AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

August 2024

Australian Framework for National Clinical Quality Registries 2024

Attachment 1: Australian CQR Logical Design and Infrastructure guideline

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

Level 5, 255 Elizabeth Street, Sydney NSW 2000
Phone: (02) 9126 3600
Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

ISBN: 978-1-922880-88-8

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

Australian Commission on Safety and Quality in Health Care. Australian Framework for National Clinical Quality Registries. Attachment 1 Australian CQR logical design and infrastruture guideline. Sydney; ACSQHC, 2024.

Disclaimer

The content of this document is published in good faith by the Australian Commission on Safety and Quality in Health Care for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your healthcare provider on particular healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

Contents

1. Introduction

1.1 Purpose

The purpose of the *Australian CQR logical design and infrastructure guideline* is to provide guidance to organisations wanting to establish or upgrade a clinical quality registry (CQR). This guideline is part of a suite of documents under the *Australian Framework for National Clinical Quality Registries 2024* (the Framework).

Well-designed CQRs – operating in partnership with Commonwealth, state and territory health departments, healthcare providers and peak clinical groups – support national reporting on the safety and quality of health care in high-priority clinical domains.

Specifically, the guidelines have been developed to:

- Drive CQRs towards international best practice for clinical outcome data collections and reporting
- Deliver efficiencies and interoperability in data collection and exchange
- Promote standardised approaches to CQR design that support the strategic and operating principles for a national approach to CQRs (refer to the *Australian Framework for National Clinical Quality Registries 2024*).
- Reduce the time and cost of developing future CQRs through the provision of a generalisable and reusable design on centrally hosted national infrastructure
- Standardise data elements and definitions to facilitate benchmarking, comparisons, and data exchange, wherever possible.

1.2 Software industry standards

Clinical quality registries (CQRs) are established and operated with the aim of improving patient care and outcomes through greater understanding of events, treatments and patient outcomes. For CQRs to meet their full potential in informing the safety and quality of health care in Australia, there must be confidence in the quality and relevance of their data. Over time, the data collected by a CQR can be analysed and used to identify positive and negative trends. These trends can then be used to identify areas of variation in clinical practice and health service provision, and benefits and costs of therapeutic interventions.

By adopting standards, CQRs will better ensure their interoperability (ability to interact with and share information between health data collections and other CQRs, etc.), security, reliability, and standardisation of processes and practices.

The software industry standards are included in Section 6 and contain listing or mapping of various technical standards that may be relevant to a CQR, identifying areas including:

- Interoperability
- Clinical communications
- Unique healthcare identifiers
- Identity management
- Secure messaging.

All health sector-specific standards are referenced in Section 6, for example, the eHealth Interoperability Framework.

Other standards referred to in this document are industry-neutral (i.e., not specific to the health sector) but have application or relevance for CQRs. These standards can be considered as best practice technology standards that can be applied to e-health and to CQRs (refer to Section 6).

1.3 Implementation

The proposed implementation acknowledges the varying levels of e-health system maturity across health systems in Australia and embraces the diverse landscape. While some hospitals boast full integration of major e-health systems, others still rely on traditional paper-based processes. As outlined in the preceding section, even in cases where healthcare organisations lack the technology for automated clinical data submission, manual entry or data uploads remain feasible. Therefore, technology should not be a barrier preventing healthcare organisations from reporting on healthcare safety and quality and patient outcomes.

This guidance aligns with the Australian Digital Health Agency (ADHA) National Healthcare Interoperability Plan 2023-2028, emphasising the importance of interoperability in modern healthcare data management. For more details, see the latest updated interoperability roadmap on the ADHA website.

1.4 Document scope

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

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

2. CQR system and process recommendation

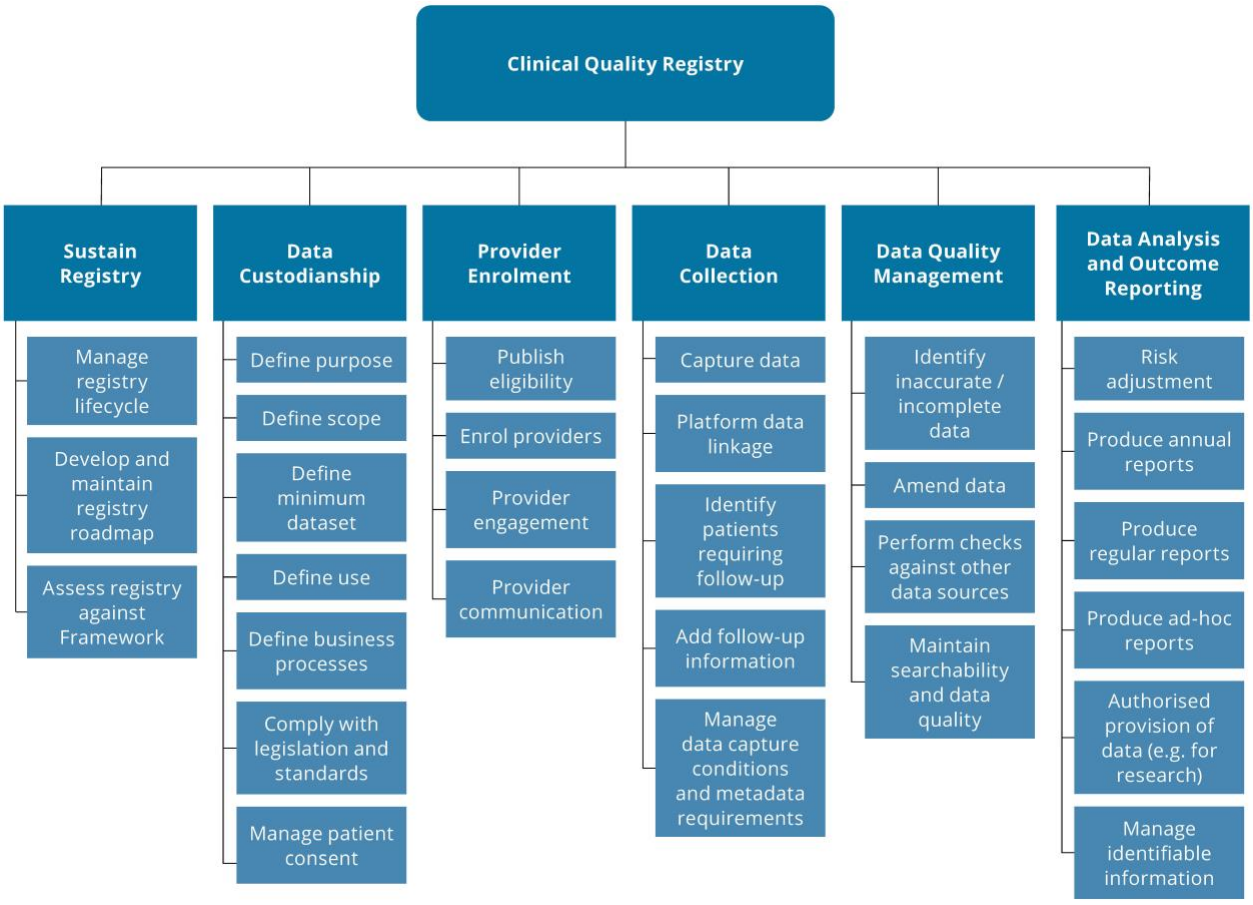
This section presents the high-level functions ordinarily undertaken by CQRs. It is intended to articulate the functions at a level that remains true across most registries, rather than at a detailed level that is specific to an individual registry.

