputs to inform healthcare safety and quality initiatives within the jurisdiction (regardless of the CQR funding source)?

## Data and quality systems checklist

**This checklist can help CQRs align their current health data safety and quality system capabilities with the best-practice national guidance provided above.**

**Data governance roles**

- ☐ Does the CQR have designated roles to ensure the good governance of the data held by the CQR?
- ☐ Has the CQR identified the data owner and the data custodian, consistent with the definitions previously provided?

**Data elements**

- ☐ Is the CQR collecting the data it needs to support its core purpose, including personally identifiable data where appropriate?
- ☐ Is the CQR taking action to minimise the identifiers collected, and the length of time they are stored in the CQR database?
- ☐ Is the CQR using indicators that have been clinically identified, and which align with the indicators published in any relevant Clinical Care Standards produced by the Australian Commission on Safety and Quality in Health Care and/or any relevant international registry, where relevant?
- ☐ Are clinical outcomes being assessed using objective measures where possible?
- ☐ Are PROMs being collected?

**Risk adjustments**

- ☐ Is the CQR applying risk adjustments to account for factors outside the clinicians' control?
- ☐ Are those risk adjustments transparent, and explained in detail in CQR reports?

**Data collection**

- ☐ Is the CQR operating in a way that optimises the use and reuse of health data for the benefit of the Australian public, in alignment with the National Strategy?
- ☐ Is the CQR making participants aware of the CQR, and providing them with sufficient information to make a decision about either consenting or opting-out of data collection?
- ☐ Is the CQR using data dictionaries to ensure a systematic approach to data entry?
- ☐ Are data dictionaries regularly reviewed in consultation with contributing jurisdictional health departments?
- ☐ Does the CQR have the capacity to integrate with other information systems?
- ☐ Does the CQR maximise the use of automated data collection systems?



## Reporting checklist

**This checklist can help CQRs align their current reporting capabilities with the best-practice national guidance.**

**Overall**

- ☐ Is reporting carried out in the most timely manner possible?
- ☐ Is the analysis of data accompanied by clinical interpretations of the findings?
- ☐ Does the CQR have in place a structured clinical governance process for peer review of statistically significant outliers and any unwarranted variation?
- ☐ Where significant outliers and/or unwarranted variation are identified, does the CQR make recommendations for the provider?
- ☐ Does the CQR have processes and capacity to provide stakeholders with additional analysis and ad hoc reports, on request, within a reasonable period of time?

**Regular reports**

- ☐ Are CQR staff able to generate routine reports and send them to authorised users through a secure portal, or by uploading to the database?
- ☐ Are participating units/institutions able to generate regular reports of their own data?

**Ad hoc reports**

- ☐ Are participating hospitals, health service organisations and jurisdictional health departments able to generate ad hoc reports of their own data using their own parameters and criteria?

**Authorised provision of data**

- ☐ Is the CQR able to export unit-record data for approved purposes?

## Outlier policy development checklist

**It is recommended that CQRs have a specific outlier policy that describes how they operationalise the national outlier guidance (previously summarised), and provided in detail in *Appendix B*. The policy should be approved by the CQR governing body, include a time frame for review and be available publicly (published on the CQR's website). The checklist below is provided to help align the policy with the national guidance.**

**Oversight**

- ☐ Does the policy identify governance arrangements for the process of outlier analyses and management?
- ☐ Does the policy describe the time frames, notification and escalation stages for running the outlier process?

**Performance indicators**

- ☐ Does the policy identify performance indicators that provide a valid measure of the safety and quality of care?
- ☐ Were the performance indicators selected with input from clinicians, consumers, healthcare professionals, medical colleges, policymakers and the community?
- ☐ Will any additional metrics collected be applied to an outlier analysis; if not, has an explanation been provided?

**Performance targets**

- ☐ Does the policy specify performance targets based on valid external or internal sources?

**Data quality**

- ☐ Does the policy describe how the data will be validated in terms of case ascertainment, data completeness and data accuracy?
- ☐ Does the policy describe which specific patient cohort the policy applies to (for example, xx audit round, patients diagnosed from YYYY–YYYY)?
- ☐ Does the policy describe what will happen when issues with data quality or completeness prevent a health service organisation from having a conclusion drawn about its outlier status?

**Risk adjustment**

- ☐ Does the policy apply risk adjustment approaches to account for differences in the mix of patients?

**Reliability adjustment**

- ☐ Does the policy apply reliability adjustment approaches to account for small sample sizes?

**Outlier definition and detection**

- ☐ Does the policy describe the metrics that will be subject to an outlier analysis?

**Outlier management**

- ☐ Does the policy describe the process to be followed in response to a persistent outlier?
- ☐ Does the policy describe where the results of the outlier analysis will be published (for example, the annual report)?
- ☐ Will the terms 'alert' and 'alarm' be adopted?
    - If yes, what metrics does the policy use to define alerts and alarms respectively?
    - If no, does the policy explain how limits of expected performance will be defined and the reasoning for an alternative approach?
- ☐ Does the policy provide recommendations to the outlier on investigating their outlier status?



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