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Good Clinical Quality Registry Practice Guide

A guide for hospital Principal Investigators and staff who participate in Australian Clinical Quality Registries

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Version 1

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Forewords

Australian Government Department of Health and Aged Care

The National Clinical Quality Registry Program (the Program) aims to improve the quality of health care and ensure better health outcomes for Australian patients. As part of this Program, the Department is leading a range of activities under the National Clinical Quality Registry and Virtual Strategy 2020-2030 (the Strategy).

Increasing CQR best practice is a key goal of the Strategy. The new Good Clinical Quality Registry Practice Guide will – for the first time – provide best practice training for hospital staff and clinicians as they begin participating in national CQRs. It will also help raise awareness of the benefits of CQRs and their value for local health care safety and quality improvement.

This Guide forms part of a broader suite of best practice materials being developed under the Program. We thank Monash University and the South Australian Health and Medical Research Institute for partnering with us on this important initiative.

Yingsong Hu
A/g Assistant Secretary

Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) contributes to better health outcomes and experiences for Australians and improved value and sustainability in the health system by leading and coordinating national improvements in the safety and quality of health care.

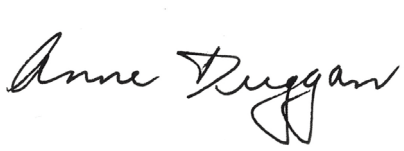
The Commission acknowledges the important contribution of Clinical Quality Registries (CQRs) to healthcare in Australia by delivering timely, valuable insights that enhance clinical practice and patient care to foster a continuous learning health system.

CQRs are essential tools in our healthcare system, providing critical data that informs best practices, improves patient outcomes, and drives continuous improvement. The 2024 Australian Framework for National Clinical Quality Registries (the 2024 Framework) sets the standard for the establishment and operation of these registries, ensuring they adhere to the highest standards of quality and accountability. The 2024 Framework emphasises the importance of a nationally coordinated approach to CQRs, fostering collaboration and consistency across the healthcare sector.

The Good Clinical Quality Registry Practice Guide (the Guide) builds on these principles, offering detailed recommendations and practical tools to help healthcare providers achieve excellence in CQR management. This Guide also supports the National Safety and Quality Health Service (NSQHS) Standards in promoting best practice in monitoring, reviewing and improving the safety and quality of clinical care.

I look forward to our ongoing collaboration with the CQR sector, clinicians, health service organisations and state, territory and Commonwealth health departments to continue driving safe, high-quality care and better patient outcomes across the nation.

Together, we can harness the power of data to drive improvements in healthcare quality and safety, ultimately benefiting patients and the broader community.



Conjoint Professor Anne Duggan
Chief Executive Officer
Australian Commission on Safety and Quality in Health Care

Introduction and Purpose of the Guide

Clinical-quality registries (CQRs) monitor the appropriateness and effectiveness of health care by collecting clinical care and outcome information in relation to individuals who undergo a particular procedure, are diagnosed with a particular disease, or use a particular health care service. CQRs analyse and report this information back to participating health care providers for quality assurance and improvement purposes. CQRs collect real-world data and outcomes that can inform clinical care improvement locally as well on a larger scale. They are recognised as critical data infrastructure necessary to support a high performing health system.

Health service participation in CQRs is viewed as a **partnership** whereby the health service shares data with the CQR, and the CQR creates information that supports the monitoring and improvement of clinical care. Participation in CQRs also assists health services to comply with the National Safety and Quality Health Service (NSQHS) Standards Action 1.28, relating to variation in health outcomes.

Hospital/site Principal Investigators (PIs) support CQR activities by assuming primary responsibility for implementation of the CQR within their organisational unit/department. This role oversees hospital engagement, data collection, communication between the registry and the health service, and review and dissemination of site reports received from the CQR.

Currently, there is no **generic guidance** to prepare Principal Investigators or other hospital/site staff when they commence participation in CQR activities. The **Good Clinical Quality Registry Practice Guide - A guide for hospital Principal Investigators and staff who participate in Australian Clinical Quality Registries** - aims to fill this gap. The concept for the guide derived from an identified need to provide introductory information for hospital Principal Investigators and staff that participate in clinical quality registries (CQRs), in the same way that Good Clinical Practice (GCP) training has supported Clinical Trials. It aims to provide an overview of CQRs from the perspective of hospital participating clinicians and staff, including what CQRs are, why they are an important component of health system quality assurance and improvement, what are their key activities, and what do health service personnel need to know to participate in them safely and effectively. The Guide **complements additional registry-specific training.**

Primary target audience for the Guide are:

- **Hospital/Site Principal Investigators/registry leads** i.e. those individuals based in a hospital/clinic/private practice who have assumed organisational responsibility for participation in a specific CQR
- **Clinicians and other hospital/private practice staff** who are involved in participant recruitment, data collection and/or other CQR activities at their site(s).

Secondary audience:

The Good CQR Guide may also be of interest to:

- registry or third-party data collectors/data entry staff who are external to hospitals/sites who recruit participants/collect data at site for a CQR
- healthcare quality and safety roles and professionals, hospital managers, researchers
- CQR staff, to support induction training
- staff working in clinical registries that are not CQRs (e.g. research only focused clinical registries).

This Guide would not be possible without the support of the Australian Government Department of Health and Aged Care National Clinical Quality Registry Program, and the CQR Guide Working Group, comprised of approximately thirty enthusiastic and committed representatives from ACTA and the CQR sector as well as health services, ethics and governance offices, and clinician representatives. The guide is aligned with the Australian Commission on Safety and Quality in Health Care's revised Framework for Australian Clinical Quality Registries 2024.

Definitions

Clinical data

Health data, often sourced from medical records.

Clinical (quality) indicators

Data that define and measure processes and outcomes (quality) of care by providers. They may measure compliance with evidence-based clinical processes that are associated with good quality care, or may monitor processes associated with low value care. They may also measure outcomes such as overall improvement or specific complications from a healthcare intervention.

Clinical Quality Registry (CQR)

Is a specific type of clinical registry that systematically monitors the appropriateness and effectiveness of health care, within a specific clinical domain, to drive ongoing improvements in safety and quality in the Australian health system. The term 'CQR' is used to represent clinical quality registry throughout this document.

CQR data

- Primary use/purpose – the primary purpose of CQR data is to drive improvements in the safety and quality of care
- Secondary use/purpose – data used for additional purposes such as for research or to inform policy or service planning.

Data custodian

The person, committee or organisation that has ultimate responsibility for decisions regarding the management and use of the CQR data.
See Section 4.1.

Data item/field/variable/element

A piece of information that can be collected, coded and analysed.

Data (collection) form

A set of data items/fields/variables/elements that comprises a CQR minimum data set (MDS).

Identifiers

Pieces of data that identify or could lead to the identification of an individual.

Minimum data set (MDS)

The elements of the data set that must be collected in order for the record to be considered 'complete'.

Participant/Patient

Often used interchangeably. The term 'participant' is used to represent participants/patients throughout this document.

Patient information sheets

Patient-facing documents with information that patients/participants need to know to ensure informed consent, e.g., the Patient Explanatory Statement (PES) or Participant Information and Consent Form (PICF).

Patient Reported Measures (PRMs)

Is data that is collected directly from the patient/participant, e.g., obtained using surveys or questionnaires. Also known as Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs). See Section 3.4.

Protocol

A document that includes a comprehensive project framework, with clear objectives for data collection, secure storage, and confidential reporting processes within the registry whilst also ensuring integrity, reliability, and usability of the collected information.

Registry-based trial

A clinical trial which utilises CQR data or infrastructure.

Risk

The probability of harm or a negative occurrence. Risk is measured by the consequences of an event and its likelihood.

Risk management

The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation. It includes a process of identifying, assessing and controlling the range of risks that impact in the safe effective delivery of the CQR.

Secure File Transfer Protocol (SFTP)

A form of secure data exchange platform.

Site Principal Investigator (PI) or Registry Lead

The clinician or healthcare professional who is nominated to have oversight of participation in the CQR at a site. There may be more than one PI for a site if multiple health professional groups contribute to the CQR. Site PI is the term for this role generally used throughout this document.

Site/Provider

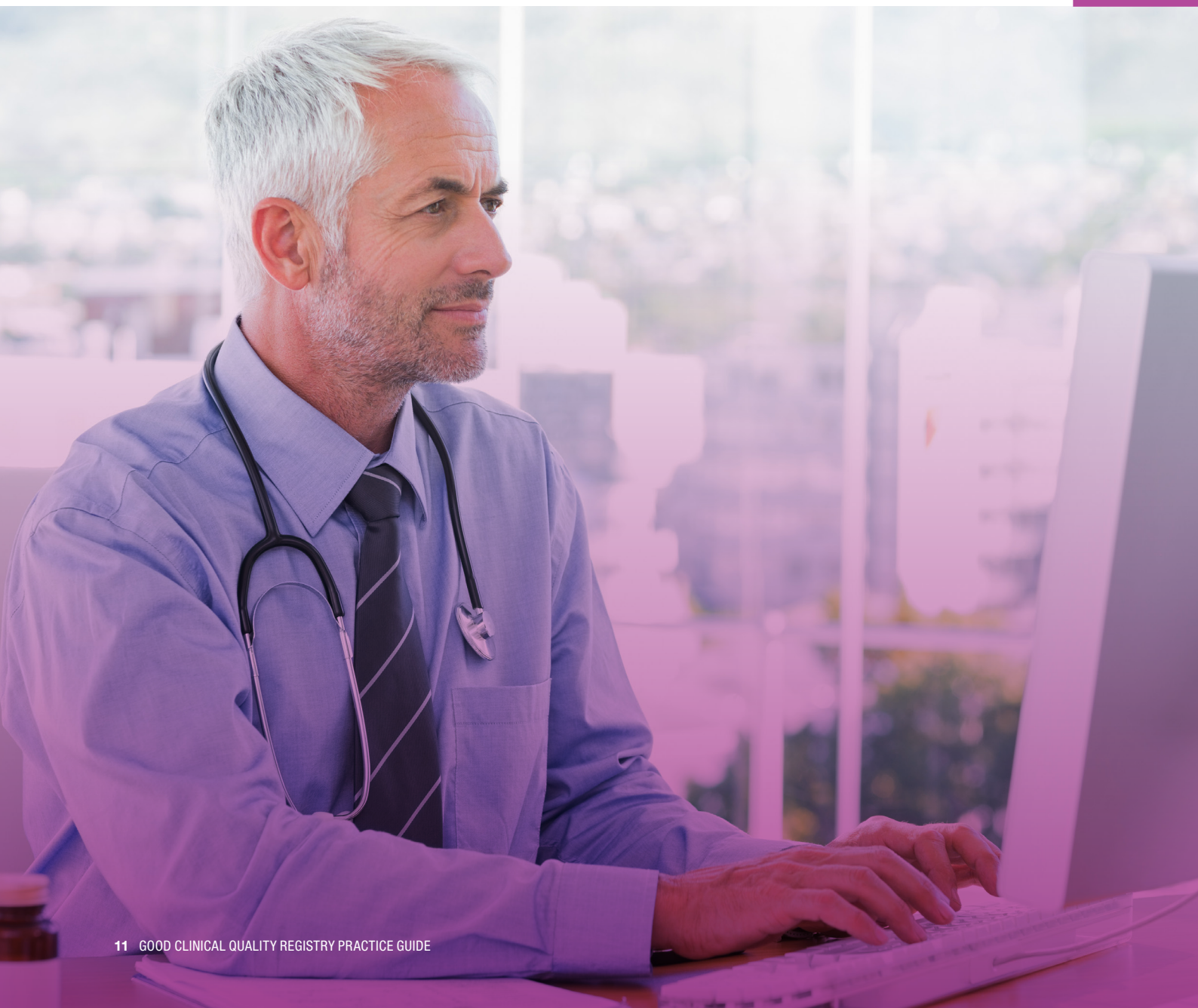
Providers of healthcare and contributors of clinical data to CQRs. 'Site' refers to the hospital, health service, clinic or private practice. 'Provider' may refer to the individual health service organisation or the participating clinician.