The high-level functions are illustrated in *Figure 1: High-level clinical quality registry functions* and then detailed below to provide a description and context. They are also cross-referenced to the *Detailed requirements traceability matrix*, which is included as Appendix A.

In Appendix B, requirements have been grouped into the following categories:

- **CQR system and process recommendations:** These are suggestions for tasks that CQRs can perform to achieve high-level business functions
- **CQR administrative recommendations:** This category includes guidelines on how a CQR shall operate administratively
- **CQR technical requirements:** The essential properties and specifications that a CQR must possess.

Figure 1: Functional overview of Australian national Clinical Quality Registries



2.1 Data custodianship

Formal governance structures must be established to oversee the CQR's operation and ensure that both the corporate and clinical goals of the CQR are met. Data governance (as a component of overall governance) is discussed in *Data and quality systems* section of the Framework.

CQRs shall make clear, publicly available statements of data ownership and data custodianship (refer to *Operating principle 2: Data governance* and *Operating principle 8: Data custodianship* in the Framework). Data custodianship requires the safe custody, transport and storage of data. It therefore requires policies for data access and reporting that take into account requirements imposed by ethics committees where secondary use of the CQR data are requested.

2.1.1 Define purpose

To provide maximum value to the health system, CQRs must be developed with clear and precisely defined purposes aimed at improving the safety and quality of health care (refer to *Operating principle 1: Organisation and governance* in the Framework). It is noted that where there is a gap in the collection of information on health care within specific clinical domains, a CQR may complement inpatient data with other information to inform improvements in quality of care.

A CQR's purpose must take into account the requirements and needs of CQR stakeholders, particularly in relation to the questions that must be answered through the CQR – both immediately and with consideration of future needs.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B09 Identifying information to support CQR purpose
- B22 Public information about CQR purpose.

2.1.2 Define scope

Clinical quality registries need to clearly define the scope of the clinical outcomes that are analysed and reported so that the eligibility criteria, or common circumstance, that determines inclusion in the CQR is clear. CQRs shall publish scope and eligibility criteria on a publicly accessible website (refer to *Data and quality systems* in the Framework).

Where business rules or other advanced data query approaches, including Natural Language Processing (NLP), are used to automate the extraction of eligible records, the business rules or algorithms shall be available for review.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B01 Publicly accessible eligibility criteria
- B03 Entire eligible population
- B04 Right to opt-out
- B05 Voluntary participation
- B35 Transparency to data extract logic
- F26 Eligibility criteria
- F27 Automatic updates to eligibility criteria and data specifications.

2.1.3 Define minimum dataset

To successfully fulfil its intended purpose, CQRs need to define the minimum dataset required. Data collected by the CQR shall be confined to items that relate to a specific case definition. CQR systems support the maintenance of their minimum dataset through the ability to:

- Maintain data definitions and descriptions for each data element and its usage
- Retire data elements to ensure that information that is no longer relevant or required for analysis is deactivated and no longer collected
- Be able to manage changes to business rules over time and identify business rules that were active on a particular date/time
- Support the ageing of metadata by maintaining accurate links with reference data over time to avoid loss of context with reference data associations
- Clearly identify sources of reference data as well as reference data currently in their data dictionary.

CQR datasets shall be compliant, wherever possible, with METeOR; Australia's repository for national metadata standards for health, housing and community services statistics and information.[1] This approach will support easier information sharing between CQRs and other healthcare organisations.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B02 Publicly accessible data specifications
- B08 Publication of metadata, data dictionaries and indicators
- F08 Multiple unique healthcare identifiers
- F09 Unique identifiers for patients, providers and products
- F78 Use of Individual Healthcare Identifiers
- F80 Record that patient has been informed of participation
- F82 Data definitions
- F83 Retire data elements
- F84 Time variant data
- F85 Manage business rules
- F86 Reference data integrity
- F89 Support for data retrieval
- F90 Reference data sources.

2.1.4 Define use

CQRs shall make clear statements of data ownership and data custodianship and make data access and reporting policies publicly available (refer to *Operating principle 8: Data custodianship* in the Framework).

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B21 Availability of policies.

2.1.5 Define business processes

CQRs need to develop and define processes and procedures for data governance, collection, lodgement, storage, and management. Procedures and methods for reporting on quality of care that include processes for addressing outliers of unexplained variation must be documented (refer to *Operating principle 1: Organisation and governance* in the Framework).

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B30 Manage registry lifecycle
- B31 Develop and manage registry roadmap
- B32 Assess registry against the Framework
- B33 Advise originating organisations of data errors
- B34 Develop, document and maintain processes and procedures.

2.1.6 Comply with legislation and standards

CQRs will comply with all relevant Commonwealth and state or territory legislation and standards related to the management of data. In addition, CQRs will maintain well-designed legislative compliance processes and incorporate a compliance register to ensure that the organisation's policies are regularly updated.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B19 Manage data in accordance with legislation and standards
- B36 Maintain compliance register.

2.2 Provider enrolment

Provider enrolment relates to enrolling participating institutions, units and/or clinicians as providers of data to an Australian CQR.

2.2.1 Publish eligibility

A publicly accessible eligibility criteria enables prospective participating institutions or participating clinicians to identify the purpose of the CQR and enables others to approach the CQR in relation to undertaking analysis or data linkage (refer to *Data and quality systems* in the Framework).

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B01 Publicly accessible eligibility criteria.

2.2.2 Enrol providers

Enrolling providers in a CQR enables participating institutions and/or clinicians and staff to be provided with access to the registry system.

CQRs will use a hierarchical model of enrolment, whereby CQRs shall have a central system administration function that will add new participating institutions (e.g. private hospital groups, public hospitals) or groups and appoint participating group (e.g. clinical colleges, state and territory government agencies) and participating institution level system administrators. Participating institutions or clinical group level administrators will allocate user rights within the institution or clinical group. This includes creating new user accounts and granting user privileges (e.g. create, read, update, and discard).

