Australian Commission on **Safety and Quality** in Health Care

Handbook November 2026

Australian Framework for National Clinical Quality Registries

CQR Framework Self-Assessment: reviewing and progressing implementation and maturity

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Contents

Introduction: About the self-assessment 4

Purpose of the CQR Framework Self-Assessment 5

Who this Self-Assessment is for 6

What the CQR Framework Self-Assessment covers 6

How to use this handbook: The self-assessment process 7

Step 1: Review the Quality Standard for CQRs 9

Step 2: Assess implementation status and maturity 9

Step 3: Plan improvements 10

Appendix 1: How to use the CQR Framework Self-Assessment monitoring tool 11

Overview of the Tool 11

CQR Framework Standards Checklist Worksheets 11

Checklist Summary 12

Highlights 12

Action Plan 13

CQR Outputs 13

Important notes 13

Appendix 2: CQR Framework summary of actions 14

Standard 1: Governance 15

Standard 2: Data and quality systems 23

Standard 3: Feedback and reporting 35

Standard 4: Data-driven healthcare improvements 40

Appendix 3: Overview of CQR outputs 44

Appendix 4: Overview of CQR functions 46

Additional information: How the CQR Framework Self-Assessment was developed 47

Acknowledgements 48

Your experience and feedback 49

INTRODUCTION

About the self-assessment

National Clinical Quality Registries (CQRs) make an important contribution to healthcare in Australia. By collecting, analysing and reporting health data, they help identify best practice, improve patient outcomes and support continuous quality improvement. CQRs provide clinicians, health service organisations and governments with the information they need to deliver high-quality care.

The Australian Commission on Safety and Quality in Health Care (the Commission) defines quality care as person-centred, safe, effective, accessible and integrated, provided in a way that is equitable, efficient and sustainable.[1] These eight interconnected domains provide a nationally consistent understanding of what quality care looks like and recognise that healthcare quality must be considered across multiple dimensions rather than through individual measures or outcomes alone. The National Model for Clinical Governance identifies these domains as the central objective of clinical governance systems and the foundation for achieving consistently high-quality and improving care.

The domains of quality care also provide an important foundation for a national approach to quality assessment and health system performance assessment. While quality assessment focuses on understanding the extent to which care delivered across the health system reflects the characteristics of quality care, health system performance assessment considers how effectively the health system is achieving its intended outcomes for patients, communities and populations. Together, these approaches support a more comprehensive understanding of healthcare quality and patient outcomes across Australia.

The National Model for Clinical Governance further reinforces the importance of measurement and evidence through Foundation 6, Using Data for Better Care. Foundation 6 recognises that timely, reliable and meaningful data are essential for understanding performance, monitoring outcomes, identifying unwarranted variation and driving improvement. Health systems require data not only to assure the quality of care, but also to support informed decision-making and continuous learning.

CQRs play a critical role at the intersection of these national frameworks. By generating clinically meaningful data and quality indicators, CQRs provide evidence that can be used to assess quality across the domains of high-quality care, support health systems in meeting their clinical governance responsibilities and contribute to broader health system performance assessment at local, jurisdictional and national levels. As healthcare becomes increasingly digital, data-driven and outcomes-focused, CQRs provide an important mechanism for transforming data

1 Australian Commission on Safety and Quality in Health Care. National Model for Clinical Governance. The foundations of high-quality care. ACSQHC; 2026

into actionable insights that support better care for patients and more effective stewardship of the health system.

As part of the Australian Government National CQR Program, the Commission published the Australian Framework for National Clinical Quality Registries 2024 (the CQR Framework[2]). The CQR Framework is a principles-based guide that outlines best practice for establishing and operating CQRs in Australia. It emphasises the role of CQRs in supporting and improving the quality of care while ensuring registry activities remain aligned with national priorities for quality assessment, clinical governance and health system performance.

Purpose of the CQR Framework Self-Assessment

To operate a high-quality, mature CQR, the CQR Framework sets the standards for best practice governance, data quality, measuring variation in care, and feedback and reporting to inform a learning health system. The Self-Assessment supports implementation of the CQR Framework as its quality assurance process.

The CQR Framework Self-Assessment is designed to help CQR operators:

- **Align registry practices with the CQR Framework quality standards**
  Provides a structured approach for registries to self-assess alignment of registry operations with the CQR Framework, with the goal of contributing to a learning health system
- **Assess registry maturity and identify opportunities for improvement**
  Enables registries to evaluate their current level of maturity on the maturity continuum and identify opportunities for strengthening best practices
- **Promote integrity and accountability**
  Enhances the integrity of CQR operators, reassures consumers of the registry's commitment to transparency and accountability, and provides a mechanism to demonstrate best practice
- **Implement the CQR Framework within the operating context**
  Encourages planning that accommodates each registry's operating arrangements while allowing flexibility in how the self-assessment is applied.

The CQR Framework Self-Assessment outlines practical actions and examples of evidence that registries can use to implement the CQR Framework in a way that suits their scope, operating environment and current level of maturity. The actions are structured to align with the CQR Framework quality standards, and to provide guidance for achieving consistency with the CQR Framework.

> "Overall, it is a really valuable tool that we plan to use to demonstrate our alignment with the CQR Framework, and maturity level, as well as having identified areas for improvement that we will work towards strengthening."
>
> ***Julie Morrison,*** *Program Manager, Australian Stroke Clinical Registry*

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

Who this Self-Assessment is for

The CQR Framework Self-Assessment is primarily designed for clinical registry operators implementing the CQR Framework. The self-assessment should be overseen by the legal entity for the registry, if different from the registry operator. The legal entity holds ultimate responsibility for the registry's quality and accountability. The self-assessment can be applied to all registry models in Australia, including aspiring CQRs.

Additional stakeholders may also find this self-assessment useful, including:

- Health service organisations (public and private) and government health departments, to inform decisions about engaging with CQRs and supporting local quality improvement initiatives
- Medical colleges and societies, and others interested in health system improvement, clinical practice variation and health outcomes
- Funders (public and private), to guide funding decisions and assessments.

What the CQR Framework Self-Assessment covers

The CQR Framework Self-Assessment focuses on the systems, processes and practices that support high-quality clinical quality registries.

The self-assessment is structured around the Quality Standard for CQRs, and the actions, grouped into domains, that indicate each standard is being met. Through the self-assessment process, registries can assess the extent to which actions are reflected in current practice, and gain an understanding of their current level of maturity.

The self-assessment is intended to support reflection, improvement planning and ongoing registry quality development. It does not prescribe how a registry should be designed or operated, and recognises that implementation will vary depending on a registry's scope, size, maturity and operating environment.

The CQR Framework Self-Assessment suite includes:

- The **CQR Framework Self-Assessment monitoring tool**, built in Microsoft Excel, which supports registries to document their self-assessment, record evidence, identify gaps and priorities, and plan improvements over time.
- This **CQR Framework Self-Assessment handbook** which includes:
  - step-by-step guidance on the self-assessment process
  - practical instructions for using the CQR Framework Self-Assessment monitoring tool (Appendix 1)
  - a summary checklist of the standards, domains and actions included in the self-assessment (Appendix 2)
  - an overview of registry outputs and a list of example outputs (Appendix 3)
  - a functional overview of CQRs, reproduced from the Australian Framework for National Clinical Quality Registries (2024) (Appendix 4).

Out of scope

It is acknowledged that there are actions that can't be addressed through the CQR Framework Standards alone and are beyond the direct scope of the standards such as funding arrangements, digital infrastructure and regulatory complexity. Actions relating to CQR finance and human resources are also out of scope for this self-assessment.

HOW TO USE THIS HANDBOOK

The self-assessment process

The CQR Framework Self-Assessment is a self-assessment designed to support registries as they progress toward becoming high quality and effectively contributing to a learning health system. It can be used at any stage of the CQR lifecycle to assess alignment with the CQR Framework. It can also be used to provide a cycle of assessment (for example annual self-assessment) for ongoing monitoring of the CQR Framework in practice. The CQR Framework Self-Assessment has the potential to be expanded upon or further developed as feedback is received from the sector on its use.

CQRs operate in diverse operational and technical environments so implementation of the CQR Framework may vary in practice. The self-assessment does not prescribe how to design or implement a registry. Instead, it describes the CQR systems and processes that should be in place for supporting a learning health system, while taking into consideration local operating arrangements and factors outside the registry's control.

Tips for using the CQR Framework Self-Assessment

The following tips can help ensure an efficient and meaningful assessment:

- **Tailor the process:** Not all actions or evidence types will apply to every registry; select Not relevant where appropriate on consideration of registry context
- **Consider context:** Requirements will vary depending on registry scope, size, maturity and infrastructure
- **Be practical:** Focus on evidence already produced through registry operations
- **Repeat the process annually:** Useful for tracking progress over time
- **Use the CQR Framework Self-Assessment monitoring tool:** It generates a summary of findings, tracks evidence, and visualises maturity.