Unwarranted variation

Variation in clinical practice that is not explained by patient-level (or disease level) differences.

SECTION 1

Overview



Overview of Clinical Quality Registries

Participation in CQRs allows clinicians and health services to contribute to a national quality improvement initiative, and measure their performance against others and over time. CQRs aim for complete capture of all eligible participants when mature to minimise selection bias and unrepresentative data.

Key Messages

- How does a Clinical Registry differ from a Clinical Quality Registry
- CQRs are primarily quality assurance (QA) and quality improvement (QI) activities
- CQRs have structures and governance that supports their primary purpose
- CQR data and infrastructure may have many secondary uses

What is a Clinical Registry?

Clinical registries were initially designed as epidemiological research tools that collected prospective clinical data usually from hospitals or private practices regarding a specific disease or condition. Clinical registries have characterised the natural history and outcomes of specific conditions or procedures over time through periodic clinical data collection and participant follow-up. Australia has over 100 clinical registries listed on the Australian Commission on Safety and Quality in Health Care (ACSQHC)'s Australian Register of Clinical Registries (see also Section 6). Clinical registries are generally multi-site activities, and may be state-wide, national or even international in their scope.

What is a Clinical Quality Registry (CQR)?

A Clinical Quality Registry (CQR) is a clinical registry that has as its **primary purpose** the collection of participants' (condition, procedure or device) data for quality assurance (QA) and quality improvement (QI) purposes. CQRs develop a **minimum data set** and specific **clinical indicators** against which system and health service provider **performance** is measured. When sufficiently mature (sufficient data volumes), CQRs generally provide public Annual Reports, and regular comparative reports for their participating providers. This enables hospitals to regularly review their performance and how it compares with clinical care standards, guidelines and peers. Additionally, provider reporting allows for detection and management of unwarranted variation in care or outcomes.

How do CQRs support QA and QI activities?

To support efforts in reducing unwarranted variation in healthcare delivery, the Australian Commission on Safety and Quality in Health Care (ACSQHC encourages healthcare providers (clinicians, hospitals) to participate in CQRs, and incorporate CQR information into their quality and clinical management processes.

The *National Safety and Quality Health Service (NSQHS) Standards*, developed by the ACSQHC in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, participants and carers, aim to protect the public from harm and to improve the overall quality of healthcare. The *NSQHS Standards Action 1.28 variation in clinical practice*, requires providers to have systems in place to monitor variation in care, to identify unwarranted variation, and to regularly review and improve the appropriateness of clinical care. CQRs are an important tool in supporting health service organisations to meet these requirements.

CQRs have structures and governance that supports their primary purpose

CQRs may be established and funded by (but not limited to) jurisdictional or Commonwealth governments, medical or surgical Colleges or associations, research grants, not for profits organisations, and healthcare insurers. Unlike clinical trials, CQRs generally aim to provide ongoing monitoring, and therefore require long-term funding, which is often via multiple funders.

The ACSQHC's *Australian Framework for National Clinical Quality Registries 2024 (the CQR Framework 2024)* provides guidance for CQRs regarding best practice structure and governance. CQRs must be managed by a legal entity (e.g. University, Institute, medical College/ Society, jurisdiction) and have a governing body (e.g. Steering Committee, Board). CQRs are led by clinicians, academics and consumers, and have technical specialist staff that undertake a range of functions including minimum data set and protocol development, ethical approval, hospital and clinician engagement, data collection, database management, regular governance and operational meetings, consumer engagement and wider communication activities, data analysis, data reporting and analysis for secondary data use.

CQRs are custodians of their CQR data, meaning that they keep and protect the data from inappropriate use, while allowing use for appropriate primary and secondary purposes.

CQR data and infrastructure may have many secondary uses

In addition to quality and safety monitoring, CQR data and infrastructure may be used for:

- secondary data analysis for research
- data linkage with other data sets
- data platforms for clinical trials, sub studies or other research studies
- post-market surveillance of implantable devices or drugs.

Participation in CQRs allows clinicians and health services to contribute to a national quality improvement initiative, and measure their performance against others and over time. CQRs aim for complete capture of all eligible participants when mature to minimise selection bias and unrepresentative data.

Resources and References (see also Section 6)

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

The Australian Environment for CQRs

This section of the Guide provides a high-level summary of the environment within which CQRs operate in Australia, and key regulatory considerations for anyone engaging with CQRs. The CQR sector in Australia is rapidly changing as CQRs become more common, more mature, and more complex, coupled with maturing digital and information technologies.

Key Messages

- **CQRs are subject to the National Health and Medical Research Council (NHMRC)'s National Statement on Ethical Conduct in Human Research (2023) (see Section 6), and generally require oversight of their activities from an NHMRC-approved Human Research Ethics Committee (HREC)**
- **The ACSQHC Framework (2024 revision) sets out a high-level set of strategic principles, operating principles and quality standards for CQRs**
- **The National Strategy for CQRs (2021) aims to maximise the outcomes of CQRs, and is implementing a program of activities that will support CQRs to help achieve their safety and quality outcomes**

CQRs are subject to the NHMRC's National Statement on Ethical Conduct in Human Research (2023)

CQRs in Australia must adhere to the same rigorous guidelines as for research involving humans, their data, or tissue, as outlined in the NHMRC's ***National Statement on Ethical Conduct in Human Research (2023)*** effective 1 January 2024. Key ethical principles from the NHMRC's Statement can be found at:

- Section 1: Values and principles of ethical conduct (p. 9-11)
- Section 3, Element 4: Collection, Use and Management of Data and Information (p. 32-38).

The Australian Government Privacy Act (1988) Sections 95 and 95A (see Section 6) provide procedures and frameworks for the disclosure and use of personal health information for medical research, emphasising the need for **HREC** review for research posing greater than low risk due to the use of identifiable health data.

The Australian Privacy Principles (APPs) set standards for the collection and use of personal information, ensuring governance, accountability, and individual rights. In addition to supporting quality improvement, national CQRs may also facilitate research via agreement and under NHMRC guidance.

Ethical oversight for CQRs

CQRs usually require **ethical approval and hospital governance authorisation** prior to commencement.

- **Review by a HREC** is required for any research that is considered to be greater than low risk. Many registries fall under this category due to the sensitivities around the use of identifiable health data. The role of this overarching ethics approval is to ensure that the CQR is conducted in a way that aligns with the NHMRC statement and ensures that the rights, safety, and wellbeing of participants are protected, including providing appropriate consent mechanisms and information to participants in the CQR (if possible to do so)
- **Hospital/Site Governance Review** focuses on the operational aspects of the CQR including compliance with site-specific policies and regulations, legal compliance and the practicalities of provision of data to the CQR.

Australian Framework for National Clinical Quality Registries, Second Edition 2024

There are significant efforts underway at a national level to maximise the value of Australia's clinical quality outcomes data to improve healthcare delivery and participant outcomes. A guiding reference for CQRs is the ACSQHC's ***Australian Framework for National Clinical Quality Registries 2024 (the Framework).*** This is a principles-based document that aims to provide support and guidance for CQRs as they work towards achieving their purpose of providing maximum value to the Australian health system. The Framework also includes a quality standard designed to mitigate risks relating to the collection and management of data, and promote the reporting of health information for safety and quality improvement.

The Australian Government's National Clinical Quality Registry and Virtual Registry Strategy

In 2020, the Australian Government released the ***National Clinical Quality Registry and Virtual Registry 2020-2030 (the Strategy).*** The **Strategy** establishes national priorities to enhance the capacity and efficiency of CQRs, aligning with the **Framework** and broader digital health reforms. The Strategy aims to drive continuous improvement in the value and quality of patient-centred health care and achieve better health outcomes for all Australians. The Strategy outlines a set of agreed national priorities and actions for governments, clinical registries, and other stakeholders to build capacity and efficiency in line with the Framework.

Resources and References (see also Section 6)

National Clinical Quality Registry Program

A National Clinical Quality Registry and Virtual Registry 2020-2030

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

ACSQHC Fourth Atlas 2021

ACSQHC National Safety and Quality Health Service (NSQHS) Standards - Action 1.28

ACSQHC User Guide for Reviewing Clinical Variation

ACSQHC Australian Atlas of Healthcare Variation Series

NHMRC's National Statement on Ethical Conduct in Human Research (2023)

OAIC Australian Privacy Principles

ACSQHC Legislation and regulation of clinical quality registries Final Report, May 2020

A useful summary of the 13 Australian Privacy Principles (APPs)

OAIC The Australian Privacy Principles

NHMRC's Research Governance Handbook, 2011, Section II

SECTION 2

Health Service and Clinician Participation in CQRs

CQR Protocol

Health Service PIs and participating clinicians should be familiar with the CQR Protocol. As the CQR Protocol is regularly revised, PIs should be aware of changes and implement protocol amendments into the registry once approved by their hospital/site.

This section provides guidance regarding what a CQR Protocol is, and that it is regularly reviewed and updated.

Key Messages

- **The CQR Protocol (or equivalent document) provides a comprehensive project framework for the core activities of the CQR**
- **The CQR Protocol is approved as part of the CQR HREC approval process and generally includes the CQR rationale, aims, governance, methods (consent, recruitment, data management), outputs (reporting, data access, secondary use for data, data linkage) and statements of alignment with relevant legislation and regulations**
- **When the CQR Protocol is varied, a protocol amendment needs to be approved by the HREC. This is generally followed by governance authorisation at participating hospitals/sites**
- **If the CQR Protocol is breached, then the CQR must notify the approving HREC as well as any affected hospitals/sites**

The CQR Protocol is the Registry 'DNA'

The **CQR Protocol** is the overarching document of a CQR which outlines the scientific rationale and demonstrates the clinical need for the CQR, and why the CQR is in the public's interest. It details the aims and methodology for the conduct of the registry, as well as how the data will be secured, analysed and reported. The proposed protocol must be approved by a Human Research Ethics Committee in line with the NHMRC's **National Statement on Ethical Conduct in Human Research (2023) (see Section 6),** and other relevant guidelines.

Components of a CQR Protocol generally include the CQR rationale, aims, governance, methods (consent, recruitment, data management), outputs (reporting, data access, secondary use for research, data linkage) and statements of alignment with relevant legislation and regulations.