Where it is decided by CQR governing bodies, CQRs shall be able to create associations between clinicians, institutions and jurisdictions to enable users with higher level system privileges to view data from all associated institutions or clinicians within their hierarchy.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- F01 Add participating institutions or clinicians
- F02 Associate groups
- F03 Central administration
- F04 Group administration
- F05 Participating institution level administration
- F12 Access for international data providers.

2.3 Data collection

For CQRs to ensure quality data are collected, meticulous attention must be paid to ensuring that all data points collected for all patients are both accurate and complete. Data points must be collected for all eligible patients within the defined clinical population within the CQR. If CQRs collect an incomplete or inaccurate set of patient data, then biases, mismatches, or other irregularities in the data may occur.

Data shall be sourced from the electronic medical record or clinical information system directly, via the appropriate available channel (e.g. data extracts, APIs).

Outcome determination is the most fundamental requirement of CQRs and shall be undertaken at a time when the patient's clinical condition has stabilised to the point that outcome information can be accurately ascertained, or when an event, such as death, has occurred and the outcome can therefore be reasonably ascertained.

Some clinical registries collect data for only a short period, such as for a single episode of care (e.g. following admission to an Intensive Care Unit), while others follow patients until they are no longer present for treatment or upon death (e.g. in the case of people with bleeding disorders or cystic fibrosis).

2.3.1 Capture data

CQRs currently use a range of data capture methods. Increasingly, however, best practice points to the use of data directly from the source systems that clinicians are using as they provide care, or from other data repositories – such as state-based clinical repositories.

The use of APIs to securely access relevant data from source systems is best practice if it does not impact the performance of the system, i.e. reporting instance or database.

As not all systems are currently API-enabled, other options for data capture include batch uploads, direct feeds from data collected as part of a patient's medical record and hospital administration systems (e.g. from pathology reports, operating theatre systems, emergency department systems/patient administration systems) and receipt of information through messages (e.g. HL7 pathology reports).

The least optimal method of data collection – which shall be used only as a last resort – is the provision of electronic forms through which participating institutions/clinicians/staff may directly enter data through a CQR portal, or offline forms that are uploaded securely to the CQR in a batch.

Information imported to a CQR through batch uploads or direct feeds will be able to be cross-checked (to avoid record duplication) and validated (e.g. simple field validation, business rules validation and computations). CQR users will have the ability to add missing data or amend incorrect information identified through automated validity checks during data import.

In addition, CQRs may provide eligibility criteria (which may be automatically updated if eligibility criteria change) in a computer processable form to allow patient administration or clinical information systems to automatically identify eligible patients based on patient events.

Please see following page for an overview of requirements.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B06 Standardised data collection approaches
- B17 Determining client outcomes
- F07 Data capture
- F08 Multiple unique healthcare identifiers
- F09 Unique identifiers for patients, provides and products
- F13 Batch uploading
- F14 Establish criteria for rejecting or partially accepting records
- F15 Apply data validation checks during import
- F16 Prompt if changes result from data import
- F17 Allow multiple episodes to be recorded
- F18 Receipt of data from existing data sources
- F19 Access control for batch upload
- F20 Authorised system upload
- F21 Cross-check data being imported
- F22 Alter records via date import
- F23 Mark mandatory fields
- F24 Correct errors identified through validation checks
- F25 Data record rejection
- F26 Eligibility criteria
- F27 Automatic updates to eligibility criteria and data specifications
- F28 Scanning of simple data fields
- F29 Barcode scanning
- F30 Include automated data validity checks
- F31 Download printable forms
- F32 Offline forms
- F33 OCR in scanning
- F34 Logic checks and rules to guide efficient data entry
- F35 Storage of paper-based data sources.

2.3.2 Perform data linkage

Data custodians shall enable linking data from different sources (refer also to *Operating principle 8: Data custodianship* in the Framework). For example, linkages with the National Death Index provide a powerful tool to assess longer term outcomes that would otherwise not be feasible to collect. Another example is linkage with infection surveillance systems to examine the rate of surgical wound infections following surgery. Detailed linked data from these CQRs provide information that could not have been derived from the CQR alone.

Any data linkage must comply with privacy and policy legislation and requirements and take into account the accuracy, completeness, reliability and validity of the secondary data source. Accordingly, data must be collected and stored using consistent definitions and standards and be transferred securely to support data linkage.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B07 Use of standard terminology and data specifications
- B18 Capacity to link or integrate with other CQRs
- B29 Produce longitudinal patient outcome information through data linkage
- NF42 Employ standard to support data linkage
- NF62 Audit trails to record data linkage details.

2.3.3 Identifying patients requiring follow-up

It is important that CQRs endeavour to determine the outcome for the highest possible proportion of registered patients to prevent the potential for biased results.

Determining the outcome of clinical care is the most fundamental requirement of a CQR and shall be undertaken at a time when the patient's clinical condition has stabilised or when an event, such as death, has occurred and the outcome can therefore be reasonably ascertained (refer to *Operating principle 4: Data elements* in the Framework).

To support this requirement, CQR systems will enable CQR staff to define the period in which an individual's record shall be updated or completed and either:

- Prompt a user (who has entered a record which now requires follow-up) when a record remains incomplete past the permitted duration for record update
- Enable production of a report that identifies records that require follow-up, or
- Produce 'to do' lists on a user's dashboard (using automated workflows) to identify records that require follow-up.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- F14 Establish criteria for rejecting or partially accepting records
- F36 Define period for record update
- F37 Prompt when record incomplete
- F81 Record patient decision to opt-out
- F87 Record opt-out notification
- F88 Flag when patient has opted out.

2.3.4 Add follow-up information

Ideally, CQRs will support linkage to administrative and/or other databases to enable the collection of outcome information without the need to contact the patient. This increases the efficiency of tracking people into the future, through multiple episodes of care and across multiple institutions.

Alternatively, out-of-hospital outcomes are commonly determined by contacting participants at a defined time after discharge and asking a small number of key questions, or through contact by CQR staff with the participating institution or clinician to obtain outcome information.

CQRs may support this function by allowing users to download printable or offline forms to aid the collection of follow-up information which is then entered into the registry system.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- F12 Access for international data providers
- F38 Report of incomplete record
- F39 Download follow-up forms
- F40 Lock record at case completion
- F41 Authorised users can unlock records
- F42 Workflows.

2.3.5 Manage data capture conditions and metadata requirements

To support timely reporting in support of quality and performance improvement, it is critical that data points are captured in a timely manner yet also in a way that does not place an unreasonable burden on either the clinician or the consumer.