Using the self-assessment in your context

The self-assessment is structured around the CQR Framework Standards, domains and actions. The actions and examples of evidence are intended as guidance to support registries in demonstrating alignment with the CQR Framework. They should be applied in a way that reflects the registry's context, operating arrangements and technical environment. Where an action does not apply, it can be marked as Not relevant.

The type and level of evidence will vary depending on the registry's context. The content and complexity of policies, processes and outputs will likely depend on the registry's scope, size,

current maturity, operating arrangements, and technical infrastructure. These factors may also influence the time required to complete the self-assessment.

What this self-assessment helps you do

The CQR Framework Self-Assessment is intended as a flexible, practical process to help CQR operators to evaluate, strengthen, and demonstrate registry quality in line with the CQR Framework. Specifically, it can assist registry operators to:

- Identify strengths and areas for improvement in relation to the CQR quality standards
- Inform action plans to enhance the registry quality and strengthen accountability.

Sharing findings from the CQR Framework Self-Assessment

CQR operators are recommended to share the findings from the self-assessment with key partners, including:

- Funders
- Health service organisations
- Government health departments
- Clinicians and allied health professionals
- Consumers.

Sharing these findings may foster collaboration, strengthen partnerships, and support stakeholders in using the CQR outputs to improve health care quality and better health outcomes.

There is no requirement to submit the findings to the Australian Commission on Safety and Quality in Health Care.

Key resources

- Australian Commission on Safety and Quality in Health Care. Australian Framework for National Clinical Quality Registries 2024.
- Australian Commission on Safety and Quality in Health Care. Australian Framework for National Clinical Quality Registries. Attachment 1 Australian CQR logical design and infrastructure guideline.
- Australian Commission on Safety and Quality in Health Care. Australian Framework for National Clinical Quality Registries 2024. Attachment 2 Australian CQR security compliance guideline.

Below is a simple, step-by-step guide to help you navigate the self-assessment process.

STEP 1

Review the Quality Standard for CQRs

Before you begin, familiarise yourself with the Quality Standard for CQRs. These are described in full in the Australian Framework for National Clinical Quality Registries 2024. A summary of the actions that demonstrate alignment to each standard is provided in Appendix 2.

The Quality Standard for CQRs aligns with the National Safety and Quality Health Service (NSQHS) Standards and includes the following components:

- Governance
- Data and quality systems
- Feedback and reporting
- Data-driven healthcare improvements.

Each standard contains a statement of intent and a set of actions that describe what is required to meet the standard, grouped into key domains. Use these to understand:

- what should be in place for each standard
- the types of evidence that demonstrate alignment with the standards.

Evidence may include governance documents, meeting minutes, standard operating procedures, data quality reports, risk assessments, or stakeholder feedback.

STEP 2

Assess implementation status and maturity

Use the CQR Framework Self-Assessment monitoring tool to assess and document the implementation status for each action across all four standards (see Appendix 1 for detailed instructions).

For each action:

- Identify supporting evidence (e.g., policies, reports, procedures, minutes)
- Select the appropriate implementation status:
  - **Developing** – Capability is in development
  - **Embedding** – Capability is developed and being integrated into practice
  - **Demonstrating** – Capability is established and operating in practice
  - **Not started** – No current activity
  - **Not relevant** – Action does not apply (provide reason)
- Document the registry's desired status for each action for the next self-assessment.

This step provides a clear view of current CQR practice and identifies areas requiring attention, forming the basis for improvement planning.

The self-assessment also provides insight into registry maturity. Maturity, in this context, refers to the extent to which registry practices are established, consistent, and able to deliver meaningful outputs and impact.

Each action within the self-assessment is aligned to a maturity level. When an action is assessed as **Demonstrating**, the corresponding maturity level is automatically identified within the CQR Framework Self-Assessment monitoring tool.

The maturity levels are represented in the rating scale below:

- **Foundational** – Supports best-practice CQR operation. Supports stakeholder engagement.
- **Functional** – Supports CQR quality assurance and accountability. Supports provider-level (health service organisation/clinician) participation.
- **Health system-enabling** – Supports provider-level (health service organisation/clinician) quality improvement and informs health-system level learning and quality improvement.

Maturity is not a score. It provides context for interpreting registry capability and helps guide improvement planning over time.

Additionally, the self-assessment allows registries to identify and document their outputs and outcomes, where appropriate. This can help registries better describe their value to stakeholders and assess whether their outputs are meaningful, useful, and aligned with stakeholder needs.

STEP 3

Plan improvements

Documenting current and desired implementation status in the self-assessment tool provides a clear snapshot of current practice and level of maturity, identifies gaps and priorities, and supports the development of a targeted action plan for continuous registry improvement.

The tool includes features to support this process, including:

- **Checklist Summary** – Provides a visual overview of results at the domain level
- **Highlights** – Summarises performance across both standards and domains, and captures the operating environment
- **Action Plan** – Provides space to document planned improvements, responsibilities, timeframes and priorities

The Action Plan can be used to support governance, reporting, and ongoing registry quality development.

APPENDIX 1

How to use the CQR Framework Self-Assessment monitoring tool

The CQR Framework Self-Assessment Monitoring Tool (the Tool) supports Clinical Quality Registry (CQR) operators to assess and monitor their alignment with the Australian Framework for National Clinical Quality Registries 2024 (CQR Framework). It should be used alongside the CQR Framework and the CQR Framework Self-Assessment handbook.

Completion of the Tool is recommended however it does not need to be submitted to the Australian Commission on Safety and Quality in Health Care. It is designed to support internal review, planning and continuous improvement.

Download the CQR Framework Self-Assessment Excel Monitoring Tool.

Overview of the Tool

The Tool includes the following worksheets:

- **CQR Framework Standards Checklist Worksheets**
- **Checklist Summary**
- **Highlights**
- **Action Plan**
- **CQR Outputs**

Each worksheet plays a specific role in supporting assessment, insight and improvement.

CQR Framework Standards Checklist Worksheets

There is one checklist worksheet for each of the four CQR Framework Standards. These worksheets are where registries can assess and document the extent to which they are implementing each action, supported by evidence. Completing the Standards Checklist Worksheets provides a detailed, action-level view of current practice, highlights gaps, and clarifies priorities for improvement. Each worksheet includes:

- the domains relevant to the standard
- the purpose of each domain
- the actions that demonstrate alignment with each domain
- examples of supporting evidence.

For each action, registries should:

- **Note supporting evidence** to assess implementation status of the action
- **Select the current implementation status** using the drop-down list or by typing directly (invalid entries will trigger an error message):
  - **Developing** – Capability is in development (Score: 1)
  - **Embedding** – Capability is developed and being integrated into practice (Score: 2)
  - **Demonstrating** – Capability is established and operating in practice (Score: 3)
  - **Not started** – No current activity (Score: 0)
  - **Not relevant** – Action does not apply (provide reason in the Evidence/Comments cell)
- **Select the desired implementation status** for the next assessment period

Where an action is rated as **Demonstrating**, the corresponding **maturity level** will automatically be identified as achieved within the CQR Framework Self-Assessment monitoring tool.

Checklist Summary

The Checklist Summary worksheet provides an automatically generated overview of results at the domain level, drawing directly from the checklist worksheets. It provides a quick, visual view of progress, helping registries identify patterns, strengths and areas requiring attention.

The main table displays percentage completion at the domain level. Percentage completion is based on the scores assigned to each action (see above) relative to the maximum possible score for that domain. In simple terms, it reflects how close the registry is to fully demonstrating all actions (where relevant) within a domain. For reference, percentage completion is calculated as:

$$\textit{\% completion} = \frac{\textit{Average score of each action under the domain}}{\textit{3 x number of actions under the domain}} \textit{ x 100}$$

Below this, a summary table provides an overview of the implementation status of actions within each standard.

Note, no data entry is required, and the worksheet is protected to maintain the integrity of the calculations.

Highlights

The Highlights worksheet provides a consolidated, high-level summary of results across the registry. It presents a snapshot of overall performance, supporting internal review, governance discussions and reporting.

The worksheet includes a section for registries to record the details of their operating environment, as well as a summary table with two components:

- The first component shows results at the domain level, and includes an overall result for each standard
- The second component presents a maturity summary, indicating the number of actions that are in place (Demonstrating rating) at each maturity level.

Note, summary data is automatically populated from the checklist worksheets, while operating environment information is entered by the registry.

Action Plan

The Action Plan worksheet is used to document planned improvements arising from the self-assessment. It serves as the Action Plan across all four CQR Framework Standards.

It includes fields to record:

- the relevant domain
- the corresponding action plan or comments
- responsible person or area
- due date and priority level (High, Medium or Low).

Registries can use this worksheet to capture the improvements required to address gaps, strengthen performance or progress priorities identified through the assessment. It provides a structured and accountable approach to improvement, supporting governance and ongoing registry quality development.

CQR Outputs

The CQR Outputs worksheet encourages registries to identify their outputs (and outcomes), intended recipients, frequency, and purpose. This can help registries better describe their value to stakeholders and assess whether their outputs are meaningful, useful, and aligned with stakeholder needs. For further information, see Appendix 3 Overview of CQR outputs.