Components of a typical CQR Protocol in more detail include:

- **Background:** The CQR Protocol states the focused clinical area or domain of the CQR, and outlines the scientific background and rationale for establishing the CQR. If it intends to use a waiver of consent or opt out approach, the background should provide the evidence that the CQR will be in the public interest
- **Aims:** The protocol includes the stated aims and objectives of the CQR

- **Methods** including the following:
  - *Governance* – the governance structure of the registry and membership, the roles and responsibilities of participating clinicians/ hospitals in the CQR
  - Identify the *data custodian* for the CQR (e.g. educational institution, government department, medical College, not-for-profit)
  - *Minimum data set* to be collected e.g. identified vs de-identified; clinical data; items derived from existing datasets such as Commonwealth administrative data (e.g. Medicare, National Disability Insurance Scheme [NDIS]); Patient Reported Outcome Measures (PROMs); Patient Reported Experience Measures (PREMs)
  - *Data dictionary* (definition and description of data elements)
  - Description about how data is provided to the data custodian, e.g. direct data entry into a web-based portal, or transfer of data extracts from systems; and timepoints of data collection
  - *Recruitment model* – how participants are identified as eligible and recruited to the registry
  - *Consent* – model(s) of consent e.g. opt in consent; opt out approach with a waiver for the requirement for consent; waiver of requirement for consent. The consent model is influenced by the type and process of data collection. The CQR may also modify methods of consent for some or all groups of participants
  - *Data quality assurance* – information about the technical and manual processes to ensure the quality and integrity of the data
  - *Analysis of data* - high-level description of routine analyses for core registry aims
  - *Reporting process* – how and where the CQR data is routinely reported including public reports; hospital/site reports; and ad-hoc/ bespoke reporting, as well as any statutory or contractual requirement for reporting e.g. to governments or funders
  - *Data access and sharing* – definition of those personnel who have access to the CQR data for operational purposes, as well as processes for third parties to request access to the data
  - Processes *for data to be provided* to/viewed by sites for quality improvement e.g. sharing via electronic access /dashboards, or via confidential reports to clinicians
  - Comparative reporting and identification and management of variation (if appropriate).

The CQR Protocol is approved as part of the CQR HREC approval process, and is required to be reviewed and authorised by hospitals/sites before data collection can begin. The protocol is a *living document* and is updated by the CQR when needed. Any *proposed changes* to the protocol need to be reviewed and approved by the auspicing HREC(s) as well as be authorised by sites. If the CQR Protocol is *breached*, then the CQR must notify the approving HREC as well as any affected hospitals/sites.

Resources and References (see also Section 6)

NHMRC's. National Statement on Ethical Conduct in Human Research (2023).

ACSQHC National Safety and Quality Health Service Standards. 2nd ed. – version 2. 2021.

Australian Institute of Health and Welfare

International Classification of Disease 10-Australia Modified (ICD-10-AM)

Victorian Admitted Episodes Dataset

NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)

NHMRC Keeping research on track II: A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)

DHAC TGA. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) Guideline for Good Clinical Practice (ich.org) as adopted by the TGA ICH Guideline for Good Clinical Practice – 2018

Ethics and Governance Requirements for a CQR

The CQR hospital/site PI is an important facilitator of CQR approval. The nominated site PI can assist the process by advocating for the CQR within their hospital/site, and reviewing and signing key HREC and health service documents that require review. CQRs may vary in the support that they can provide to PIs regarding preparation and submission of paperwork for site approvals.

Key Messages

In general, the following are required to commence CQR activities including participant recruitment, at a hospital/site:

- **Ethics approval for the registry and participating sites**
- **Site-specific authorisation (governance)**
- **An agreement signed by the CQR and hospital/site**

Approval requirements for CQRs

CQRs that aim to collect health information are (generally) required to (1) undertake review by a suitable HREC; (2) obtain specific governance authorisation from each participating site, health service or hospital group; and (3) execute a registry agreement with each participating site, health service or hospital group. A CQR cannot commence participant recruitment at a site until these requirements are met for each site.

Ethical Approval for CQRs

CQR ethical approval comprises initial approval by a *'lead'* or *'primary'* HREC. This HREC is generally one that is operating under the *National Mutual Acceptance (NMA) scheme* (see Section 6) and is *often aligned with a large public health service*. The lead HREC reviews the ethical and scientific aspects of the CQR's application.

The NMA scheme allows other health services to recognise and accept the approval of the 'lead/primary' HREC, without undertaking an independent review of the CQR's application. However, this is not mandated and individual HRECs may still decide to undertake a full review of the CQR application.

The *ethical review pathway* that a CQR undergoes depends on the risk profile of the registry. Risk is a potential for harm or discomfort, and the likelihood and severity of that harm or discomfort. Determination of risk relates to a number of factors including the participant consent approach (explicit opt-in, opt-out approach and/or waiver) and the type of data being collected (including its identifiability and sensitivity) as well as the cohort characteristics (e.g. vulnerability). Depending on the level of risk assessed by the lead HREC, the CQR ethical review pathway may be *Low/Negligible Risk* or higher than this.

Site Governance Authorisation for CQRs

In addition to having HREC approval, CQRs generally require *approval by each participating health service*. The authorising unit within health services may be a hospital Research Governance Office (RGO), particularly in the public sector. In public health services and some private sites, a Site-Specific Assessment (SSA) is generally used for CQR assessment. In private hospitals, site approvals for CQRs may be provided by other processes such as the Medical Advisory Committee or Clinical Governance unit within the hospital.

The role of *governance authorisation* at each participating hospital/site is to ensure that the hospital agrees to participate in the CQR and understands the roles and responsibilities of both parties in relation to CQR activities at that hospital.

Site governance requires *nomination of at least one participating clinician(s) from each health service to participate in the CQR*. The clinician who has oversight of participation in the CQR at a site is generally nominated as the Principal Investigator (PI) or Site Registry Lead. There may be more than one PI for a site if multiple health professional groups contribute to the CQR.

In private hospitals there may not be a designated PI, and participating clinicians may individually choose or not to contribute. CQRs aim to recruit all clinicians from participating sites to ensure that their contributed data is representative of their patient population, and therefore will provide meaningful information when reported back to the health service and clinicians.

Specific Jurisdiction Authorisation requirements

Some jurisdictions may have additional approval requirements. For example:

- Queensland requires CQRs to apply for approval with Queensland Health (approval via the Public Health Act) before seeking approval for individual or group hospitals within Queensland
- application for CQRs at sites in Victoria and Western Australia requires completion of the Victorian Specific Module (VSM) and the Western Australian Specific Module (WASM) respectively
- application for CQRs at sites in New South Wales (NSW) public health organisations must comply with *Policy Directive Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations*.

Site-specific CQR Agreements

As part of the site-specific approval, an *agreement between the CQR and the hospital/site* is required to be signed by both parties prior to commencement of participant recruitment.

Some CQRs use a modified version of the *Clinical Trial Research Agreement (CTRA)* as the CQR agreement with hospitals/sites. These are generally recognised by public hospitals. Alternatively, many private hospitals and some public hospitals may require bespoke agreements.

Other Ethics Requirements for CQRs

Following HREC approval, CQRs must undertake the following activities:

- submit an annual progress report to each approving HREC and hospital governance body/ RGO, as per individual site requirements
- submit an amendment for any changes to the registry protocol including personnel changes to the lead HREC and the relevant hospital governance bodies
- submit any reports regarding a deviation or breach to the CQR protocol to the lead HREC and affected hospitals/sites.

Resources and References (see also Section 6)

NHMRC's National Statement on Ethical Conduct in Human Research 2023, particularly Sections 2.1 and 2.3

Site and Clinician Onboarding

It is important that all clinicians and sites electing to participate in the CQR acknowledge and agree to their responsibilities and obligations. Whilst it is not a requirement of all CQRs to have a formal agreement with the clinicians who are willing to be involved, such agreements lend weight to those responsibilities. Participating clinicians and any of their staff who will be involved in the enrolment of their patients in the CQR should undertake training to ensure that they understand appropriate procedure and processes.

Key Messages

- **Once an HREC and hospital/site has approved a CQR, the hospital may prepare for participation in the CQR**
- **Many hospitals/sites nominate a Principal Investigator/CQR Lead for that site (or may be more than one site PI if more than one clinician group contributes to the CQR). The site PI(s) encourage(s) additional clinicians to participate in the CQR from that site**
- **In general, only fully trained clinicians (fully qualified healthcare professionals) are nominated to recruit participants for the CQR from each site. Trainee clinicians may participate in the collection of data under a nominated fully qualified member of staff**
- **CQRs will generally provide specific information, training and resources to site PIs and others regarding their specific roles and responsibilities in relation to the CQR, often including agreements for clinicians who choose to participate**
- **CQRs may regularly review personnel at each hospital/site that have access to the CQR database to confirm that they remain active users**

Principal Investigators (PIs) and initial participating clinicians are generally identified for each hospital/site during the CQR's application process. The PI has particular roles and responsibilities in relation to overseeing and assisting with CQR participation at that site.

The Hospital/Site CQR Lead role

The role of the CQR Lead or PI includes the following responsibilities:

- be a point of contact for the CQR at the site
- engage and nominate eligible clinicians to participate in the CQR at that site
- understand and support site compliance with the CQR Protocol and supporting documents
- maintain appropriate documents as required for the CQR activities
- undertake and/or support participant recruitment and/or data collection in accordance with the CQR Protocol and any related guidelines
- respond to participant queries about the CQR

- promote hospital/site participation in the CQR
- uphold the CQR's ethical requirements to protect the privacy and confidentiality of CQR participants, particularly as relates to use of CQR data infrastructure
- ethics and governance reporting requirements or amendments that require site PI approval
- collaborate with the CQR to investigate and manage any breach of a CQR protocol at the site
- review and disseminate to participating clinicians, reports provided by the CQR to the site
- comply with CQR variation management or outlier policies and processes by investigating clinically significant reports of variation in care or outcomes.

Nominating staff

Clinicians and other health professionals who agree to recruit participants at a site are provided with training by the CQR before commencement. During this training they are made aware of their ethical and legal responsibilities in taking part in the CQR. Often, they sign an agreement with the CQR regarding their intention and capability to undertake the CQR duties.

Training

To support clinician onboarding, the CQR provides clinicians with specific training regarding the CQR including their roles and responsibilities, which may include:

- identifying the eligible CQR population e.g. those with a specific medical condition or procedure, and their timepoint of entry to the CQR (e.g. at time of diagnosis or time of surgery)
- requirements for informing participants of the registry, including the model of consent or opt-out processes used by the CQR
- demonstrating data collection process(es) e.g. the data entry platform (where applicable)
- describing the minimum data set and data items, including the CQR data dictionary
- discussing data quality assurance processes to minimise missing and erroneous data
- advising of how and when site CQR information is provided back to the site e.g. via reports or online dashboards.

Specific CQR training may be undertaken in person or online. The CQR generally provides all relevant documents for site participation, which may include participant information sheets (PIS), data dictionary, user guide for an online registry platform, data collection forms, access requirements to systems for data entry, as well as access to any other systems required e.g. access to any secure platform for sharing of data sharing extracts between sites and the CQR platform.