The move towards the future-focused model where data points are routinely extracted from clinical systems to support clinical quality improvement will relieve this issue. However, in the interim, where data are to be inputted through other means, the capture shall be undertaken by a trained data collector and recorded once per episode to avoid duplication and redundancy. Data quality shall be verified and tested by conducting accuracy and validation checks on a sufficiently large sample that is representative of the data as a whole. The appropriateness and size of the sample shall be reliably defined and take into account the critical nature of this data accuracy.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B10 Avoid data collection burden on consumers
- B11 Timely capture of data
- B15 Collect covariates for risk adjustment
- B23 Avoid redundant data capture
- B24 Trained data collectors
- B25 Use of existing data
- B26 Adequate sample sizes for data accuracy checks
- B27 Specific case definitions
- B28 Considerations in determining time to outcome assessment.

2.4 Data quality management

The use of clinical data for benchmarking outcomes via CQRs and assessing compliance with best practice guidelines mandates that data be accurate and reliable, ensuring provider confidence in CQR-generated information. Collection of data from widely dispersed sites is a well-established risk factor for poor data quality.

A continuing focus on data quality is a fundamental function of the work undertaken by CQRs. Data used to monitor the quality of care must be capable of taking into account the basic requirements of accuracy and reproducibility that underpin reliable clinical data. Where data elements are

identified as missing, incomplete or inaccurate, correction in the source systems rather than in the CQR itself will be the appropriate data quality intervention.

2.4.1 Identify inaccurate/incomplete data

Where data are collected through automated extracts or APIs, inaccurate or incomplete data must be communicated to the data owner of that data source for rectification.

CQR systems shall support the identification of inaccurate or incomplete data through:

- Defining logic checks that constrain the information able to be entered into a field
- Incorporation of in-built data validation checks (e.g. data range and context sensitive validation)
- Use of probabilistic matching of identifying information to avoid record duplication and ensure that all information pertaining to an individual is appropriately identified
- Identification of a random sample of cases in which to conduct audits against source records
- Production of reports to users about the quality of data collected based on data quality standards and their data entry error rates
- Production of reports on the outcome of data audit checks by case, episode or facility.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B12 Monitor quality in accordance with plans
- B13 Prompt identification of data quality lapses
- B33 Advise originating organisations of data errors or omissions
- F43 Define logic checks
- F44 In-built data validation checks
- F46 Probabilistic matching
- F49 Audit for accuracy against source
- F51 Identification of sample for audit
- F53 Production of audit reports
- F54 Feedback on data entry error rates
- F72 Data extraction to be audited
- F79 Specify when record is included in reports.

2.4.2 Amend data

When inaccurate or incomplete data are identified within registry data, data custodians shall be able to amend the data in accordance with their user access rights. CQRs shall consider advising participating organisations of errors or omissions in the data provided so that organisations have the opportunity to correct their data at source. There shall also be a process whereby the source system corrects the errors and advises the CQR of the corrections and authorises the CQR to do the same with the original data received. In this way, the source system and the CQR shall contain the same information. An updated data file incorporating the updates shall be sent to the CQR to replace the original file.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B14 Prompt actioning of incomplete data records
- B33 Advise originating organisation of data errors or omissions
- F45 Record reason for overriding validity checks.

2.4.3 Perform checks against other data sources

CQRs sometimes seek information from routine administrative collections (such as hospital statistics or deaths) to determine the completeness of the CQR's collection and to validate information contained in the CQR data collection.

CQR systems shall support this function by being able to produce reports on the consistency of data contained in the CQR compared with data from other sources.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- F48 Consistency of data from different sources
- F52 Feedback on data quality.

2.4.4 Maintain searchability and data quality

To mitigate risk of duplication, authorised users are to be allowed to search for patient identifiers to reduce duplication at the point of data entry. Reports are to be produced on data quality based on data quality standards.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- F47 Search identifiers to reduce duplicate records
- F50 Double entry to check accuracy.

2.5 Data analysis and outcome reporting

CQRs have a fundamental requirement to report without delay on the information they collect, including to health service organisations, clinicians, state and territory health departments, funders, consumers and the broader community (refer to *Operating principle 10: Information output* in the Framework).

Evidence suggests that quality improvement is driven by the provision of outcome data to healthcare providers, hospitals, health jurisdictions, professional credentialling bodies and the public.

CQRs inform improvements in care, in part by providing clinicians with information about how their outcomes compare with clinical guidelines, standards and other clinical outcomes. To be effective in driving change, CQRs must be able to provide reports as soon as possible after episodes of care. Delayed reporting lessens the clinical value of CQR data, as the relevance of the findings to contemporary clinical care is reduced.

2.5.1 Risk adjustment

In determining whether quality of care differs across healthcare providers, CQRs need to adjust for variation in patient outcomes that is the result of differences in patient characteristics that are outside the control of the healthcare providers. When outcomes are compared among healthcare organisations or when attempts are made to investigate poor outcomes, it may be appropriate to apply statistical adjustments that take these other factors into account. Case-mix adjustment is the statistical process of identifying and adjusting for variation in outcomes resulting from differences in patient characteristics or risk factors.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B15 Collect covariates for risk adjustment
- B16 Timely reports that include risk adjusted analyses.

2.5.2 Manage identifiable information

Consent must be obtained from or approved by an ethics committee in order to share identifiable information with external parties.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B20 Provision of identifiable information.

2.5.3 Reporting

Analysing and reporting data promptly, along with clinical interpretations, is pivotal for safety and quality improvement and is a cornerstone of CQR functionality. CQR reporting is the most prominent output derived from the extensive efforts of CQRs, and aims to pinpoint substantial variation and establish benchmarks for safety and quality. This critical function not only helps empower consumers to make informed decisions about their health care, it reflects the commitment of CQRs to transparency and accountability. CQRs have documented policies and procedures in place to systematically report on the quality of care, communicating instances of outlier performance or unwarranted variation. This comprehensive approach ensures that the reporting function of CQRs meets regulatory standards and serves as a valuable resource for continuous quality improvement across the healthcare sector.