Important notes

- Checklist worksheets are formatted for A3 printing to accommodate all columns and ensure readability.
- To ensure the Tool functions correctly:
  - Do not delete worksheets. You can hide non-essential worksheets.
  - Do not rename worksheets. This breaks hyperlinks.
  - Do not delete rows for hyperlinked cells. This breaks hyperlinks.
  - Do not delete hyperlinks. This breaks hyperlinks from that cell.
  - Do not sort columns. It affects the placement of hyperlinks.
  - Try not to overwrite the formula in the 'Estimated completion score' column (hidden). This happens when you manually change the percent value in that column. When this happens, the column is no longer linked with the 'Current implementation status' column.
  - Do not forget to back up your self-assessment tool.

APPENDIX 2

CQR Framework summary of actions

This appendix provides a summary of the domains and actions aligned with the four Quality Standards for CQRs described in the Australian Framework for National Clinical Quality Registries 2024.

The summary is intended as a reference resource to support understanding of the standards and the actions associated with each domain. The actions describe the systems, processes and practices that demonstrate alignment with the CQR Framework.

The appendix provides a standard-by-standard summary of:

- domains of registry quality
- actions associated with each domain
- examples of evidence that may demonstrate implementation.

At the end of the appendix, a summary table outlines the number of actions associated with each standard, by domain and maturity level. This reflects the understanding that registries operate at different stages of development and capability, and that actions support different levels of registry maturity.

A table showing the number of actions required within each standard, by domain and maturity level, is provided on page 42.

This summary should be used alongside the Australian Framework for National Clinical Quality Registries 2024.

This appendix is provided as a reference resource only, and is not intended as a working tool for self-assessment. Registries should use the CQR Framework Self-Assessment Excel Monitoring Tool developed by the Australian Commission on Safety and Quality in Health Care to document implementation status, record supporting evidence, identify gaps and priorities, and plan improvements over time.

STANDARD 1

Governance

Intention of Standard 1

CQRs implement the Australian Framework for National Clinical Quality Registries, have a health care quality improvement focus and engage with stakeholders to ensure the effectiveness of the CQR.

To meet the requirements in this standard, CQRs should:

- Establish and maintain a governance framework
- Have a clear rationale for operating
- Engage key stakeholders in its development and maintenance
- Implement policies and procedures to comply with jurisdictional legislation and requirements
- Define the roles and responsibilities of its staff.

Mapped to CQR Framework

Strategic Principles 1, 2, 3, 4 and Operating Principle 1: Organisation and Governance and Standard 1: Governance

DOMAIN 1.01

Governance, leadership and culture

Purpose

The CQR has an appropriate governance structure and processes that enable it to achieve its core purpose(s) and activities.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has in place a governing body that is responsible for the effective governance and management of the CQR.

b. The CQR is associated with a legal entity that has core functions such as financial management, legal advice, human resources management, data/information security and management, Occupational, Health and Safety (OH&S) policies.

c. The CQR governing body endorses, maintains and monitors a governance framework aligned to the Australian Framework for National Clinical Quality Registries, which is tailored to the scope, size, maturity and operating environment of the registry.

d. The CQR leadership group (or equivalent) reflects a diversity of skills, ages, genders, backgrounds, cultures, and ethnicities, including groups that are historically disadvantaged or under-represented.

e. The CQR advisory group is made up of internal and external members including consumers.

f. The CQR management group (or equivalent), includes a balance of clinical experts, technical experts and consumer representatives.

g. The CQR governing body evaluates the CQR's performance against its governance framework.

h. The CQR has one or more advisory groups capable of providing knowledge, critical thinking and analysis to increase the confidence of CQR decision-makers.

i. The CQR management group (or equivalent) oversees an effective complaints-management system.

j. Most key stakeholders in the CQR clinical area are aware of or collaborating in the CQR.

k. Subcommittees may be established for secondary purposes e.g. research.

Examples of evidence, including but not limited to:

- Policy documents that describe the:
  - governing body structure
  - roles and functions of the governing body
  - strategic, business or risk management plans that describe the priorities and strategic directions
  - processes for partnering with key stakeholders (including clinical, data custodians, government, funders, consumers, academics)
- Committee and meeting records in which governance, leadership, quality, accountability, and partnering with consumers are discussed
- Terms of reference or letters of appointment to the governing body that describes members' roles and functions
- Additional examples of evidence include but are not limited to: corporate policies and guidelines (e.g. staff code of conduct; staff recruitment); delegations of authority; standard operating procedures and policies; Human Research Ethics Committee (HREC) and research office policies and processes; high level committee terms of reference and meeting papers; a selection of position descriptions.

DOMAIN 1.02

Clinical leadership

Purpose

CQRs operate in close coordination with clinical groups and the input of clinicians to ensure the CQR achieves its purpose.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR engages clinical expertise in the leadership and governance of the CQR (for example, Individual clinician leadership and craft group/society/college leadership are present).

b. The CQR ensures clinical leaders operate within the Australian Framework for National Clinical Quality Registries to ensure ongoing quality of the CQR.

c. There is clinical input into the registry data set.

d. There is clinical input into the registry outputs.

e. A majority of eligible clinicians are participating in the CQR.

Examples of evidence, including but not limited to:

- Governing committee Terms of Reference includes members roles and responsibilities
- Clinical input into CQR dataset design and data collection methodologies
- Clinical input and review of CQR outputs
- Clinical input into the CQR vision and strategy.

DOMAIN 1.03

Legislation, regulation, policies, and procedures

Purpose

The CQR has current, comprehensive and effective policies, procedures and protocols that cover risks and compliance with legislation and regulations.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR governing body has identified the relevant laws, regulations and jurisdictional guidelines and policies relating to the work of the CQR (together with the CQR associated entity).

b. The CQR governing body is actively ensuring that the CQR complies with the relevant laws, regulations and jurisdictional guidelines and policies relating to the work of the CQR (together with the CQR associated entity).

c. The CQR reviews and maintains the currency and effectiveness of the CQR's policies, procedures and protocols (together with the CQR associated entity).

Examples of evidence, including but not limited to:

- Documented processes for developing, authorising and monitoring the implementation of the CQR policy documents
- Register of policy document reviews, including the date of effect, dates that policy documents were amended and a prioritised schedule for review
- Examples of policy documents that have been reviewed in response to identified risks, or changes in legislation, regulation or best practice
- Policies/ procedures/plans may include:
  - Terms of Reference for each committee
  - Confidentiality undertaking
  - Disclosure of interests and management of conflicts of interest

- Risk management
- Complaints
- Privacy
- Data management
- Data sharing/access/use
- Data linkage
- Release of information
- Publications/Authorship
- Healthcare variation/outlier management
- Clinical trials and studies
- Media/communications.

DOMAIN 1.04

Risk Management

Purpose

The CQR identifies and manages risk effectively.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR/CQR's associated entity has a risk management plan.

b. The CQR identifies and documents its risks.

c. The CQR reviews and acts to improve the effectiveness of the risk management plan (together with the CQRs associated entity).

d. The CQR reports on risks to the CQR governing body.

e. The CQR proactively manages material cybersecurity risks and threats (together with the CQR associated entity).

f. The CQR ensures secure internal and external exchange of health information, and virtual services (together with the CQR associated entity).

Examples of evidence, including but not limited to:

- Policy documents that describe the processes for implementing and monitoring risks
- Risk register that includes actions to manage identified risks relating to CQR operations
- Committee and meeting records regarding oversight of risk management.

Useful resources

- CQR Framework Attachment 2: Australian CQR security compliance guideline.
- ISO 31000 Risk Management Guidelines.
- Australian Signals Directorate.
- Cyber security guide for small healthcare businesses.

DOMAIN 1.05

Registry rationale

Purpose

Having a clear rationale will ensure participation and buy-in to the CQR from clinicians and stakeholders.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a clear rationale and value proposition for operating.
b. Feasibility is assessed against funding sustainability.
c. The CQR has a process for reviewing its rationale and value proposition (every 3-5 years).
d. Feasibility against funding sustainability is regularly reviewed (every 3 to 5 years).
e. Rationale is embedded in stakeholder activities and evolves with stakeholder needs.

Examples of evidence, including but not limited to:

- CQR protocol outlining the rationale and feasibility for establishing the CQR, that considers the following:
  - Can the key CQR data items be feasibly collected? (feasible dataset)
  - Can the CQR identify the eligible population (denominator)?
  - Can eligible sites and clinicians be clearly identified? (population capture)
  - Are the size and scope of the registry feasible based on available resources? (costs vs funding)
  - Are there existing standards/guidelines against which care can be measured?
- Registry rationale is reviewed every three to five years to see if it is still relevant/changed/no longer exists.