Non-clinical site staff such as hospital Information Technology (IT) or business intelligence teams may also be involved in supporting the CQR e.g. via providing data extracts or uploads to the CQR. It is generally the responsibility of the PI together with the CQR to collaborate with these staff regarding their role in supporting the CQR's data collection.

Resources and References (see also Section 6)

NHMRC's National Statement on Ethical Conduct in Human Research 2023, particularly Sections 2.1 and 2.3

SECTION 3

Participant Data for CQRs

Participant Recruitment and Consent

CQRs have different consent options available to enrol participants

- opt-in consent
- a waiver of consent or
- an opt-out approach.

Whatever methodology it proposes, the approach must be approved by the lead HREC and must be followed in accordance with the National Statement and relevant privacy legislation.

The NHMRC's National Statement on Ethical Conduct in Human Research (2023) (see Section 6) requires an individual's participation in research to be voluntary and informed, as appropriate to the level of risk to the individual. This section provides an overview of participant recruitment and consent models employed by CQRs.

Key Messages

- An appropriate model of CQR participant consent must be approved by an HREC and obtained for all CQR participants
- Unlike interventional research, where a specific intervention is undertaken that may have health associated risks for participants, CQRs are observational studies, thus risk to participants is much reduced
- Models of participant consent typically used for CQRs include (1) Waiver of Consent; (2) Opt-out Approach; or (3) Opt-in Consent
- Many CQRs employ opt-out approach, which provides for participants to withdraw consent from participating in the CQR at any time

CQR participant recruitment usually involves an ethically-approved consent process.

Depending on the nature of the CQR, different approaches to consent during recruitment may be justified and approved by a HREC. In general, the HREC will assess the risk of participation for each CQR and balance this against the benefits the CQR may generate.

Consent models used by CQRs include:

i. Waiver of consent

An HREC may grant a waiver of consent for either prospective or retrospective CQR data collection. Explicit consent is not sought from the participant, and they will not know that their data is used for the CQR. In general, in order to approve a waiver of consent, the HREC must be satisfied that the research carries no more than low risk to participants, that it is impracticable to obtain consent (e.g. patients that are in an Intensive Care Unit), and that the research is in the public interest.

ii. Waiver/Opt-out approach

The waiver/opt-out approach is where a waiver is granted for a member of the clinical team at a participating site (e.g. a clinician) to provide participant contact details to a CQR for the purposes of recruitment. The CQR team then contact participants identified by the clinician and provide them with information about the CQR (usually in the format of a Patient Explanatory Statement [PES] that has been approved by the CQR's lead HREC). The PES describes the CQR, the data items collected, and potential uses of the data.

The opt-out process allows for a period of time to elapse (e.g. 2 weeks) following CQR provision of the PES to the participant. Following this time period, clinical data collection into the CQR may commence. Participants that do not wish to be included may opt out via methods described in the PES. Opting out may occur prior to the 'opt-out' (e.g. 2-week) period, in which case no clinical data will have been collected by the CQR; or participants may withdraw their consent at any time following the opt-out period. Participant information will then be removed from the registry, and no or limited participant information will be retained in the CQR database, as per the CQR HREC-approved protocol.

iii. Opt-in consent

In certain instances, CQR may utilise opt-in consent. This is usually when the HREC does not believe that the CQR meets the requirements for an opt-out approach or a waiver. This consent model requires the that the CQR provide eligible participants with a Participant Information and Consent Form (PICF). The participants then opt in to the CQR by directly communicating their consent (e.g. signing on the PICF). As with opt-out consent, participants may withdraw from the CQR at any time. Implied consent is also a form of opt-in consent; when the participant's action (e.g. completing a questionnaire), is taken as an indication that they are agreeing to participate in the research.

Participant groups that require specific ethical considerations

According to the *NHMRC National Statement*, specific ethical consideration is required in certain circumstances: women who are pregnant; people highly dependent on medical care who may be unable to give consent; people with a cognitive impairment, an intellectual disability or a mental illness; people who may be involved in illegal activities; Aboriginal and Torres Strait Islander Peoples; and people from other countries.

Person Responsible

If a participant lacks the capacity to give informed consent or is unable to opt-out, then a person responsible may be approached by the clinician/CQR and provided with the relevant information and asked to act on the participant's behalf. This person may decline participation, or opt-out on behalf of the participant.

Resources and References (see also Section 6)

NHMRC's National Statement on Ethical Conduct in Human Research (2023)

NHMRC Ethical consideration in Quality Assurance and Evaluation Activities (2014)

OAIC The Australian Privacy Principles

CQR Datasets

CQR datasets are carefully selected after consensus is reached by subject matter experts. They are reviewed and refined regularly throughout the lifetime of the CQR to ensure they remain relevant to the outcome and quality indicators measures tracked by the CQR, and to contemporary clinical practice. The Data Dictionary is a living document describing the fields within the CQR dataset and is a key supporting document to good governance and high-quality data collection. Site PIs are advised to familiarise themselves with the CQR data dictionary.

This section provides an overview of the components of a typical CQR minimum dataset (MDS), and how the dataset is reviewed and maintained over time by development and regular updating of the CQR Data Dictionary.

Key Messages

- **CQR datasets are purposeful collections of data items relating to individuals with a particular condition or undergoing a particular disease**
- **The datasets are typically built around a set of Clinical Quality Indicators (CQIs) that monitor processes and outcomes of care. Where possible, CQR CQIs are aligned with recognised standards or guidelines for clinical care**
- **CQR datasets typically comprise participant recruitment and demographic information; diagnostic and clinical assessment; procedural or treatment information; and usually outcome data at various time points**
- **CQR datasets are fully described in the CQR Data Dictionary, and are regularly reviewed to ensure that they remain relevant to practicing clinicians**

CQR dataset

A typical CQR dataset will comprise a demographic section including participant's age, and significant comorbidities/medical history of relevance to the CQR, often for the purposes of risk-adjustment. Other CQR information may include diagnostic information and clinical assessment; procedural or treatment data, and outcome information including at longer term follow-up. Many CQRs contact participants directly and therefore also have participant contact details such as name and contact details.

Selection of Data Elements

CQR datasets are purposeful collections of participant data that are usually developed around key CQIs that reflect best practice/care and outcomes for the particular condition or procedure. Good processes and outcomes of care are identified usually by reviewing existing clinical guidelines or standards of care, as well as research studies, and the datasets of similar CQRs. Often this information is refined by a group of clinical and registry experts, consumers and other subject-matter experts. The process usually involves review and refinement of a large initial proposed dataset until consensus on the final dataset is achieved.

For most CQRs, a high level of case ascertainment and low level of missing data is required (see section 4.2 on Data Quality), thus the data elements that are selected will generally be those that are able to be collected reliably and in a timely manner. CQR data elements are generally periodically reviewed to ensure that the CQR continues to capture clinical items of most relevance to clinicians, and that reflect evolving clinical practices.

CQR Data Dictionaries

CQR data dictionaries list and describe all the data elements that comprise the CQR data collection, including both clinical and patient-derived data and measures. They also provide information about the 'metadata' (characteristics of the data such as an item's source, response options and interdependencies with other data elements). They are key supporting documents of good data governance and high-quality data collection.

Data dictionaries can be presented in various formats (excel spreadsheets, word documents, etc) but, regardless of format they generally address the following points (at a minimum) for each data element:

- the name and definition of the data element
- these should be referenced, wherever possible, to existing data dictionaries and vocabularies such as METEOR, FHIR-AU, SNOMED-CT, ICD-10-AU (see Section 6), and discipline-specific reference sets
- the purpose of collecting that data element (e.g. treatment vs outcome variable)
- database variable/ field names and system mechanism (dropdown, checkbox, free text, etc)
- permissible values including ranges, and code sets
- relationships between the fields such as conditional relationships, or derived or calculated values
- designated data elements that are mandatory and those that allow an unknown or not stated response.

Some CQRs may not collect participant identifiers, and all participant contact is via the participating sites/clinicians and not the CQR. CQR datasets that do include identified participant data generally include the minimum identifying elements required, to minimise privacy risks. Elements that can directly or indirectly identify participants include:

- Name
- Date of birth
- Address (postal or email)
- Mobile phone number
- Hospital record identifier (URN, MRN)
- Individual Health Identifier (IHI)

As with the CQR dataset, a data dictionary is a living document that is version controlled and is updated regularly during the lifetime of the CQR. Any updates made to variables are approved via a formal governance process and recorded.

Resources and References (see also Section 6)

OAIC Privacy guidance for organisations and government agencies; Handling requests for personal information; De-identification and the Privacy Act – March 2018

Collecting Data for the CQR

Specific responsibilities for site PIs in relation to data collection are to:

- assist the CQR such that only approved site personnel are able to access participant records for the purpose of data collection
- facilitate site training in data entry by the CQR
- assist with any required honorary appointment in relation to external data collection, and any internal extraction from hospital/site systems
- be aware of and comply with any additional data management and security transfer protocols of their site/hospital.

CQRs may collect participant data via a range of methods, that may also vary based on the hospital or site. Similarly, data transfer methods to the CQR may also vary depending on the site or clinician. Irrespective of the data collection and transfer method(s) used, the need for accurate, timely and complete data collection is crucial to high quality data.

Key Messages

- Timely and complete data collection is essential to the quality of the CQR outputs. To support this, CQRs provide those who collect data with training and resources
- Common methods of participant data collection for CQRs include (1) direct database entry; (2) data extraction from systems by hospital staff; and (3) third party data collection, often from direct access to hospital systems. Use of a combination of data collection methods for CQRs is common
- Where data collection requires transfer of the data from the hospital to the CQR, a secure process should be used to maximise participant privacy and minimise the risk of data breach
- Where a party external to the hospital/clinic collects participant data for the CQR, they may require some form of approval or appointment from the hospital to undertake this

Methods of access to and transfer of data to the CQR

CQR data collection can be performed by the site PI, site clinicians and other health professionals, or other nominated site data entry personnel. Alternatively, some hospitals provide data to CQRs from their existing electronic systems (from Electronic Medical Records [EMR] or other bespoke systems). Also, some CQR staff or subcontracted third parties collect data by accessing participants' data from a hospital/clinic medical record, either on-site at the hospital or remotely/electronically.

Different hospitals or jurisdictions have different policies and processes in relation to these models of data collection. Whatever system(s) the CQR uses will be described in the CQR's HREC-approved protocol. Additionally, CQR staff requiring access to hospital data will likely be required to apply for hospital/jurisdictional approval for this.

CQRs generally collect data throughout the year, although some CQRs may have periodic data collection. CQRs frequently nominate specific dates when data is required to be entered to be included within a particular reporting cycle. This may include data for upcoming Annual or Site reports.