Requirements specification (for detail, refer to *Appendix A: Detailed requirements traceability matrix*)

- B37 Reporting
- B38 Sharing reports
- B39 Public reporting
- B40 Data model
- B41 Documentation
- F55 Different report formats
- F56 Access to restricted reports
- F57 Secure access to reporting from central registry
- F58 Record authorisation to provide identifiable data
- F59 Web access to reports
- F60 Patient summary
- F61 Generate standard reports
- F62 Scheduled reporting
- F63 Individual facility reports
- F64 Benchmark reports
- F65 Clinical and epidemiological reporting
- F66 Coverage of eligible population report
- F67 Contributing units can produce centrally configured reports
- F68 Export of unit record data
- F69 Default format of unit record data export
- F70 Ability to export data for research purposes
- F71 Ability to record purpose of data export
- F72 Data extraction to be audited
- F73 Encrypt exported identifiable information
- F74 Compatibility of data extracts with statistical packages
- F75 Ad hoc data analysis available to participating units
- F76 Define parameters for ad hoc reports
- F77 Use report parameters to generate ad hoc reports.

3. CQR solution design

3.1 Background

CQRs will require application capabilities that support:

- Data acquisition and translation
- User authorisation and management
- Metadata definition, management and publication
- Application of business rules
- Statistical analysis
- Reporting.

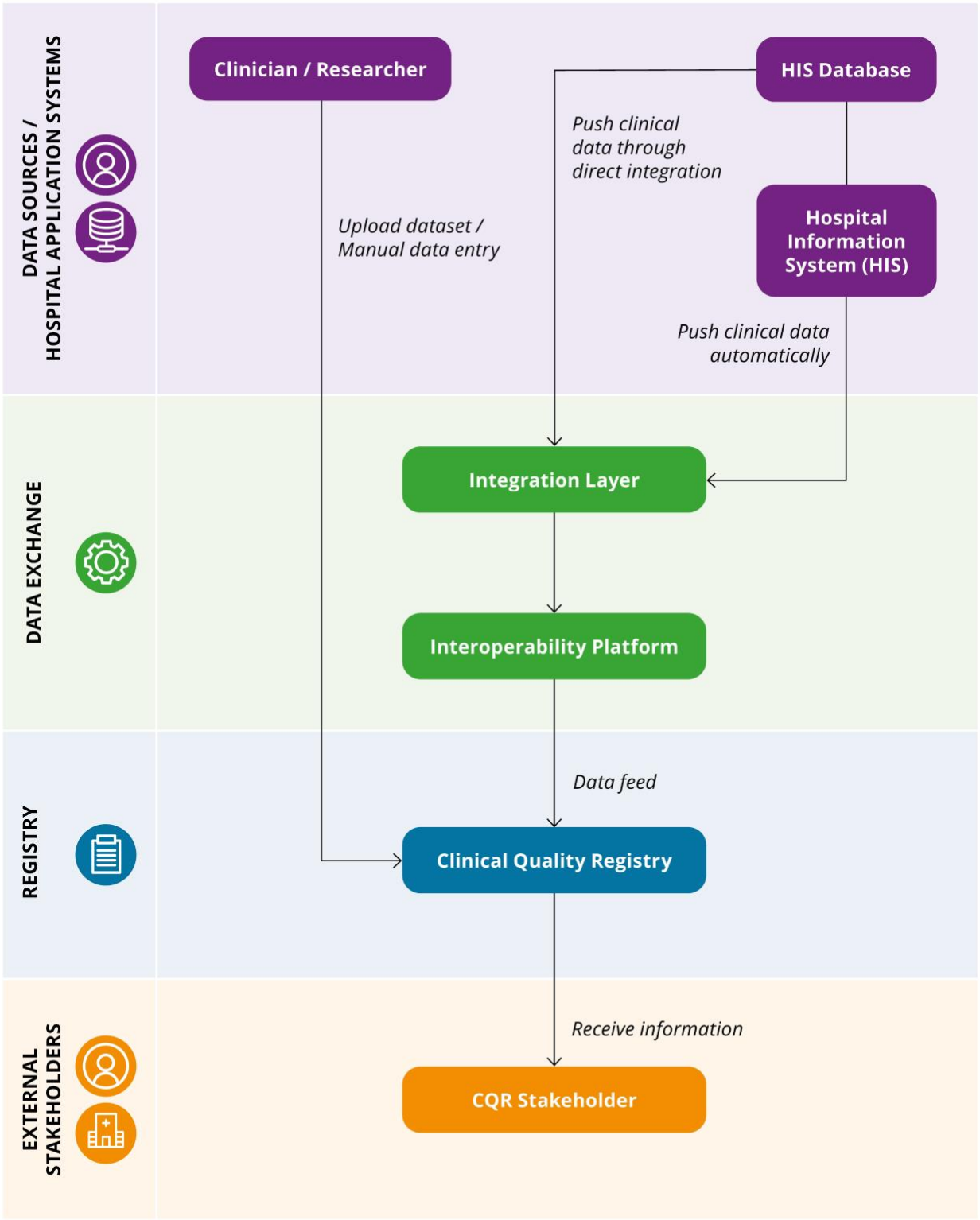
This section outlines CQR logical solution architecture and covers key interaction scenarios.

3.2 CQR architecture

Conceptually, the CQR solution (as depicted in Figure 2) introduces the ability for an additional data feed, originating directly from health source systems via an interoperability platform, while still allowing users to enter the data manually. The proposed architecture is designed to automatically receive data from the Hospital Information System (HIS) or, alternatively, directly from the HIS database. This integration streamlines the data inflow, reducing manual input requirements and enhancing the overall data quality and availability for the CQR. This approach also mitigates the issue of data duplication and human workload.

Please see following page for Figure 2.

Figure 1: Conceptual CQR solution diagram



The logical design shown in Figure 3 allows a CQR to be established at any level. To reduce the number of CQR instances, it is recommended that, where possible, a CQR is established at the highest level of the organisation (i.e., group, health service organisation, or state and territory).

Within this model, health source systems consistently update the CQR with clinical information, clinical events, and clinical outcomes. Key patient demographics and clinical events will be extracted from the data message generated by the Patient Admission System (PAS) (i.e. HL7, FHIR) to link patients with the health events and all other related clinical data points.

Clinical documents such as discharge summary, post-operative reports, and specialist letters can be sourced directly from the respective EMR systems. Pathology results and imaging reports can be produced by LIS (Laboratory Information System) and RIS (Radiology Information System) systems. The pharmacy system will provide dispensed medication records. The patient outcome reports will come from the PROMs system (where these systems are in place).

Stakeholders can view CQR data which can only be accessed by authorised data custodians, health service organisations, clinicians and the quality care team to view, search, analyse or export the data. The patient record can be identified within the highest level of the CQR, where they need to be identified. The patient records shall be de-identified when being broadcasted to the CQR.

Real-time data sourced directly from e-health systems adds significant value. However, clinical data can be generated in different formats by different e-health systems and only be transmitted by specific protocols, which makes it challenging to order the health system vendors to refactor the existing systems to meet CQR data standards. To overcome this problem, an interoperability platform must act as an orchestrator and transformer to receive the clinical data from the source systems and securely transmit them into the CQR.