DOMAIN 1.06

Registry purpose

Purpose

The CQR must assure itself that a primary purpose of the CQR is to monitor and provide feedback on the safety and quality of health care to inform clinical decision-making to support health care improvement.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR governing body has defined the purpose of the CQR, and its intended outcomes.
b. The CQR defines a primary purpose of the CQR as being aimed at improving the safety and quality of health care.

c. CQR is developing secondary areas of focus in addition to safety and quality, including: research; providing data access; service planning; supporting external quality improvement projects; use of CQR infrastructure for clinical trials; monitoring of new drugs/devices for a disease/procedure registry.

d. CQR has an extensive range of stakeholder reporting and data sharing activities.

e. CQR has embedded multiple secondary areas of focus in addition to monitoring safety and quality.

Examples of evidence, including but not limited to:

- CQR vision and/or mission statement that includes healthcare quality improvement as a primary purpose
- CQR aims and objectives that are aligned with improving the safety and quality of health care
- CQR vision and/or mission is reviewed/updated every three to five years.

DOMAIN 1.07

Stakeholder engagement

Purpose

CQRs require engagement with key stakeholders to enable them to undertake their core business, which is to improve the safety and quality of healthcare.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has processes to systematically engage with clinicians, consumers, carers, communities of diverse cultures, government health departments, health service organisations, and funders to develop and maintain the CQR.

b. The CQR governing body has clear and consistent practices in terms of what is communicated to whom, how, when and why.

c. There are mechanisms in place to enable a productive working relationship between the CQR and its funder(s).

d. There are processes in place to use the CQR outputs to inform healthcare safety and quality initiatives within the jurisdiction and enhance state/territory health department engagement (regardless of the CQR funding source).

Examples of evidence, including but not limited to:

- Stakeholder engagement plan that considers whether the CQR has the support of key groups/societies/colleges (ideally these groups would have representatives on the CQR governing body/committees; consumers and consumer groups; funders; other users of the data such as governments and their agencies, researchers)
- Provider enrolment procedure (clinician/health service organisation/participant)
- Communication plan that outlines what is communicated to whom, how, when and why.

DOMAIN 1.08

Registry sustainability

Purpose

CQRs are long-term activities that aim to continue for 10-15 years or more. It is important that potential sustainable funding models are identified at the commencement of the CQR, otherwise the aims of the CQR may not be achieved.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a strategic/business plan which explores diversified funding strategies.
b. The strategic/business plan describes processes where funding is reviewed regularly.
c. The risk management plan includes mitigation strategies regarding registry sustainability.

Examples of evidence, including but not limited to:

- CQR strategic/business plan that considers the:
  - CQR's funding model
  - potential funding sources regularly reviewed
  - objectives and activities of the CQR aligned with the funding available.

DOMAIN 1.09

Ethical considerations

Purpose

Careful attention to the ethical considerations associated with the design and operation of a CQR promotes public trust.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR applies and embeds ethical principles to the design, development and delivery of its operations.
b. CQR protocol is approved by a Human Research Ethics Committee (HREC) (or equivalent).
c. HREC and Research Governance Office (RGO) approval (or equivalent) for all participating sites are in place.
d. Progress reports are provided to RGOs.
e. Site approvals are continuously maintained.
f. HREC approval of CQR amendments and progress reports are in place as required.

Examples of evidence, including but not limited to:

- CQR protocol addresses the ethical considerations associated with the CQR activities
- Review/approval of the CQR protocol by a certified Human Research Ethics Committee (HREC) or regulatory body (Commonwealth Qualified Privilege Scheme)

- Endorsement by each participating health service organisation by the appropriate delegate before being onboarded to the CQR
- Progress reports to the HREC and endorsing health service organisation
- Policy on managing a breach of the CQR protocol
- Education and training in good CQR practice for the CQR workforce and participating health service organisations.

Useful resources

- National CQR Program - Best practice materials - Good CQR Practice Guide.
- National Statement on Ethical Conduct in Human Research. National Health and Medical Research Council.

DOMAIN 1.10

Qualified workforce

Purpose

CQR staff are appropriately skilled and experienced to perform their roles.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a process to ensure staff involved in the design and operations of the CQR have the necessary skills, experience and qualifications.

b. Position descriptions are developed for CQR staff.

c. Review and refinement of workforce to focus on outputs/use of data for health care improvement (not just data collection and management).

d. Workforce focused on primary and secondary data usage, dissemination of outputs and identification and enhancement of opportunities for impact.

Examples of evidence, including but not limited to:

- Staff position descriptions that describe the responsibilities and accountabilities for the CQR workforce
- Staff training procedures (induction/onboarding)
- Education and training in good CQR practice for the CQR workforce and participating health service organisations.

Useful resources

- National CQR Program - Best practice materials.

STANDARD 2

Data and quality systems

Intention of Standard 2

CQRs implement an appropriate data governance framework for the collection, holding and analysis of patient-level data.

To meet the requirements in this standard, CQRs should:

- Establish and maintain a data governance framework to ensure good governance of the data it holds
- Comply with jurisdictional legislation and requirements for the development and maintenance of health data collections
- Implement processes to ensure a systematic approach to data collection
- Implement a quality management plan for ensuring completeness and accuracy of data
- Source data directly from clinical information systems where possible.

Mapped to CQR Framework

Strategic Principle 5, Operating Principle 2: Data governance, Operating principle 3: Data collection, Operating principle 4: Data elements, Operating principle 5: Risk adjustment, Operating principle 6: Data security, Operating principle 7: Ensuring data quality and Operating principle 8: Data custodian and Standard 2: Data and quality systems.

DOMAIN 2.01

Data governance

Purpose

CQRs are accountable for the safety and integrity of the data they handle and have sound processes in place.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Basic data governance systems in place suitable for data collection activities.

b. Information is managed to ensure the protection of patient privacy and adherence to jurisdictional/national legislation.

c. The CQR has designated roles to ensure the good governance of the data held by the CQR.

d. The CQR has identified the data owner and the data custodian consistent with the definitions provided in the Australian Framework for National Clinical Quality Registries.

e. CQR undertakes staff training in CQR data collection and management.

f. CQR provides user access based on role.

g. Processes for data access and sharing approvals are in place.

h. Data quality assurance procedures in place, for functions such as data reporting, data audits, case ascertainment and data linkage.

i. External data request procedures in place and commence with approval (including for secondary purposes).

j. A publicly available data dictionary that is reviewed annually.

k. A data management procedure that is reviewed annually.

l. Implements an appropriate data governance framework for the collection, storage and analysis of patient-level data.

m. Part-automated CQR data collection, and data quality assurance activities.

n. Data readily available in real time to providers.

Examples of evidence, including but not limited to:

- Data governance framework outlining the designated roles to ensure good governance of the data it holds
- A data dictionary is developed and regularly updated
- Indigenous data governance and sovereignty policy.

DOMAIN 2.02

Data elements

Purpose

The CQR collects the minimum data required for effective safety and quality monitoring.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Initial dataset determined and refined.

b. The CQR is collecting the data it needs to support its core purpose, including personally identifiable data where appropriate.

c. The CQR is taking action to minimise the identifiers collected, and the length of time they are stored in the CQR database.

d. The CQR is developing risk-adjustment processes.

e. The CQR is 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.

f. The CQR collects data items which are epidemiologically sound, that support the measurement of clinical quality indicators, using data collection methods that are systematic and consistent.

g. Clinical outcomes being assessed using objective measures where possible.

h. The CQR applying risk adjustments to account for factors outside the clinicians' control.

i. Regular review of CQR minimum data set against clinical practice.

j. Regularly reviews and updates its risk adjustment processes.

k. Risk adjustments are transparent, and explained in detail in CQR reports.

l. Expansion of CQR dataset to include sub studies or post-market surveillance, as appropriate.

Examples of evidence, including but not limited to:

- Procedure on minimum data set
- A documented process for determining the data items to be collected that is consultative, and based on clinical best practice
- Procedure on risk adjustment
- Collecting objective, reliable variables to support risk adjustment of factors outside the control of clinicians when benchmarking
- Taking action to minimise the identifiers collected, and the length of time they are stored in the CQR database
- Using clinical quality 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 international registry, where relevant
- Clinical outcomes assessed using objective measures where possible
- Patient-reported measures being collected
- Datasets are reviewed regularly to make sure they remain relevant and updated as appropriate.

DOMAIN 2.03

Person-centred care

Purpose

The CQR incorporates the patient voice through collecting the patient's experience and outcomes of healthcare.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Participants provide feedback regarding CQR outputs.

b. The CQR collects and analyses patient-reported measures where these data provide useful information for quality improvement and data collection is feasible.

c. Patient reported measures (if collected) are reported to various audiences.

Examples of evidence, including but not limited to:

- CQR participants/consumer representatives are involved in the CQR governing committee
- CQR participants/consumer representatives provide feedback to the CQR regarding the CQR's outputs
- Collection of patient-reported outcome measures (PROMs)/patient reported experience measures (PREMs) data
- PROMs/PREMs are included in CQR reporting activities.

Useful resources

- CQR Framework Appendix A: Patient-reported measures.
- Australian Commission on Safety and Quality in Health Care. Patient-reported outcomes.