Generally, data collection falls under one of the methods outlined below:

1. **Direct database entry:** A clinician participating in the CQR, or their delegated nominee, enters participant data from their hospital directly into a (e.g. web-based) CQR database. This usually requires review of some information in the participant's medical record by hospital/private practice staff.
2. **Data extract:** Staff employed by the hospital provide data extracts of recruited participants from hospital systems to the CQR on a regular basis. This requires a level of EMR and/or digital maturity at the hospital. The extracted data then needs to be transferred to the CQR. This may be via a Secure File Transfer Protocol (SFTP) to the CQR, or via an API (direct external conduit) directly into the CQR database.
3. **External data collectors:** Data is collected by a party external to the hospital/clinic. This may include data collectors employed or managed by the CQR, or staff who are subcontracted by the CQR to another third party to undertake data collection on-site or remotely via access to the hospital/site EMR. Often the external data collector requires some form of approval or appointment from the hospital/site to undertake this activity.
4. **Other methods** of data collection for CQRs include hospital clinical or support staff completing and sending paper forms to the CQR which are then uploaded manually or automatically into the CQR system; or CQRs may also undertake data linkage with external (e.g. non-hospital) data sets and incorporate this data into their datasets. The methods of collecting and providing/transferring participant data to a CQR is described and documented in the HREC-approved study protocol. Accurate, timely and complete data collection is essential to the quality of the CQR reports and outputs. Methods of data access and collection often vary between health services, often due to the level of individual health service digital maturity.

Evolving methods of CQR data collection

While in the long-term it is aimed that CQRs will source data directly from hospital digital information systems (e.g. EMRs), it is recognised that there are current limitations to this including - that not all clinical care providers (particularly private health services) have hospital-wide digital systems; EMRs are not standardised nationally or even at a state level (e.g. in Victoria); EMRs do not usually contain the majority of CQR items required to monitor quality and safety; EMR data may not be of high quality (e.g. may be unstructured on incomplete); and health care providers may not have sufficient internal resources or capability to undertake the regular data extraction required for each individual CQR. Newer technologies such as Fast Health Interoperability Resources (FHIR-AU) may overcome some of these challenges. Nevertheless, it is a long-term aim of CQRs to reduce duplication of data collection by incorporating more existing clinical data into CQRs from existing data sources.

The most suitable method of data access, collection and transfer for each CQR is described in the CQR protocol, and is an important component of training for site PIs and nominated hospital/site support staff during the site onboarding process.

Central to any data collection method is the need for high quality data collection and compliance with project and site data management and security policies and protocols. Data collection methods may vary from one site to another and encompass a combination of onsite access and data entry, remote access and data entry, data extraction, and third-party systems depending on the site capability and CQR requirements.

Patient Reported Measures (PRMs) Collection

PRMs are used to capture the participant's and/or their carer's perspective of their health outcomes and experiences. Hospital/Site PIs should be aware of whether the CQR they contribute to collects PRMs, and the PRMs collection methods. If PRMs collection is via the clinician or hospital then the PI will need to be provided with information and training by the CQR to support this activity. For CQRs where PRMs are collected as an adjunct to clinical care, the PI and site clinical staff should regularly review their PRMs survey data where possible.

Patient Reported Measures (PRMs) include Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs). PRMs are patient surveys that provide a patient perspective of their experience and the service quality and outcomes of care provided to them. Similar surveys may also be provided to patient carers and proxies (e.g. for children/ other vulnerable populations). Capturing the patient's and/or their carer's perspective through collection and analysis of PRMs provides a unique perspective that can assist clinicians and health service providers to improve the quality and experience of care that their patients receive.

Key Messages

- PROMs and PREMs are surveys/questionnaires that measure healthcare experiences, service quality, and outcomes from the patient's perspective
- CQRs may collect PRMs to provide additional information to support providers in delivering high quality care
- CQRs may utilise different consent models for PRMs collection. They may also implement PRMs via different methods. Methods of survey administration may include telephone interview, paper, email or text message
- CQRs may distribute PROMs/PREMs surveys to participants at the time of diagnosis/ procedure (baseline), or at one or more standardised later (follow-up) time-points

Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs)

As well as collecting clinical data (data recorded by clinicians or hospital staff), CQRs may also collect data from participants (patients, carers, proxies). These data - PROMS and PREMs - enable measurement of patient experiences and outcomes directly from the patient, and are used increasingly in CQRs. Because PRMs do not necessarily require clinician involvement, they may be collected by CQRs at time points in addition to those where clinical data is collected. In particular, PRMs data may be collected prior to regular clinical review, or following discharge from a hospital admission or period of clinical care.

PRMs may be used by CQRs for:

- helping to guide appropriate and personalised clinical care for existing or future patients
- to evaluate and monitor the services they are providing and to review their effectiveness over longer periods
- enhancing clinician-patient interactions (e.g. when PRMs are collected prior to patients' regular clinical review)
- providing aggregate information regarding patient outcomes over time, between patient groups, between different treatment interventions, or between providers. Analysis of this information may assist clinicians or hospitals in improving clinical care for future patients
- population-level surveillance (e.g. over time, group comparisons) for research and informing policy or program development. Some generic PRMs tools may also be used for health economic analysis (e.g. costs, healthcare utilisation) in the health system.

PROMs capture the participant's perspective of their health status via participant completion of a series of questionnaires regarding their quality of life, daily activity, disease impact and wellbeing.

PREMs ask participants to describe their perception of their experience during their healthcare encounter. In both cases, the completion of questionnaires comes directly from the patient and does not involve interpretation or influence by the clinician or anyone else. The use of PRMs in combination with clinical data provides important multi-dimensional information to care providers of the experiences and outcomes that are important both clinically as well as to the participant.

PRMs Tools (Surveys)

CQRs often use PRMs surveys that have been validated by researchers to ensure that they accurately measure key items that align with the CQR's aims and objectives. CQRs may choose tools that are specific to a particular condition (e.g. a cystic fibrosis-specific survey) or to measure patient experiences and outcomes that are relevant across many different health conditions. Thus, PRMs may be **Generic** - that measure aspects of experience/ health that are common to most patients - or **Condition-specific** - that include questions that directly relate to specific health conditions and their associated treatments. Both types of measures have advantages and disadvantages, and often more than one type of tool is used by the CQR.

PRMs Consent and Administration

CQR participants should be informed via the PES that the CQR collects PROMs. CQRs may involve their participants in PRMs via a variety of consent models including opt-in consent or opt out (implied). The consent model used (see section 3.1) is documented in the CQR Protocol.

Timepoints for administering the PROMs will vary depending on the specific condition and will be influenced by disease-specific treatments. Ideally, PRMs are collected at the time of diagnosis or prior to treatment, although this is not always possible. PRMs are generally collected for at least two time points for each participant.

PROMs can be administered in a variety of modes including paper based, electronic or text message questionnaires completed by the eligible participant, or they may be conducted as an interview by CQR or hospital staff, face to face or telephone.

Resources and References (see also Section 6)

ACSQHC Patient-reported outcomes measures

ACSQHC Australian Hospital Patient Experience Question Set

SECTION 4

Data Governance for CQRs

Data Governance

There are many ethical, scientific, regulatory and legislative obligations in how data is collected, stored, used, shared and reported. Site PIs should know the data governance arrangements that are in place for the CQR, and their site's role in complying with these. As a Site PI, your part in data governance is to ensure that you and staff participating in the CQR at your health service understand your obligations, follow the rules e.g. policies/ procedures set out by the CQR to meet these obligations, and ask the CQR any questions if the roles or responsibilities are not clear.

Data Governance provides control over the data activities of CQRs. Given the highly sensitive nature of the personally identifiable or re-identifiable health data collected about participants, and the obligations to protect such data, it is important that all those involved in CQR activities understand the rules as set out in policy, procedures and the systems used by the CQR to govern their data.

Key Messages

- **CQRs collect personally identifiable or re-identifiable health data from participants, and therefore must meet specific legislative and regulatory requirements, as well as industry standards, institutional policies and procedures, and consent/participation requirements**
- **CQRs have a set of rules and processes that must be followed by hospitals/sites to ensure that the CQR data activities meet their data governance requirements**
- **CQRs have policies and procedures that describe the roles, responsibilities, systems and processes for CQR data activities**
- **Hospital/site staff and external data collectors should be informed and trained in the CQR's data collection, quality assurance, data transfer and reporting processes and data systems**

Definition of Data Governance

Data Governance can be described as *"a cross-functional framework for managing data as a strategic enterprise asset. In doing so, data governance specifies decision rights and accountabilities for an organisation's decision-making about its data. Furthermore, data governance formalises data policies, standards, and procedures and monitors compliance."* The purpose of data governance is to define the decision-making and control over data activities.

CQRs collect personally identifiable (or re-identifiable) health data, and so must meet the obligations that flow from legislation, regulation, industry standards, institutional policies and procedures, and the CQR protocol itself. CQRs have rules to control its data activities that cover:

- Why and how data is to be collected/ generated
- How the data is defined and quality maintained
- How the data will be stored, accessed and managed while it exists
- How the data will be analysed, used and communicated to inform decisions
- If and how data will be shared with others.

In formulating these rules, it should be clear who has decision making authority. These rules should underpin any data system or process that is developed, and be clearly communicated in policies, procedures and agreements as well as through training.

Data Governance Mechanisms

CQRs generally use the following data governance mechanisms;

i. CQR Data Roles and Responsibilities

Common data governance and management roles and responsibilities include:

- *Overall Data Controller* (e.g Data Custodian, Data Steward): the person, committee or organisation that has ultimate responsibility for the data
- *Data Sharing Approval*: the person, committee or organisation that is responsible for approving sharing of the CQR's data for the secondary use in research or other quality improvement activities
- *Data Manager* (e.g Systems Administrator, Data Processor): the person (or organisation if third-parties separate to the controller are engaged) who has delegated authority to manage the data on a day-to-day basis
- *Data Collectors*: the people who are delegated authority to collect data from hospitals or private clinician systems and provide it to the CQR.

ii. CQR Data Policy/ Procedures

Both the CQR's legal entity/organisation and the CQR itself generally have a range of data governance policies and procedures including (but not limited to):

- Data Quality/ Assurance and Verification
- Access to Data Systems
- Data Protection, Privacy and Security
- Data Sharing for Secondary Purpose
- Outlier and Other Reporting of Data

iii. CQR Data Systems, Processes and Tools

All CQRs have systems, processes and tools (both digital and physical) to collect, collate, store, aggregate, analyse and report data. These may include:

- The CQR's data dictionary
- Data collection and reporting systems
- Data sharing platforms/systems

Resources and References (see also Section 6)

Abraham R, Schneider J, vom Brocke J. 2019

EDPB Data controller and data processor

A-GD Government response to the Privacy Act Review Report 2023

Data Quality Assurance

PIs have an important role in maximising the quality of CQR data collected through encouraging clinician participation at their hospital/site, as well as regularly monitoring and reviewing the completeness and quality of the data submitted from their site to the CQR.

The quality of the outcomes and recommendations from a CQR are only as good as the quality of the data collected. Data quality can be measured across a number of domains, and CQRs take a number of approaches to ensure the quality of their data. One of the key issues for CQRs is missing data, particularly missing cases that may affect overall outcomes. Everyone has a role to play to ensure the quality of CQR data and therefore, its usefulness.