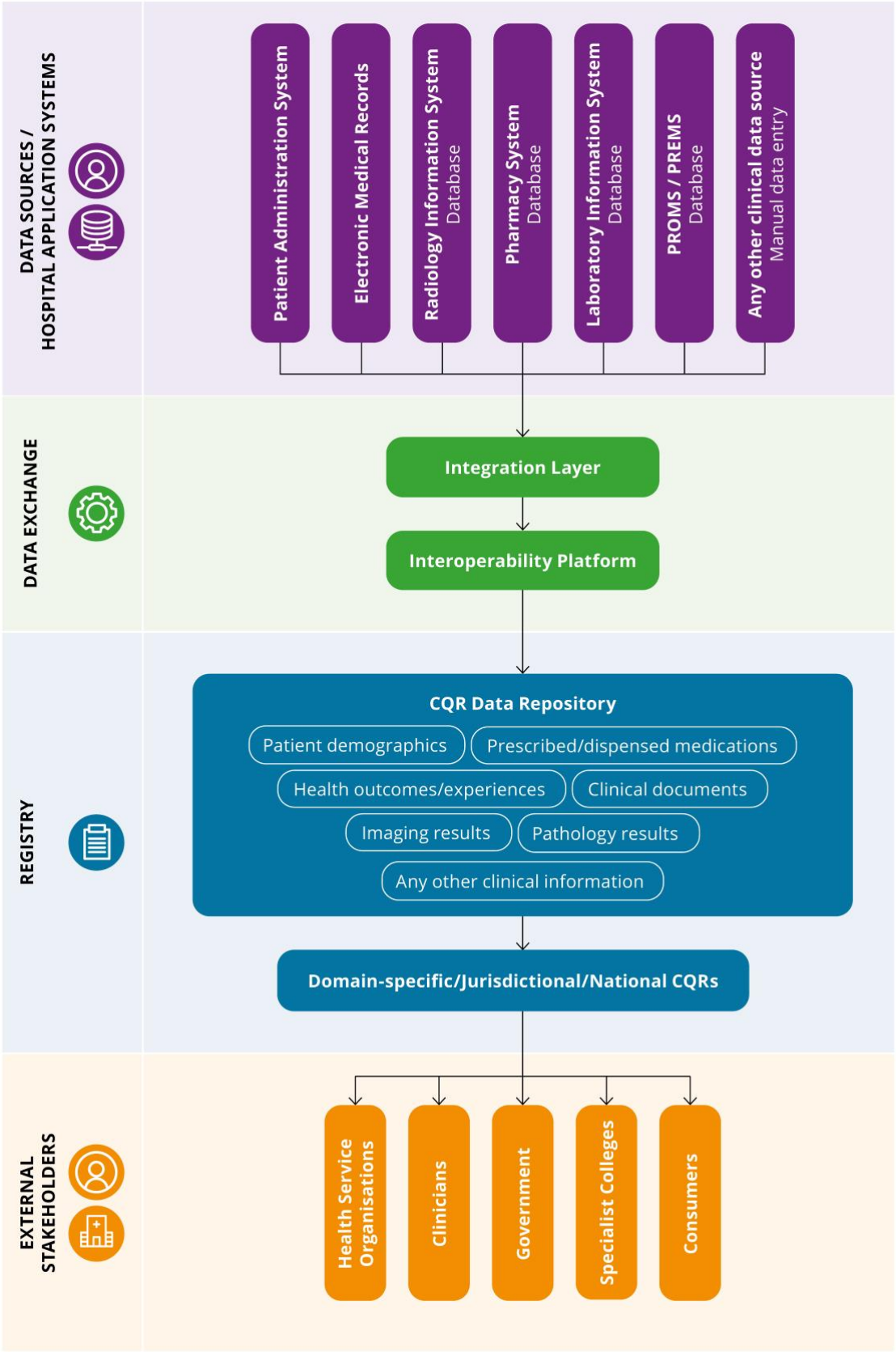
The interoperability platform shall provide the following capabilities to meet the business requirements:

- Can receive and transmit clinical data via different protocols (HTTPS, TCP/IP, SFTP, etc.)
- Can interpret clinical data encapsulated in different formats (XML, JSON, HL7, etc.)
- Can be configured with business logic to validate the key data fields contained in the clinical message
- Can be configured to link the patient with related clinical data/documents with the patient identifier
- Can be configured to normalise clinical data with any international recognisable code system (such as SNOMED-CT and LOINC)
- Can be configured to map the clinical data into the common message model so it can be transmitted and recognised by the CQR
- Can be configured to send the formatted clinical data to the CQR via secured API
- Can be configured to de-identify patient records
- Can be configured to broadcast updates from one CQR to other CQRs.

So long as it can fulfil the above responsibilities, the interoperability platform can be provisioned in any environment regardless of the organisation’s existing ICT infrastructure.

Please see following page for Figure 3.

Figure 2: CQR logical design



3.3 CQR key system usage scenarios

3.3.1 Source system adds data into CQR

Figure 4 presents a model for data acquisition. At the hospital/health service organisation level, clinical data will be captured continuously by different healthcare providers through various clinical events triggered by a patient journey. Patient demographic information, alerts, and allergies will be captured by the Patient Admission System (PAS) when a patient is admitted to the hospital. As the patient is transferred to a ward, admitted to an emergency department, treated in a theatre, or discharged from the hospital, various clinical documents will be generated by the EMR system.

When a pathology test is ordered, a pathologist can process the pathology order and record the result in the Laboratory Information System (LIS). Subsequently, the results data feed can be sent into the CQR using a common health interoperability standard such as HL7 ORU.

Similarly, a radiologist produces imaging examination reports in RIS when a patient takes an imaging exam. Imaging report data feed can be sent into the CQR using a common health interoperability standard such as HL7 ORU.

When medications are dispensed, a pharmacist uses the pharmacy system to dispense medications and the dispense medication report can be sent into the CQR using a common health interoperability standard such as the HL7 format.

The PROM system will allow the health service organisation to capture the patient outcome information from the various health service organisational level surveys.

The goal of the interoperability pathway is to utilise and reuse the existing data feeds from the various clinical system(s) that may already exist within the health service organisation, using an integration platform to remove the burden of the CQR system integration.