DOMAIN 2.04

Registry coverage

Purpose

CQR case-ascertainment is an important measure of CQR maturity and therefore impact.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR aims to achieve population-level coverage, or broadly representative coverage if this is not.

b. < 50% of eligible patients/procedures captured.

c. The CQR provides public reports of its register coverage annually.

d. 50-80% of eligible patients/procedures captured.

e. >80% of eligible patients/procedures captured.

Examples of evidence, including but not limited to:

- Identify the number and percentage of eligible sites (if denominator can be ascertained) that have agreed to participate
- Identify the number and percentage of eligible sites (if denominator can be ascertained) that have commenced data collection
- Identify the number and percentage of the eligible population (Australia-wide) participating in the CQR (if national comparative data is available)
- Reports on the number of participating sites provided to key stakeholders and published on the registry website.

DOMAIN 2.05

Data collection

Purpose

CQRs should collaborate with the public and private sectors to maximise the value of clinical quality outcomes data to achieve better patient outcomes across the healthcare system.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Digital data capture (via web-based entry or data transfer/linkage) is the primary collection method.

b. CQR uses standards such as METEOR where possible.

c. The initial Data Dictionary is developed and publicly available.

d. The CQR is 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 CQR Strategy.

e. The CQR is using data dictionaries to ensure a systematic approach to data entry.

f. The data dictionaries are regularly reviewed in consultation with contributing jurisdictional health departments.

g. The CQR sources data directly from clinical information systems where possible and, as appropriate, works in partnership with government health departments, the private health sector, clinical leaders and patients and carers to collect data which is not routinely collected.

h. The CQR has the capacity to share data with other information systems.

i. Use of recognised standards for semantic interoperability of most or all data elements (facilitates the exchange of and access to health data that are being documented in electronic health records (EHRs) examples include SNOMED CT, ICD-11, FHIR).

Examples of evidence, including but not limited to:

- Maximises the use of automated data collection systems (where possible)
- Operates in a way that optimises the use and reuse of health data for the benefit of the Australian public, in alignment with the National CQR Strategy
- Makes participants aware of the CQR, and provides them with sufficient information to make a decision about either consenting or opting out of data collection
- Using data dictionaries to ensure a systematic approach to data entry
- The CQR has the capacity to integrate data from other information systems
- Audits to assess compliance with the policy (Data Management Policy) on the collection, use, disclosure, storage, transmission, retention, and destruction of data, and take action to remedy issues identified (Risk register).

DOMAIN 2.06

Privacy

Purpose

The impact of the CQR on privacy rights and legislative obligations is assessed, and risks to the privacy of consumers are managed, minimised, or eliminated.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a privacy policy that is compliant with privacy laws, privacy principles and best practice; upholds consumer rights and choices, and is readily available to service providers and consumers before and while contributing data to the CQR.

b. Privacy training available to CQR staff and clinicians/providers provided.

c. Any privacy breaches are reviewed by CQR governance and strategies developed to mitigate these.

d. The CQR undertakes (in conjunction with CQR associated entity) regular assessments of privacy risks associated with managing the CQR in accordance with best practice.

e. The CQR advises service providers and, where relevant, consumers of changes to privacy policies in a timely and comprehensible way.

Examples of evidence, including but not limited to:

- Has a Privacy Policy that is regularly reviewed and updated as required
- Privacy risks are identified, rated and managed via the CQR Risk Register.

Useful resources

- The Five Safes framework. Australian Institute of Health and Welfare.
- Australian Privacy Principles. Australian Government Office of the Australian Information Commissioner.
- Guide to developing an Australian Privacy Principles privacy policy. Australian Government Office of the Australian Information Commissioner.
- Open and transparent management of personal information. Australian Government Office of the Australian Information Commissioner.

DOMAIN 2.07

Consent

Purpose

Consumers have control of how their data are collected, stored, distributed and used.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR is providing participants with sufficient information to make a decision about either consenting or opting out of data collection.

b. The CQR has mechanisms for consumers to consent to the use of personal data by the CQR for the purposes as specified.

c. The CQR has mechanisms for consumers to withdraw or withhold consent for the collection, storage or distribution of their personal data and records.

d. The CQR has mechanisms for consumers to opt out from the sharing of their personal data and records.

e. The CQR has mechanisms for consumers to access, copy and amend their personal data and records.

f. The CQR has mechanisms for consumers to request deletion of their personal data and records.

Examples of evidence, including but not limited to:

- HREC approval of the level and form of consent required to use data for the CQR purpose and activities
- CQR Protocol that covers:
  - recruitment
  - how the CQR obtains consent from consumers for the use of their data
  - how consumers can withdraw or withhold consent for the collection, storage or distribution of their personal data
  - how consumers can opt out of sharing of personal data
  - how consumers can view, copy and amend their personal data
  - how consumers can request deletion of their personal data
  - the processes to de-identify data
  - how data are distributed or used
- Patient Explanatory Statement for consumers to consent to personal data being used
- Analysis of incident reports relating to the use of personal data and records without consent.

Useful resources

- Australian Privacy Principles. Australian Government Office of the Australian Information Commissioner.
- National Statement on Ethical Conduct in Human Research. National Health and Medical Research Council.
- Ethics in quality assurance and evaluation activities. National Health and Medical Research Council.

DOMAIN 2.08

Data validation

Purpose

CQRs validate the data collected to monitor data quality.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a process to ensure completeness of key data elements.

b. The CQR has a process to ensure case ascertainment, for example audits, data linkage.

c. The CQR has a range of processes and tools to validate/verify the data collected (manual/automated).

d. The CQR publicly reports the completeness of key data elements.

Examples of evidence, including but not limited to:

- Processes to validate data may include:
  - Audits against medical records at the site level

- Review against publicly available datasets
- Data linkage with jurisdictional or other datasets.

- Frequency of validation depends on level of maturity.
- Aggregate results of data validation are communicated for broader data quality improvement purpose.

DOMAIN 2.09

Data quality

Purpose

High quality CQR data is a key requirement to support health care safety and quality improvement.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a range of policies/procedures/processes to monitor and maximise the quality of its data.

b. The CQR undertakes data quality checks and monitoring processes.

c. The CQR regularly reviews case ascertainment.

d. The CQR regularly reviews data completeness and data accuracy.

e. The CQR publicly reports data completeness of key data items.

f. The CQR publicly reports case ascertainment, data completeness and data accuracy at a site level and national level.

Examples of evidence, including but not limited to:

- The CQR minimum data set is designed to support feasible, accurate data collection
- The data collection system has in-built validation rules
- The CQR has a comprehensive data entry, cleaning, data query and verification process (and outlined in the Data Management Plan/Policy/Procedure)
- Data completeness at the individual data item level is reported for core data items (transparency).

DOMAIN 2.10

Data retention and storage

Purpose

CQR data requires long-term storage to support core CQR functions of quality and safety monitoring. The CQR stores its data securely to prevent data loss/loss of data integrity, while providing access to CQR data, where required, to perform the CQR's activities.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has a policy on the retention of data.

b. The CQR has systems in place to ensure that CQR data is stored securely.

Examples of evidence, including but not limited to:

- Data Management Plan
- The CQR has procedures/policies that support:
  - Secure data storage systems
  - Secure data transfer processes
  - Operational access to stored data based on user role
  - Access via approval for secondary purposes
  - Processes to delete and archive data where appropriate.

DOMAIN 2.11

Data linkage

Purpose

The CQR regularly considers opportunities to improve its data collection/validation via data linkage.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR uses data linkage to support the core functions of collecting and validating data as appropriate.

b. The CQR routinely links data to enhance the number and quality of data outputs.

Examples of evidence, including but not limited to:

- Procedures on data linkage
- Data linkage activities following approved data linkage processes
- Data linkage activities undertaken with an experienced data linkage provider
- Data linkage may be used for data validation
- Data linkage may be used for data collection related to the core CQR purpose of safety and quality monitoring
- Data linkage may be used for secondary purposes (e.g. research, drug monitoring)
- An experienced provider/workforce oversees CQR data linkage activities.

DOMAIN 2.12

Information management

Purpose

An information security management system is in place that protects the security and stability of the CQR.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has in place policies and procedures, tools and mechanisms which ensure the information security management of the CQR data.

b. The CQR uses an ISO-accredited (or equivalent) data platform provider.

Examples of evidence, including but not limited to:

- Documentation relating to the CQR's information security management system, including
  - procedures for Information and Communication Technology (ICT) security
  - multifactor authentication and other privacy and security processes and tools
  - documentation on how data security breaches are managed if one occurs
  - system functionality is regularly updated assessed against the operational needs of the CQR
  - procurement processes for data systems
- If the CQR utilises third party providers for information management, seek regular checks/reviews of their security practices. (Ideally their data providers will have ISO27001 accreditation/compliance) with documentation on:
  - information security management systems in place for the CQR
  - roles and responsibilities for information security management for the CQR
  - processes for updates and patches to CQR services
  - processes in place to ensure the CQR can run effectively when there is a change or an interruption to its operations
  - how the CQR communicates with users about any changes, interruptions, or discontinuation of the service
- Reports from audits or reviews of information security management and action plans that remedy any identified issues
- Analysis of incidents relating to information security management
- Committee or meeting minutes that discuss or assess information security management of services
- Committee and meeting records that show planning for backup and recovery and managing updates and patches
- Records of conducting an information and data inventory
- Feedback from the workforce on information security management
- Analysis of incidents relating to changes to platform or operating systems, and action plans addressing any issues identified
- Organisational privacy and security education and training activities.