Key Messages

- **For CQRs to achieve their aim of improving the safety and quality of healthcare, it is critical that the data being analysed and reported is high quality. In particular, missing data is a common data quality issue for CQRs**
- **Data quality domains identify attributes of high-quality data. The Australian Bureau of Statistics (ABS) identifies six dimensions of quality – relevance, accuracy, timeliness, accessibility, interpretability, and coherence**
- **CQRs have a variety of mechanisms to ensure high quality data - such as policies and procedures; automated or manual data validation checks; or CQR data verification against external data sources, such as audits of health service medical records, or linkage with health service administrative datasets**

Data Quality Assurance in CQRs

CQRs aim to improve the safety and quality of healthcare. This can only be done if the data that is being used to measure outcomes is high quality. Quality in health and research data can be measured in a number of ways (see *COSMIN Consensus-based Standards for the selection of health Measurement Instruments for research data* (see Section 6)*, or ONCHIT US Office of the National Coordinator for Health Information Technology for US health data)* (see Section 6). The Australian Bureau of Statistics' ABS Data Quality Framework (see Section 6) is the most widely used in Australia. It identifies six dimensions of data quality:

- Relevance - are the right data elements being collected to report on relevant outcomes?
- *Accuracy* - is the input and output data correctly defining what it aims to measure?
- *Timeliness* - is the data timely enough to make decisions?
- *Accessibility* - can the data be accessed routinely?
- *Interpretability* - can the data be understood and interpreted correctly?
- *Coherence* - does the data make sense with other data/ information that is available (internal and external consistency)?

The relevance of the data (often referred to as validity within research) will have been determined by the clinical team involved in establishing the CQR, and/or relevant clinical peak bodies. This group will have determined the appropriate outcomes to be measured and how they should be measured to ensure quality and safety.

In addition, CQRs will usually have a Data Quality Assurance policy or procedure (see Section 4.1) that outlines what the CQR will do to ensure their data quality is maintained. It should outline in detail the regular processes in place to ensure accuracy and coherence such as:

i. in-built data verification checks of the data systems (e.g. range and value violation checks, business rules, duplicate record restrictions)
ii. regular manual verifications checks performed by the CQR staff (e.g. internal validity checks, unexpected values, distributions or association checks, incomplete processes, incomplete data, duplicate records)
iii. sample audit of CQR data against medical records for case ascertainment, and validation of key fields that align with the CQR's quality indicators
iv. comparison with other data sets to confirm coherence.

CQR case ascertainment and levels of data completeness

For a CQR, case ascertainment relates to the proportion of patients/ providers/ encounters that the CQR has captured, compared to the total eligible population across the health system. CQR case ascertainment can be considered as capture of:

i. health service provider participation – the proportion of (Australian) health services that manage the CQR's eligible population that participate in the CQR, vs those that do not. As has been noted, it is a time consuming and costly process for health services to be approved and onboarded to participate in CQRs. It often takes many years for a CQR to have a majority of eligible health services across Australia participating in the CQR
ii. clinician participation – the proportion of clinicians within participating health services who participate in the CQR, vs those who do not. Even when a health service has the approvals to participate in a CQR, each individual clinician may not have completed the necessary agreement or training to be able to participate
iii. clinical form completion – Each CQR data form that is completed by a site clinician or other nominee may have some data items incomplete. This may be due to the clinician having insufficient time, competing priorities, or the information required is not readily available. Additionally, individual clinicians may not always submit every eligible patient into the registry, due to oversight, other priorities, or a reluctance to include patients with poorer outcomes.

CQR participation by health services and clinicians is not mandatory, and it can take many years before a CQR is mature and has a population-level of data capture. During this time, CQRs regularly estimate the proportion of eligible hospitals, clinicians and participants that they are capturing so that users of the CQR data can take this into account when interpreting the CQR data.

Timeliness and data quality

The timeframes involved in the CQR data collection, verification, and production of an output/report can affect the usefulness of the data. CQRs must balance the time taken for data collection and quality assurance versus the need to regularly report the data back to providers. In general, CQRs have regular timeframes around when outputs or reports are produced that are acceptable to the community of users and decision makers they serve, including contributing sites.

Resources and References (see also Section 6)

OVIC The Limitations of De-identification – Protecting Unit-Record Level Personal Information

Data Privacy and Confidentiality

While CQRs are low risk activities, their main risk to participants is of breaches of participant privacy. Site PIs and their staff should undergo specific training in data privacy, including in preventive measures to minimise data breaches. When collecting, transferring, communicating and reporting CQR data, PIs should ensure that patient privacy is prioritised, and that secure processes and systems are used at all times.

Data privacy and confidentiality is critical to how CQRs govern their data, given the highly sensitive nature of the personally identifiable or re-identifiable health data collected about participants.

Key Messages

- **CQRS may be assessed by the HRECs at variable level of risk to participants, however, the main risk is the risk of a breach of personal participant information, which may cause participant concern**
- **CQRs generally have a Privacy Policy which sets out how and why participant information is collected, used, disclosed and stored, in accordance with national privacy principles**
- **A privacy breach of a CQR occurs when a CQR participant (participant or clinician)'s information held by a CQR is accessed or disclosed without authorisation, or is lost. CQRs have specific reporting requirements if a privacy breach occurs**
- **Hospital/site staff participating in CQRs should undergo specific training in data privacy including preventive measures to minimise data breaches**

Privacy considerations for CQRs

The conduct of a CQR is similar to observational research. Given there is no participant intervention, the main risk posed to CQR participants is one of breach of data privacy. At all times when CQR staff, health service clinicians or other staff handle participant data, they are obliged to maintain the participant's privacy in accordance with national and state privacy and health records regulations and guidelines.

CQRs and participating sites need to comply with various acts, regulations and principles in relation to privacy. Commonwealth legislation includes the 1988 Privacy Act, that also includes the Australian Privacy Principles. Jurisdictional Acts cover how health data may be collected, managed and disclosed within that jurisdiction. Important data privacy principles include:

- the minimum CQR participant data necessary must be accessed/used
- CQR data should only be used for its authorised purpose(s)
- staff who collect, manage, analyse and report using participant CQR data should be trained in data privacy.

In addition, CQRs usually have a Privacy Policy that sets out how and why information is collected, used, disclosed and stored for their particular CQR. At all times when the CQR collects or uses participant data, CQR and site/hospital staff must

be sure that participants have consented (by whatever method of consent is relevant to the CQR) to the management and use of their data in this way (or the HREC has granted a waiver in particular circumstances). While identified data has greater potential for a privacy breach, de-identified data may still breach privacy requirements, particularly if the CQR has a small number of participants (e.g. in rare disease registries).

Privacy Breaches

A privacy breach occurs when a participant's personal information is accessed, disclosed without authorisation, or lost. A privacy breach can harm an individual whose personal information is affected. They can, for example, suffer emotional distress or humiliation. The following are examples of potential causes of CQR privacy breaches:

- enrolling a participant in a CQR despite them requesting not to be included
- sending someone's personal information to the wrong person
- putting documents containing identifiable information in the rubbish or recycling, instead of designated locked confidential bins for destruction
- the CQR's database is hacked or access by unauthorised personnel.

Privacy breaches may be caused by an accident or genuine mistake; a failure of an organisational process or system; or by staff not following established processes.

Preventing Privacy Breaches

The risk of privacy breaches can be reduced by preventive strategies such as;

- CQR or site staff undertaking privacy training and signing confidentiality agreements
- ensure only those that require access to CQR data have that access
- employing methods that preserve participant privacy when communicating to participants via email, text or mail
- verifying contact details of participants before sending communications
- using recognised secure methods of transferring participant level data between CQRs and the site PI or staff. Using a SFTP as a platform for data exchange, or an API is good practice.

Managing a Privacy Breach (or one that is suspected)

If a CQR site PI or other member of staff becomes aware of a privacy breach, they should inform the CQR team as soon as possible. The CQR will undertake communication, investigation and mitigation actions to minimise any harm to participants that may arise from the breach. Site PIs may have internal reporting obligations at their own hospital/institution. Once a CQR becomes aware of a breach of privacy, they will report it to the relevant responsible HREC and site governance body, as well as any other organisational reporting requirements. They will also taking steps where possible to reduce the likelihood of similar breaches occurring in the future.

A Word on De-identification

In the current age of big data, it is difficult to fully "de-identify" data at person-level, but it is widely agreed that merely removing a person's name, address and other direct identifiers is no longer sufficient (see Office of the Australian Information Commissioner [OAIC] advice – see Section 6). Thus, CQRs and related staff should remain vigilant in relation to data privacy, even if participant data has undergone a de-identification process.

Resources and References (see also Section 6)

ACT Government Health Records (Privacy and Access) Act 1997

OAIC Privacy Act (1988)

Data Security

CQRs hold personal and sensitive data, therefore there may be personal and/or reputational consequences if CQR systems are inadvertently or maliciously breached. All users of CQR systems, including PIs and hospital/site staff need to practice good data security hygiene. This includes controlling and regularly reviewing who has access to CQR data at their site(s); adhering to CQR system password and screen and workstation security requirements; and use of institution-approved data infrastructure. PIs and clinicians should also be aware of and comply with their institution's data privacy and security policies, and participate in regular training to identify and manage data security risks within their environment.

CQRs are the custodians of personal and sensitive data, and thus if data is breached, there may be consequences to CQR participants, regardless of whether the breach was malicious or inadvertent. CQRs need to have systems and processes that protect their data assets that are involved in the collection, storage, transmission and sharing of data, from unauthorised access. CQRs and their legal entities are responsible for implementing a range of measures to protect participant and clinician confidentiality, ensure data integrity, and minimise risk of harm from misuse. Poor data security exposes CQR data to risk of theft, loss and modification, which may result in participant harm, reputational damage to a CQR, the CQR operator, and/or the health providers involved in care. It is critical that all staff involved or participating in CQRs practice 'good data security hygiene'.

Key Messages

- CQRs hold sensitive and personal information; therefore, CQRs and their legal entities have a responsibility to protect this data from unauthorised access and misuse
- To enhance data security, CQRs require effective and robust operational processes to securely manage routine use of data; clear data governance roles and responsibilities; information and resources to manage, investigate and report data security incidents; and regular staff training
- At all stages of CQR operations, from data collection to analysis and sharing, the CQR organisation and hospital/site should promote good data security practices and ongoing vigilance to potential risks

CQRs exist within institutional or organisational legal entities. These entities may include universities, research institutes, government departments or agencies, not for profits, or health services. Such entities have their own policies regarding data security, cybersecurity, data privacy and confidentiality.

CQR data may be managed by the CQR's legal entity (in-house) or alternatively some data management activities may be outsourced via partnerships with external data hosting or management providers.

Either way, data security can be considered as a combination of people, technology, processes, and policies working together to protect data to ensure its:

- confidentiality (i.e. no unintentional use and unauthorised access)
- data integrity (i.e. ensuring data is not altered maliciously)
- data availability (i.e. data is not held to ransom and is available when needed).

Security measures are implemented across many CQR activities. Examples of good data security practice include, but are not limited to:

Collection and Use of data

- Access Controls – CQRs ensure that only individuals who are authorised to access CQR data may access it, and individual access is regularly reviewed e.g.
  - swipe card access to physical data e.g. locked cabinets, access to specific rooms/data infrastructure
  - follow standard operating procedures to allow individual users access to CQR systems, and setting individual permissions in CQR data systems based on need or role
  - regular audit of user access to CQR data infrastructure
  - require strong passwords and multi-factor authentication (MFA) for access to CQR systems
  - screen and workstation security processes (e.g. locking screens when away from desk, logging out of systems after short periods of inactivity).