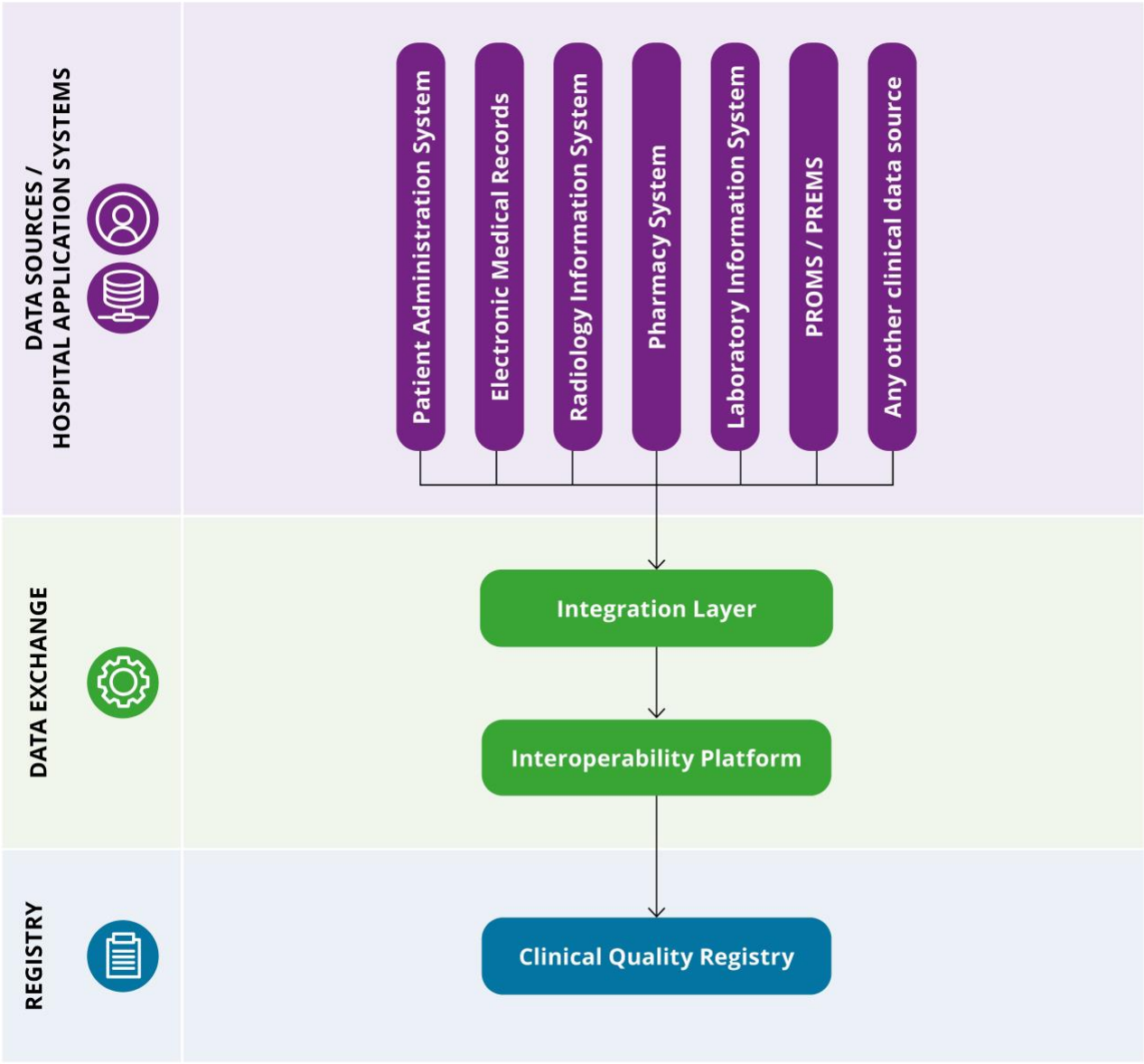
Once the interoperability platform receives the HL7 messages, certain business rules can be configured to perform basic checks on the key data fields. For example, the rules can be configured to check the completeness of the patient demographic data and alert the source system if any key fields are missing. However, since the CQR's main purpose is not to monitor the quality of incoming data, the alerts can be sent back to each of the source systems and it is up to the department to decide what to do with it.

The interoperability platform can also perform the patient linkage activity to link all the clinical documents/records to the right patient. It can build the patient index where the patient identifiers can be stored and used to link to all the clinical documents related to the same patient. In addition, the patient index should store different types of patient identifiers. For example, a patient can have a different Medical Record Numbers across various hospitals but share the same IHI. The interoperability platform should be able to search all types of patient identifiers from an HL7 message, match to the ones stored from the patient index, then link the clinical data to the right patient.

The interoperability platform should also be responsible for standardising the clinical data and transforming them into a common message model so all the CQRs can recognise them. International recognisable code systems can be used to enforce the standardisation process. For example, SNOMED CT is a terminology that can cross-map to other international terminologies, classifications, and code systems. Using the code system can enable data reuse and bring data consistency between different CQRs. However, data cannot be easily understood by different CQRs unless a common message model is defined. The common message model should define the data format of each field and the data specifications.

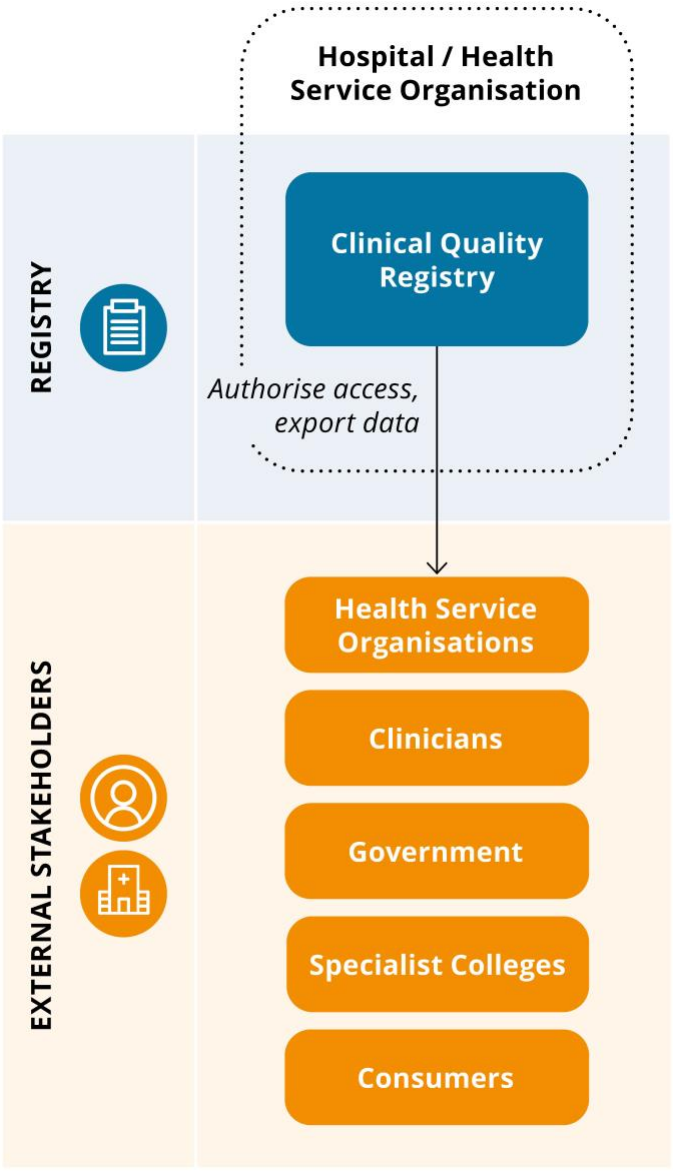
Please see following page for Figure 4.