Useful resources

- ISO/IEC 27000 series.
- Cyber security for healthcare providers. Australian Digital Health Agency.
- Australian Digital Health Agency – Online Learning Portal.
- Australian Government Information Security Manual.
- National CQR Program - Best practice materials - Good CQR Practice Guide.

DOMAIN 2.13

Transparency

Purpose

The sharing and use of CQR data is transparent to stakeholders including service providers and consumers.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Consent requirements and process are publicly available.

b. The details about the collection, use, disclosure, storage, transmission, retention, and destruction of data are publicly available.

c. Processes for storage and management of patient data are publicly available.

d. Data elements are transparent via a publicly available data dictionary.

e. CQR data case ascertainment and analysis methods are publicly reported e.g. in Annual Reports.

Examples of evidence, including but not limited to:

- Policy/procedures (Data sharing policy, Data Access Policy, CQR Protocol) that includes information about:
  - the types of data collected
  - how data are used
  - data sharing for any reason, including via data sharing agreements or requests by external parties
  - whether data are transferred outside of Australia
  - the management of data if the CQR organisation ceases operation or changes ownership or if a consumer dies
- CQR Patient Explanatory Statement that includes:
  - a clear explanation of how their information is collected, used, disclosed, stored, transmitted, retained and destroyed, and the safeguards that apply
- What rights and choices they have about the collection, use and disclosure of their personal information.
- CQR Policy for requests by external parties (Data Access Policy) to inform decisions about the release of information and clearly state when consumer consent is required in different circumstances, for example if a consumer wishes for their data to be provided to a third party (e.g. next of kin) following identify verification processes.
- Policy on data breaches (Data Management Policy) covering:

  - the actions required in response to a data breach, along with clear roles and responsibilities for managing the associated process
  - advising individuals affected by a data breach (a legislated requirement in some circumstances).

- Policy (Data Management Policy) on when a CQR ceases to operate or changes ownership, including:
  - clear guidelines that outline how data will be managed if a CQR is retired, ceases to operate, or ownership is transferred to another CQR organisation.

Useful resources

- Privacy Act 1988.
- Guide to data analytics and the Australian Privacy Principles. Australian Government Office of the Australian Information Commissioner.
- De-identification Decision-Making Framework. Australian Government Office of the Australian Information Commissioner.
- Data breach preparation and response. Australian Government Office of the Australian Information Commissioner.
- Australian Privacy Principles guidelines, Chapter 5: APP 5 – Notification of the collection of personal information. Australian Government Office of the Australian Information Commissioner.

STANDARD 3

Feedback and reporting

Intention of Standard 3

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

To meet the requirements in this standard, CQRs should:

- Establish and maintain procedures to ensure timely analysis and reporting of CQR data to stakeholders
- Implement processes to enable the clinical interpretation of findings and the quality review of CQR reports
- Partner with stakeholders to support the dissemination of CQR reports and quality improvement activities.

Mapped to CQR Framework

Strategic principle 6 and Operating principle 10: information output, and Standard 3: Feedback and reporting

DOMAIN 3.01

Reporting for quality improvement

Purpose

Bench-marking reports allow participating sites to compare their local performance against similar departments, identifying areas of strength and areas needing improvement.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Reporting is carried out by the CQR in the most timely manner possible. For Reporting frequency refer to CQR Framework 2024 (Table 1).

b. The CQR provides descriptive reports to providers/health service organisations.

c. The analysis of CQR data is accompanied by clinical interpretations of the findings.

d. Benchmarking is based on robust statistical methodology.

e. Where significant outliers and/or unwarranted variation are identified, the CQR provides this information to the provider(s) in line with the CQR's outlier policy.

f. The CQR has processes and capacity to provide stakeholders with additional analysis and ad hoc reports, on request, within a reasonable period of time.

g. CQR staff are able to generate routine reports and send them to authorised users through a secure portal, or by uploading to the database.

h. Participating units/institutions are able to generate regular reports of their own data.

i. Participating hospitals, health service organisations and jurisdictional health departments are able to generate ad hoc reports of their own data using their own parameters and criteria.

j. The CQR is able to export unit-record data for approved purposes.

k. The CQR provides benchmarked reports regularly to stakeholders regarding the quality and safety of their processes of care and outcomes to support improvement.

l. Ability to provide real-time, disaggregated data to inform learning healthcare systems and support service improvements through quality improvement.

m. CQR seeks feedback regarding the value of reports produced/provided.

n. CQR monitors processes and outcomes of care over time to see if they are improving.

o. Report recipients include regulators and industry.

p. CQR has options for static and real time reporting for primary purpose.

Examples of evidence, including but not limited to:

- Procedures on reporting (ad hoc report production, annual report production, unexpected variation/outlier reporting, public reporting)
- Descriptive reports to participants
- Benchmarked reports provided (where relevant) to stakeholders, including:
  - Participating health service organisations
  - Clinicians
  - State/Territory health departments
  - Industry
  - Regulators
  - Consumers
  - Upon request
- Feedback from stakeholders regarding the value of the reports
- Use of CQR data to highlight best practice, promote optimal care and showcase improvements in safety
- Generate and disseminate reports on risk-adjusted outcome analyses in a timely manner, once a representative proportion of data has been collated
- Peer-review process with key clinical leaders to verify findings from data before the publication of findings.
- Publicly accessible reports.

Useful resources

- Australian Framework for National Clinical Quality Registries Table 1: Type and frequency of CQR reports.
- Australian Atlas of Healthcare Variation. User Guide for Reviewing Clinical Variation.

DOMAIN 3.02

Partnerships that support quality improvement

Purpose

To ensure CQRs have effective stakeholder engagement and management processes.

Actions for strengthening registry quality and alignment with the CQR Framework

a. A stakeholder identification and management plan is in place.

b. The CQR is providing regular communication to key stakeholders.

c. The CQR is engaging with governments and health service organisations to support health care improvement through data and analysis.

d. Insights from CQRs where consistent patterns of system-wide issues are identified across states and territories, enabling cross-jurisdictional collaboration on insights and improvements.

e. Outreach activities to help governments and health service organisations make improvement in patient care such as provide training on data quality, timeliness and quality improvement methodology/action planning for sites/states informed by the data.

f. CQR information is readily accessible to the public.

g. The CQR collaborates and engages with clinicians, health service organisations and others (e.g. governments/regulators/industry) in relation to improvement activities and the NSQHS Standards.

Examples of evidence, including but not limited to:

- Stakeholder identification and management plan
- Regular communication to key stakeholders
- Reports in a format that is meaningful to the report recipient
- Reports or undertakes additional publications on insights where consistent patterns of system-wide issues are identified across states and territories, enabling cross-jurisdictional collaboration on insights and improvements
- Providing specialised expertise to support rapid innovation and implementation of new models in health service organisations.

Useful resources

- Australian Atlas of Healthcare Variation. User Guide for Reviewing Clinical Variation.

DOMAIN 3.03

Capabilities and infrastructure to support clinical research

Purpose

CQRs can enhance their impact by using CQR infrastructure for other purposes such as for research or to support clinical trials.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR has the capacity which supports research.
b. The CQR has the infrastructure which supports research.
c. The CQR has a formalised process to share data for research.
d. The CQR uses their data collection and storage infrastructure (including patient data) to support or lead research activities or clinical trials.
e. The CQR uses or shares data for research.
f. The CQR research outputs are communicated to the CQR community/stakeholders.

Examples of evidence, including but not limited to:

- Process to share CQR data or infrastructure for research activities
- Research outputs are communicated to stakeholders.

Useful resources

- A guide for registry-based trials – National Clinical Quality Registry Program.

DOMAIN 3.04

Registry impact

Purpose

CQRs create value and impact through their primary and secondary purposes.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Production of CQR annual and site reports.
b. Initial publications to raise CQR awareness.
c. The CQR has the mechanisms to measure its impact.
d. The CQR facilitates an annual survey amongst its stakeholders seeking feedback on its outputs and examples of where these have had an impact.
e. The CQR provides examples of impact in its annual report.
f. Sharing and reporting of data for:
    i. Local quality improvement projects

ii. Health service planning
iii. Policy in CQR domain
iv. Research.

g. The CQR contributes to supporting high-quality care and improvements in patient outcomes by generating insights that can lead to meaningful impact in healthcare.

h. National and international level collaborators and outputs.

i. CQR is considered a highly valued resource by stakeholders.