Storage and Transmission of data

- CQR use of institution-approved systems that have undergone appropriate privacy and security review (e.g. data systems, data collection tools, data transfer systems, participant communication tools, email and file storage servers)
- CQR data is held in jurisdictions approved by the governing jurisdiction's privacy laws
- qualified personnel and required technological infrastructure used to support all data systems:
  - preventative strategies such as antivirus protection, regular patching, ensuring systems have the latest software versions
  - detection and response including auditing, monitoring and incident response management
  - encrypting data in transit and at rest
  - network segmentation e.g. within servers
  - external auditing and/ or certification to ensure standards (eg ISO27001, NIST framework).

Sharing of data

- CQR Data Governance processes are led by qualified and trained personnel to oversee the technical and system management of CQR data
- Sharing of CQR data in secure environments maintained by the CQR operator (eg a safehaven)

Other

- Regular training to CQR staff may be provided by the CQR organisation/legal entity and /or by individual health services regarding their own processes and systems
- Training comprises key relevant legislation, policies and practices that optimise CQR-specific data security practices and policies
- CQR and participating sites need to report or escalate identified risks or breaches of data as soon as possible so that they can be managed and harm can be minimised within their local environment.

Resources and References (see also Section 6)

ACSQHC Australian CQR security compliance guideline consultation version, Second Edition, 2022

ACSQHC Framework for Australian CQRs Second Edition consultation version, 2022

CQR institutional data security protocols and processes

SECTION 5

When to Engage with the CQR Team

Communicating with the CQR

Communication between sites and CQRs may occur in a variety of ways. The Site PI/CQR Lead should feel free to contact the CQR at any time if an issue arises or they have questions which require clarification. Site PIs should communicate with the CQR if they have any challenges with their data contribution, have queries about their data, wish to provide feedback to the CQR, or request to use CQR data. CQRs communicate with sites regularly regarding their data quality and completeness, but also communicate via email, newsletters, meetings, and social media to more broadly engage and promote the CQR.

Regular communication between a CQR and its participating sites improves site engagement with the CQR, data quality, and promotes a mutually beneficial relationship. This section provides an outline of the key communication activities between a CQRs and its participating sites. Site teams should feel free to contact the CQR if they have any questions or concerns. CQR personnel should be available to assist and support participating sites with relevant issues and queries relating to CQR participation.

Key Messages

- **Regular, scheduled communications between the CQR and sites has a positive impact on the CQR achieving complete and accurate data collection, enabling high quality reporting back to sites**
- **Communications between the CQR and hospitals/sites are required at specified times and for specific activities, as well as informally**
- **There are various forms of communication that CQRs can use to interact with the sites that participate in the CQR**

Communications are a vital part of CQR operations. Good practice in communication will result in higher rates of engagement and improve the value of CQR outputs.

Regular Communication

Many CQRs establish proactive communication activities with participating sites, such as checking in periodically with the Hospital/Site PI to assist with any issues or challenges. In addition, communication between the CQR and sites may occur for the following reasons:

i. Communication from participating site to CQR

Participating sites are expected to nominate a point of contact such as a Site PI or CQR Lead, with a back-up nominated in case of extended absence or leave.

Hospital/Site PIs should generally inform the CQR team in the following situations –

Operational changes:

- changes in participating hospital/site personnel or contributing staff, or data collection resources.

Data submissions and quality checks:

- planned delays, outages or downtime that may affect data collection/transfer to the CQR
- if the site is experiencing difficulty in submitting data to the CQR by the required timeline
- site data is missing or incorrect and requires rectification by the CQR
- site protocol breaches (including data breaches at the site) should be notified to the CQR team as soon as possible. The CQR team will undertake any non-site-specific actions and reporting.

Reporting and variation:

- the site will confirm who are the nominated recipients of hospital/site quality reports from the CQR, including whether these are reported to individual clinicians, Heads of Units or health service governance personnel
- following review of site reports provided by the CQR, the site may wish to check its case ascertainment/data against its data held by the CQR, to check data validity and accuracy
- sites may apply for use of their CQR data (or aggregate CQR data usually following an approval process) for secondary purposes, research, QA or publication
- provide feedback to the CQR regarding how the CQR site data are being used to improve clinical care or outcomes, or how CQR information/ reports can be improved to enhance impact at the site.

ii. Communication from CQR Team to participating site

The CQR Team will usually nominate a named point of contact, including CQR organisation contact details for all participating sites. Contact details are also often publicly available on the CQR website.

The CQR Team will provide communications regarding the following to participating sites:

Data submission and quality checks:

- communication with sites regarding possible data errors or missing data items in the database that have been identified by the CQR which may impact on the overall quality of CQR data. This is particularly important to be addressed before data deadlines if possible.

Newsletter and updates:

- CQRs often use newsletters to promote the activities of the CQR; e.g. to notify sites of upcoming deadlines, advise of changes, and celebrate site and CQR milestones and achievements
- CQRs regularly communicate any changes in their staff/personnel, and promotional activities for the CQR such as webinars, user groups and committee meetings. This communication can be via newsletters, more formal communiques and via CQR websites or social media.

Annual reports are also often distributed by CQRs to their participating sites as they are a good opportunity for the site team to see the result of their contributions and helps to promote the CQR. Similarly, CQRs often use medical Society/ College conference meetings to interact with their participating clinicians and stakeholders, and promote their activities and outcomes.

Resources and References (see also Section 6)

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

Hospital/Site CQR Risk Management

Risk management is an important aspect of ensuring the delivery of a successful CQR. In particular, Site PIs and staff at participating sites should be aware of risks relevant to their participation, such as site ethics/governance risks, legal and privacy risks, data privacy and security risks, and risks related to sustaining site service delivery and resources. Site PIs and CQRs need to regularly communicate and engage to ensure that they identify and communicate these risks in a timely way, to prevent adverse consequences occurring.

CQRs face many of the same risks as other entities and organisations. However, there are additional requirements placed on CQRs by Australian law to keep participant information securely stored and confidential. CQRs have strict privacy and security procedures that must be followed. Only authorised staff can access information, and participant information cannot be identified in reports produced by the CQR.

This section outlines the various risks associated with hospitals/sites contributing to a CQR, including data collection and management, and how to manage a deviation from desired completeness and quality of data.

Key Messages

- CQRs hold and manage sensitive personal data, so both the CQR and the participating sites/clinicians need to identify, assess and mitigate associated risks which may lead to harm or a negative outcome
- Principles of risk management include the design and implementation of a proactive program of activities that reduce the likelihood or consequences of identified risks
- CQR-specific risks include those related to site governance, ethics or legal requirements; data privacy and confidentiality; data security and quality; and stakeholder engagement and site resources
- Realisation of risks may result in adverse consequences to the CQR, health service or CQR participants

This section outlines some specific risks associated with participating in a CQR, and how they can be managed.

- risk is the probability of harm or a negative occurrence. Risk severity is determined by the consequences of an event and its likelihood
- risk management is the design and implementation of a proactive program of activities to identify, avoid and minimise risks to participants, staff and the organisation
- identifying and reporting risk is the responsibility of all CQR staff and participating hospitals/sites.

Areas of Risk

While each CQR is responsible for undertaking its own risk assessment, examples of generic risk categories associated with CQRs that are relevant to PIs and participating sites are listed below.

- Governance/ethics (e.g. breach of CQR protocol at site)
- Legal/privacy (e.g. non-compliance with privacy legislation when transferring/sharing data)
- Data (e.g. limited data collection leading to poor data quality at a site)
- Data systems and security (e.g. poor management of database access controls at a site)
- Service delivery (e.g. lack of site engagement/ consistent participation)
- Resources (e.g. lack of site personnel/electronic systems to contribute data to CQR).

Governance/Ethics/Legal Risks

CQRs have overall governance structures and ethics or quality assurance approvals in place to undertake their activities. Each participating site/ hospital also requires site governance approval for the CQR before recruitment can commence. Additionally, some jurisdictions require additional approvals. Obtaining and maintaining these approvals may be the role of the CQR team and/ or staff at the participating site. It is a complex process, with risks that approvals may lapse, or protocol updates may not be implemented, the consequences of which may be that CQR activities are suspended at that site until the appropriate approvals are in place. The CQR and participating sites need to communicate regularly to ensure that site approvals remain up to date.

Privacy and Confidentiality

CQRs and site staff involved in transferring and sharing data must maintain participant privacy and comply with legal requirements, by following an appropriate data governance framework at all stages of the process. Risks associated with participant privacy and confidentiality are mitigated by clear communication of and assistance with required transfer/sharing processes from the CQR to the site.

Data security and quality

Risks are associated with insufficient staff training in CQR activities such as the CQR protocol, or poor site data security hygiene e.g. poor site database access controls. Both the CQR and the site PI/site personnel should ensure that participating staff are trained and can seek assistance from the CQR at any time. If site staff believe that a data risk (i.e. breach) has been realised, they should contact the CQR to seek assistance.

Stakeholder engagement and site resources

Inadequate site resources to consistently support CQR data collection activities can be a significant risk to successful participation in a CQR. At the time of seeking site governance approval, site PIs should confirm internally that they have support and sufficient resources to enable their participation in the CQR. Support for key site CQR activities may vary throughout a site's participation. CQRs will engage and communicate with sites to support their continued participation where possible.

Resources and References (see also Section 6)

ONDC Data Availability and Transparency Act 2022

AIHW The Five Safes framework Australian Digital Health Agency. National eHealth Security and Access Framework v4.0 - 2019

ACSQHC Australian CQR security compliance guideline consultation version, Second Edition, 2022

ISO - ISO 31000 — Risk Management

The Victorian Government Risk Management Framework

Primary CQR Outputs – Reporting for Improvement

There are a number of ways that sites and PIs can maximise the value that they obtain from reports provided to them from the CQR. These include:

- Engaging participation from all clinicians at the site, and encouraging timely, high quality data entry to ensure that it is incorporated into reports
- Reviewing CQR reports when received, ideally by all participating individuals, and by clinical management where appropriate
- Identifying opportunities for improvement from reports, and planning and implementing appropriate change activities, with the support of the health service
- Communicating with the CQR regarding any further reporting information or needs

The primary purpose of Australian CQRs is to drive improvements in the overall safety and quality of health care provided and health outcomes. CQRs do this by analysing data and generating risk-adjusted reports (output) and providing these reports, in a usable format and timely manner to relevant stakeholders who use the information to implement change for improvement. This reporting function is the primary output of the work of CQRs.

Key Messages

- CQRs are a national, valuable contributor to clinical quality improvement for the Australian health system, via their reporting to healthcare providers
- Data collected from participating sites is analysed by the CQR and reported regularly to participating sites to support QA and QI activities
- CQR reports are most effective when they provide information in ways that increase the likelihood of improvements in care and outcomes for participants, which may be different for different CQR cohorts

Local CQR Reporting

Timely data analysis and reporting locally to healthcare providers, accompanied by clinical interpretation, plays a critical role in local safety and quality improvement, and is among the core functions of a CQR. CQRs usually commence reporting to sites when they are collecting data from a sufficient, representative sample of the eligible population, and have sufficient data to provide meaningful comparisons. This usually occurs within the first few years of a CQR's establishment.