Examples of evidence, including but not limited to:

- CQR impact is achieved when stakeholders use the CQR data for clinical practice or other uses because it is perceived as high quality and meaningful.
- The number of participating sites/clinicians, the number and type of outputs, as well as funding sources, are all indicators of CQR value to external stakeholders.
- Feedback from stakeholders via surveys following the release of registry outputs (annual reports) listing impacts: change in care, policy, resources/capacity, workforce capability.

Useful resources

- Australian Atlas of Healthcare Variation. User Guide for Reviewing Clinical Variation.
- National CQR Program - Best practice materials – A Guide to Demonstrating Impact.
- National CQR Program - Best practice materials – Impact Case Studies.

DOMAIN 3.05

Registry networks

Purpose

CQRs enhance their impact when they interact with, and support aligned activities.

Actions for strengthening registry quality and alignment with the CQR Framework

a. The CQR participates in networks related to primary function e.g. clinical college/society networks.

b. The CQR participates in networks/collaborations related to secondary purposes e.g. research.

c. The CQR participates in jurisdictional safety and quality network activities and national data networks and activities e.g. Australian Institute of Health and Welfare.

Examples of evidence, including but not limited to:

- Contribution to/participation in a range of network activities including:
  - Jurisdictional safety and quality network activities
  - International registry networks
  - Research networks
- Assist health service organisation/CQR providers to network with peers demonstrating stronger performance on areas they may wish to strengthen or improve.

STANDARD 4

Data-driven healthcare improvements

Intention of Standard 4

By providing benchmarked reports to health service organisations and government health departments, CQRs can monitor variation in processes and outcomes of care.

To meet the requirements in this standard, CQRs should:

- Establish and maintain a policy for monitoring variation in care to identify unwarranted variation and inform quality improvement.

Mapped to CQR Framework

Strategic principle 6 and Operating principle 10: information output and, Standard 4: Data-driven healthcare improvements.

DOMAIN 4.01

Clinical variation and management

Purpose

Establish and maintain a policy for monitoring variation in care to identify unwarranted variation and inform quality improvement.

Actions for strengthening registry quality and alignment with the CQR Framework

a. Variation/outlier management policy on the work plan.

b. Variation/outlier management policy in development (e.g. when has 50% of case ascertainment of sites).

c. The CQR has effective policies and procedures in place that identify variation in processes or outcomes of care, and strategies to highlight patient risks to clinicians. The CQR:

i. identifies the governance arrangements for the process of outlier analyses and management including a structured process for peer review of statistically significant outliers and any unwarranted variation.

ii. describes the time frames, notification and escalation stages for running the outlier process

iii. identifies existing indicators that provide a valid measure of the quality of care, or develops its own (ideally derived from CQR data)

iv. outlines if any additional metrics collected will be applied to an outlier analysis, if not, an explanation will be provided

v. specifies performance targets based on valid external or internal sources

vi. describes the specific patient cohort the policy applies to (e.g. cumulative, annual or 3-year rolling data periods)
vii. outlines how the data will be validated in terms of case ascertainment, data completeness and data accuracy
viii. describes the application of reliability adjustment approaches to account for small sample sizes
ix. describes the assessment of the accuracy of variation identified based on data completeness/quality
x. outlines the application of risk adjustment approaches to account for differences in the mix of patients
xi. outlines the process to be followed in response to a persistent outlier
xii. outlines where the results of the outlier analysis will be published (for example, the annual report)
xiii. adopts the terms 'alert' and 'alarm' (If yes, the policy describes the metrics to define alerts and alarms respectively)
xiv. if the terms 'alert' and 'alarm' are not adopted, the policy explains how limits of expected performance will be defined and the reasoning for an alternative approach
xv. provides recommendations to the outlier on investigating their outlier status in line with the CQR's outlier policy.

d. Variation/outlier management policy implemented and regularly reviewed.

Examples of evidence, including but not limited to:

- Policy for variation/outlier management health service organisation reporting (noting a policy is needed when the CQR has sufficient data at hospital level).

Useful resources

- CQR Framework Appendix B: Approaches to outlier measurement.
- Australian Atlas of Healthcare Variation. User Guide for Reviewing Clinical Variation.

Table 1. Number of actions per CQR Framework quality standard by domain and maturity level.

CQR Framework Standard	Domain	Number of actions	Foundational	Functional	Health system-enabling
Standard 1: Governance	**1.01** Governance, leadership and culture	11	06	05	-
	1.02 Clinical leadership	05	01	03	01
	1.03 Legislation, regulation, policies and procedures	03	01	02	-
	1.04 Risk management	06	01	05	-
	1.05 Registry rationale	05	02	02	01
	1.06 Registry purpose (including primary and secondary purposes)	05	02	-	03
	1.07 Stakeholder engagement	04	03	-	01
	1.08 Registry sustainability	03	01	02	-
	1.09 Ethical considerations	06	02	04	-
	1.10 Qualified workforce	04	02	01	01
	Total	**52**			
Standard 2: Data and quality systems	**2.01** Data governance	14	08	04	02
	2.02 Data elements	12	06	03	03
	2.03 Person centred care	03	-	02	01
	2.04 Registry coverage	05	02	02	01
	2.05 Data collection	09	03	04	02
	2.06 Privacy	05	02	03	-
	2.07 Consent	06	01	05	-
	2.08 Data validation	04	02	02	-
	2.09 Data quality	06	01	03	02
	2.10 Data retention and storage	02	02	-	-
	2.11 Data linkage	02	-	01	01
	2.12 Information management	02	02	-	-
	2.13 Transparency	05	01	03	01
	Total	**75**			

CQR Framework Standard	Domain	Number of actions	Foundational	Functional	Health system-enabling
Standard 3: Reporting and feedback	**3.01** Reporting for quality improvement	16	01	03	12
	3.02 Partnerships that support healthcare quality improvement	07	01	01	05
	3.03 Capabilities and infrastructure to support clinical research	06	03	02	01
	3.04 Registry Impact	09	03	01	05
	3.05 Registry networks	03	01	01	01
	Total	**41**			
Standard 4: Data-driven healthcare improvements	**4.01** Clinical variation and management	04	01	01	02
	Total	**4**			
	Grand total	**172**			

APPENDIX 3

Overview of CQR outputs

The overall purpose of CQRs is to drive improvements in the quality of the Australian health system by providing access to clinical information for quality improvement. Registry outputs are one of the main ways clinical quality registries (CQRs) can demonstrate this impact.[1]

Reporting is the most visible output of registry activity. These reports can identify significant variation in care, establish benchmarks, and drive quality improvement. They can also support consumers to make informed decisions about the care they receive and where they receive it.

Registry outputs are not limited to formal reports. Other outputs may include public reporting on performance, data provided to governments, information used for quality improvement programs, research publications, support for clinical trials, post-market monitoring, or contributions to policy and accreditation activities.

As part of this self-assessment, registries are encouraged to identify their outputs (and outcomes), intended recipients, frequency, and purpose. This can help registries better describe their value to stakeholders and assess whether their outputs are meaningful, useful, and aligned with stakeholder needs.

Understanding registry outputs can also help demonstrate registry maturity and value. For example, evidence of how outputs are used, the impact they have had, or how they support improvements in care can aid discussions about registry sustainability, funding, and investment.

A suggested list of registry outputs* is provided below. For further information, see the Feedback and Reporting section of the Australian Framework for National Clinical Quality Registries (CQR Framework).

** Suggested outputs are informed by the CQR Framework and sector feedback, including from the Monash University Australian Clinical Registry Survey 2025.*

List of suggested CQR outputs

This list is intended as a guide and may not apply to all registries. Registries should select outputs that are appropriate to their purpose, scope, maturity, and stakeholder needs. Over time, there may be an opportunity to refine this list based on feedback from the sector.

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

Reporting registry data

Community and patients

- Publish routine annual CQR report

Providers and health services

- Provide routine provider reports
- Provide routine unit reports
- Provide site-level benchmarked reports
- Provide benchmarked reports to hospital, health district chief executives, or relevant executives
- Provide aggregated reports for private hospital groups

Clinicians

- Provide routine clinician-level reports

Jurisdictions and governments

- Provide state or territory Government reports
- Provide data to state or territory Governments upon request

Quality of care

- Monitor adherence to clinical standards (should be covered in provider reports)
- Inform quality improvement or evaluation programs
- Report improvements in process or outcome measures
- Reports for hospital or service-level accreditation or certification purposes

Policy

- Inform health care policy within the clinical registry domain

Regulatory

- Provide device or medicine post-market reports

Clinical trials and research

- Support clinical trials
- Produce regular academic publications

Integration with data frameworks or platforms

- Integration with government data frameworks or platforms

Useful resources

- CQR Framework Feedback and Reporting
- CQR Framework Table 1: Type and frequency of CQR report
- Australian Atlas of Healthcare Variation. User Guide for Reviewing Clinical Variation
- National CQR Program - Best practice materials - A Guide to Demonstrating Impact.
- National CQR Program - Best practice materials - Impact Case Studies.

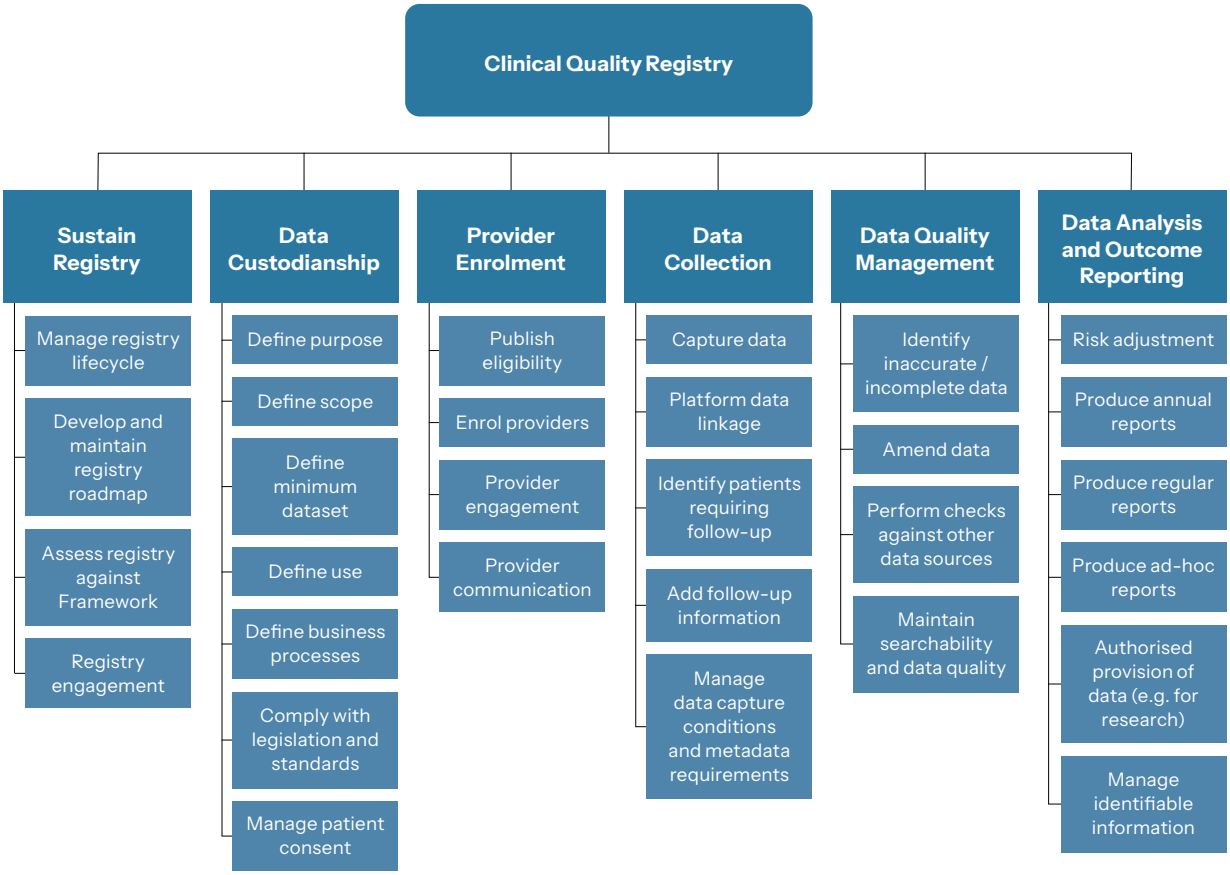
APPENDIX 4

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 Australian Framework for National Quality Registries 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 CQR Framework Attachment 1: Australian CQR Logical Design and Infrastructure Guideline.

Figure 1: Functional overview of Australian national Clinical Quality Registries



ADDITIONAL INFORMATION

How the CQR Framework Self-Assessment was developed

The CQR Framework Self-Assessment supports the Commission's purpose to lead improvements in the safety and quality of health care so all Australians receive better care, everywhere. It aligns with the Commission's four key priority areas of focus:

- **High-quality care in an evolving environment**: health care is delivered consistently, reliably and equitably for all Australians.
- **Strong outcome focused clinical governance**: clinical governance, integrated standards and accreditation drive better patient outcomes.
- **Empowered patients, carers and communities**: health care is designed and delivered with patients and communities.
- **An improvement driven workforce culture**: better health care is everyone's responsibility, every day.[1]

The CQR Framework Self-Assessment was developed through a collaborative process involving experts in CQRs, clinicians, and representatives from Australian, state and territory health departments.

This self-assessment builds on the CQR Framework and reflects contemporary thinking on the role of CQRs in supporting a learning health system and informing clinical quality improvement.[2,3,4,5,6,7]

The CQR Framework that underpins the CQR Framework Self-Assessment sets out nationally consistent principles under which all CQRs should be operating and provides clear, practical guidance on how those principles can be implemented. The CQR Framework includes four quality standards designed to mitigate risk relating to the collection and management of data,

1 Australian Commission on Safety and Quality in Health Care/About us www.safetyandquality.gov.au/about-us/what-we-do

2 Australian Commission on Safety and Quality in Health Care. Evidence Check: Governance, accreditation, and quality assurance of clinical quality registries Australian Commission on Safety and Quality in Health Care. Sydney: ACSQHC;2019.

3 Kirsten J Parker, Louise D Hickman, Caleb Ferguson, The science of clinical quality registries, European Journal of Cardiovascular Nursing, Volume 22, Issue 2, February 2023, Pages 220–225, https://doi.org/10.1093/eurjcn/zvad008

4 Ahern S, Honardoost MA, Kartik A, Chung E, Dalli L, Eshetie TC, Turner C, Merenda M, McDonald S. Monitoring performance and improving outcomes: characteristics and outputs of Australian clinical registries. Health Inf Manag. 2025 Jun 26:18333583251345039. doi: 10.1177/18333583251345039.

5 Dewan Md. Emdadul Hoque, Rasa Ruseckaite, Paula Lorgelly, John J McNeil, Sue M Evans, Cross-sectional study of characteristics of clinical registries in Australia: a resource for clinicians and policy makers, International Journal for Quality in Health Care, Volume 30, Issue 3, April 2018, Pages 192–199, https://doi.org/10.1093/intqhc/mzx196

6 Blumenthal S. The NQRN Registry Maturational Framework: Evaluating the Capability and Use of Clinical Registries. EGEMS (Wash DC). 2019 Jul 17;7(1):29. doi: 10.5334/egems.278.

7 Gliklich RE, Leavy MB, Dreyer NA (sr eds). Registries for Evaluating Patient Outcomes: A User's Guide. 4th ed. (Prepared by L&M Policy Research, LLC, under Contract No. 290-2014-00004-C with partners OM1 and IQVIA) AHRQ Publication No. 19(20) EHC020. Rockville, MD: Agency for Healthcare Research and Quality; September 2020.

and to promote the reporting of health information for safety and quality improvement. The standards address requirements for:

- Governance (including data governance)
- Data quality and quality systems
- Feedback and reporting
- Data-driven healthcare improvements

It is acknowledged that alignment with these standards requires registries to implement strategies that are suited to their context and operating and technical environments.

The CQR Framework Self-Assessment supports activities under the National Clinical Quality Registry and Virtual Registry Strategy 2020-2030[8] (National CQR Strategy). This National Strategy is led by the Australian Government Department of Health, Disability and Ageing and outlines actions for governments, registries, and other stakeholders to build capacity and efficiency in line with the CQR Framework and support the adoption of digital health and other key health reforms.

This Self-Assessment also aligns with the National Safety and Quality Health Service (NSQHS) Standards (second edition).[9] The NSQHS Standards promote the use of CQRs to measure and monitor the effectiveness of care. The NSQHS Standards encourage health service organisations to contribute data to CQRs (where available) and to use CQR data and reports to identify priorities for safety and quality improvement.

Health service organisations that integrate CQR data into clinical quality improvement activities can meet, in part, NSQHS Standards Second Edition accreditation requirements, specifically:

- **Actions 1.08 and 1.09:** Measurement and quality improvement
- **Action 1.28:** Addressing variation in clinical practice and health outcomes.

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We also thank the CQR Advisory Group (listed below) for their valued leadership and expert guidance in shaping this resource.

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- Distinguished Professor Sandy Middleton (Chair)
- Professor Susannah Ahern
- Professor John Beltrame AM
- Dr David Gill
- Mr Richard Gillett
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- Ms Tamara Hooper

8 National Clinical Quality Registry and Virtual Registry Strategy. Commonwealth of Australia as represented by the Department of Health 2020

9 Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards guide for hospitals. Sydney: ACSQHC; 2017.

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Your experience and feedback

The Commission welcomes your suggestions for making the CQR Framework Self-Assessment as practical and user-friendly as possible. Please provide any feedback by emailing the CQR project team at CQR@safetyandquality.gov.au. You can also provide feedback online here or contact the CQR team for a Word version of the feedback form. We greatly appreciate your input.

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