When sufficiently mature, CQRs generate benchmarked reports on the appropriateness and effectiveness of health care, and these reports are risk-adjusted (i.e. account for factors beyond the disease and provider's control that may affect health outcomes) where appropriate.

The frequency of provider reporting should be appropriate to the focus and purpose of the CQRs as a quality assurance activity, and the periodic site caseload. Alternatively, some CQRs provide feedback to sites via regularly updated clinical dashboards.

CQR reports may include written and/or other guidance to providers and other recipients of the reports, to assist them in interpretation of the data and its usefulness for driving improvements. CQRs may also present their findings via webinars, conferences or publications.

Health Service/Clinician Provider Reports

When sufficiently mature, CQRs provide regular confidential risk-adjusted and benchmarked reports to clinicians, health services, and jurisdictions (if applicable) to support structured QA reviews and inform policy, practice and quality improvement activities. Currently most CQR comparative reports to sites and clinicians are confidential, enabling them to review their performance against their (non-identified) peers.

CQR provider reports may include feedback to providers regarding their CQR data activity and completeness; how their patient cohort compares to others; processes and outcomes of care compared to others (benchmarked); trends over time; patient-reported data collected from the CQR; and device, drug or service utilisation. In particular, CQRs provide feedback to sites in relation to processes or outcomes of care that are regarded as best practice (Clinical Quality Indicators) or low value care.

Access to a contributor's own data and associated reports, as well as Medical Board and College requirements for regular review of performance and measuring of outcomes can be strong incentives for clinician participation in a CQR. CQRs also often enable or provide clinicians with access or reports relating to their own data upon request to support local practice improvement activities.
Recipients of registry reports are encouraged to provide feedback to the CQR so that reports can be tailored to meet their specific QA and QI needs.

Public Reporting

- to drive innovation and impact in a self-improving health system, the CQR National Strategy encourages CQRs to contribute to national reporting, including moving towards appropriate public reporting of CQR data
- CQRs also generally publish a public-facing Annual Report to increase stakeholder access to CQR information.

Outlier Results and Unwarranted Variation

CQRs collect data on real-world populations, so it is expected that when data between providers is compared for the first time, there will be variation in clinical practice and outcomes. However, when risk-adjusted for factors beyond the participant or clinician's control, variation may be more likely to reflect variation in care rather than be due to participant risk factors.

Positive variation can identify providers that are performing above their peers in relation to high quality healthcare practices. However, poorer than expected outcomes (outliers) from risk adjusted data may suggest that the provider's variation is unwarranted, and there may be opportunities for clinical care and/or service improvement at that site in relation to the activities monitored by the CQR. In such cases, the CQR would usually alert the site/clinician to any outlying variation, and recommend it be investigated internally. Mature CQRs have in place established policies and processes to effectively communicate instances of outlier performance or unexplained variation. They may also recommend that the outlying provider investigate opportunities to initiate improvements for identified clinical safety and quality issues. **These actions are the responsibility of the relevant stakeholder, and not the CQR.**

Resources and References (see also Section 6)

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

Secondary CQR Outputs – Data for Research and Sharing

Secondary CQR data outputs are an important means of maximising the use of high quality CQR data. Secondary users of CQR data must meet appropriate ethics requirements, and data must be provided to external parties in ways that meet data sharing regulations and legislation. Participating providers (health services, clinicians) are also encouraged to use their own or aggregate CQR data for these purposes.

CQRs are a rich clinical data source that can be made available (including sharing with others) for secondary purposes such as research, in order to maximise the impact of CQRs in achieving better health outcomes.

Key Messages

- **CQR data secondary purposes may include use for research, clinical trials or data linkage**
- **The use of CQR data for secondary purposes must meet ethical and privacy requirements**
- **Participating sites are encouraged to use CQR data for secondary purposes**

CQR data for research

Secondary use of CQR data by third parties for research presents an enormous opportunity to enhance the impact of the CQR data collection. Examples of secondary data use include clinical or health services research; epidemiological studies; monitoring drug or device performance; service planning; clinical guideline development or monitoring; policy development; service evaluation and may more. Outputs of these activities include publications and conference presentations, information to support regulatory approval decisions, or to guide clinical or service planning and/or evaluation.

Whatever type of secondary activities that are undertaken using CQR data must be noted in the PES provided to the participant at the time of their recruitment into the CQR. In general, CQRs do not provide identified participant data for secondary research purposes. If requested, the clinician responsible for recruitment of the participant must provide consent for this.

In addition to providing data for research, CQRs may support research activities such as registry-based trials. Registry-based trials combine the high internal validity of traditional trial methodology with the high external validity of CQR cohorts and systems to expand clinical research capability and reduce duplication of effort.

Data linkage

CQR data whether identified or de-identified, may be linked with data from other sources for a range of purposes including (1) determining capture rate of procedures or devices against another data source, or (2) collection and analysis of additional specific information relating to CQR participants e.g. relating to medication use, health service utilisation, or death. Linked data is particularly useful in providing information to the registry about longer term outcomes for CQR participants.

Approval process and policies

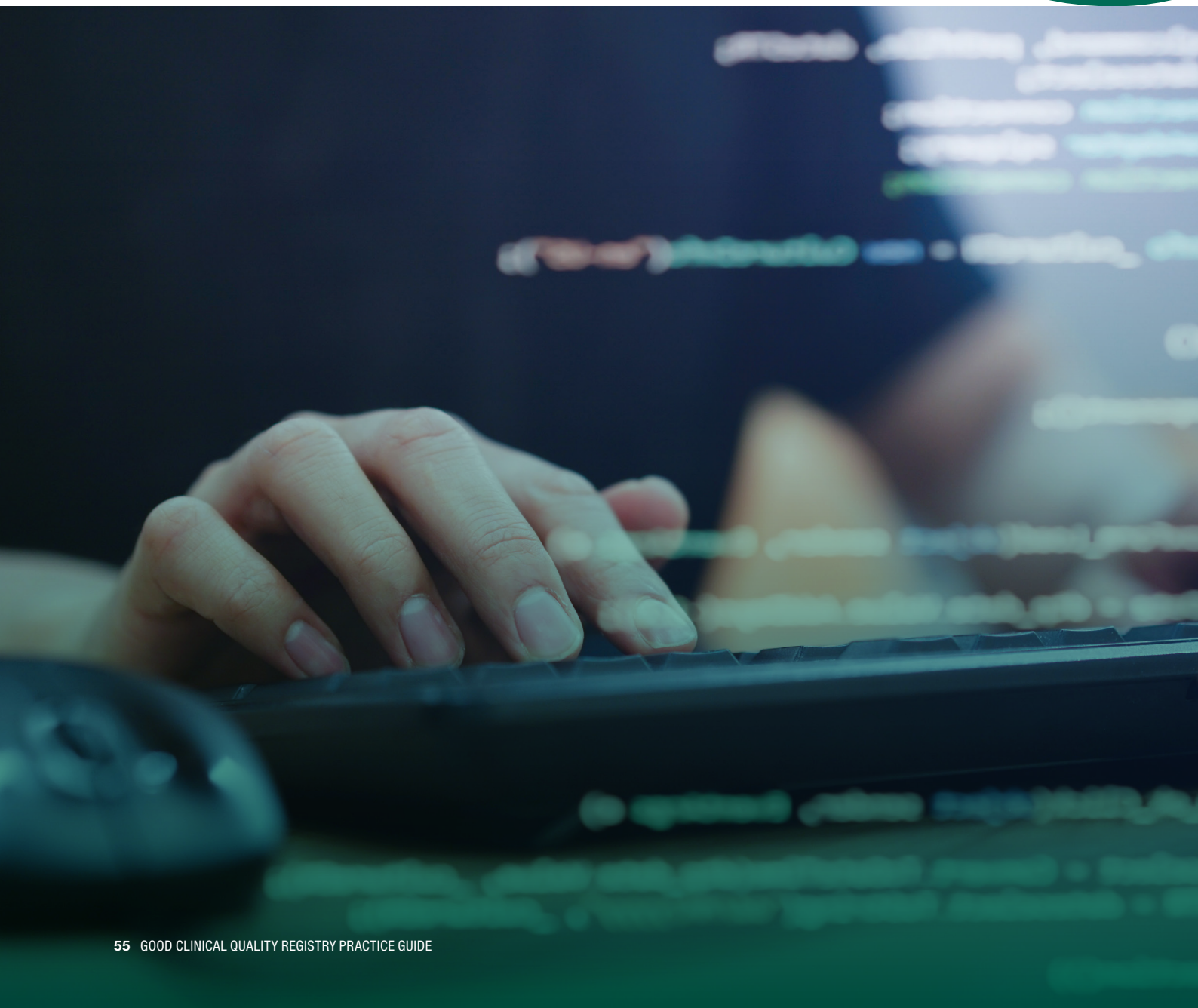
CQRs have policies and procedures to support data sharing for secondary purposes that reflect the various regulations and legislation relevant to sharing data. Third parties wishing to access CQR data for research must seek approval from the CQR and usually obtain HREC approval (usually low risk).

Resources and References (see also Section 6)

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

SECTION 6

Resources and References



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Acronyms

ABS	Australian Bureau of Statistics
ACSQHC	Australian Commission on Safety and Quality in Health Care
API	Application Programming Interface
APPs	Australian Privacy Principles
CME	Continuing Medical Education
COSMIN	Consensus-based Standards for the selection of health Measurement Instruments for research data
CPD	Continuing Professional Development
CTRA	Clinical Trial Research Agreement
CQI	Clinical Quality Indicator
CQR	Clinical Quality Registry
EMR	Electronic Medical Record
FHIR-AU	Fast Health Interoperability Resources (Australia)
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
ICD-10-AU	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification
IHI	Individual Health Identifier
ISO	International Organization for Standardization
IT	Information Technology
MDS	Minimum Data Set
METEOR	Metadata Online Registry
MFA	Multi-Factor Authentication
MRN	Medical Record Number
NDIS	National Disability Insurance Scheme
NESAF	National eHealth Security and Access Framework
NHMRC	National Health and Medical Research Council
NIST	National Institute of Standards and Technology
NMA	National Mutual Acceptance
NSQHS	National Safety and Quality Health Service
NSW	New South Wales
OAIC	Office of the Australian Information Commissioner
ONCHIT	US Office of the National Coordinator for Health Information Technology for US health data
PES	Patient/Participant Explanatory Statement
PI	Principal Investigator
PICF	Participant Information and Consent Form
PREMs	Patient Reported Experience Measures
PRMs	Patient Reported Measures
PROMs	Patient Reported Outcome Measures
QA	Quality Assurance
QI	Quality Improvement
RGO	Research Governance Office
SFTP	Secure File Transfer Protocol
SNOMED-CT	Systematized Medical Nomenclature for Medicine – Clinical Terminology
SSA	Site-Specific Assessment
URN	Unique Record Number
VSM	Victorian Specific Module
WASM	Western Australian Specific Module

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