Figure 4: CQR data acquisition



3.3.2 Clinical care quality team view reports from CQR

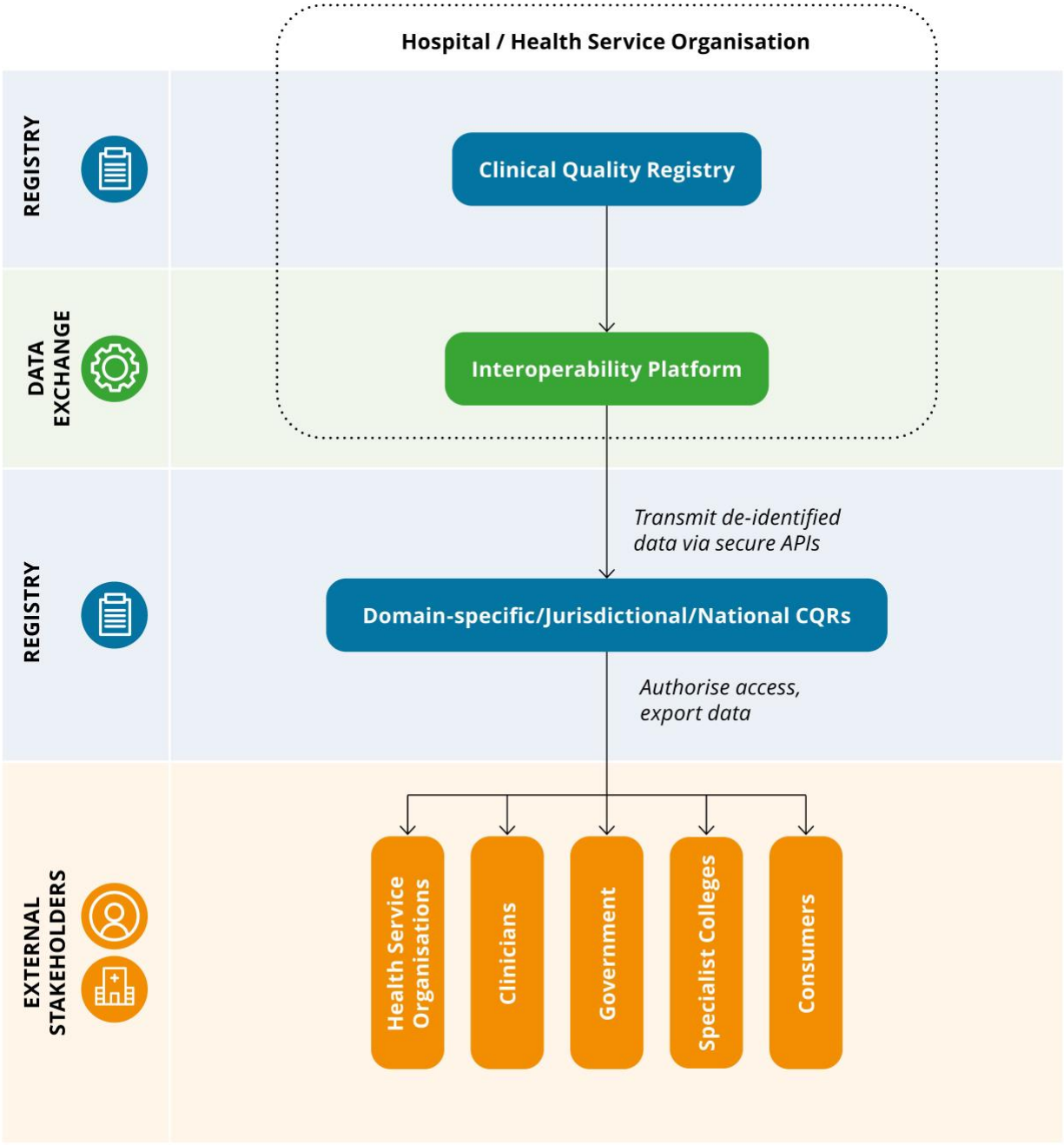
Figure 5: Viewing CQR data



When a CQR is established at the hospital/health service organisation level, only authenticated clinicians and the members of the quality care team within this organisation can access it. The identifiable patient clinical data will be directly sourced from the e-health systems. Strict authorisation must be applied to each user so they can only search, view, and analyse the clinical information they are allowed to. As a result, the clinicians and quality care team can continuously report on clinical outcomes and performance to monitor the appropriateness and effectiveness of health care.

3.3.3 CQR sends data to other authorised CQRs

Figure 6: Sharing CQR data with other CQRs



From the hospital/health service organisation level CQRs, the clinical data can be shared to the centrally hosted CQR as well as to other domain-specific CQRs, such as a stroke registry or cancer registry. In this case, the clinical information broadcast can be triggered at either the interoperability platform or the hospital/health service organisation layer, depending on the business requirement.

When the interoperability platform receives clinical data from the source systems, it can be programmed to de-identify the patient record (and/or healthcare provider record) and broadcast it

to the centrally hosted jurisdictional/national CQR or the domain-specific CQRs, depending on the diagnoses or medical conditions. This approach will allow the CQRs to have up-to-date health information.

Another approach is to allow the clinicians or the quality care team to decide when and what can be updated to the centrally hosted jurisdictional/national CQR or domain-specific CQRs. This approach can give the hospital or the health service organisation more control over their clinical data. When the update is triggered, the data will be packaged and transmitted to the external CQRs via the interoperability platform which will de-identify the patient programmatically. With the common message model that is proposed as part of the Framework, the interoperability platform can use the secure APIs to exchange health information with other CQRs.

The centrally hosted jurisdictional/national CQR will provide the aggregated view of de-identified health information to the authenticated and authorised clinical quality audit team who can search, view, and analyse the data across different hospitals and jurisdictions, compare their performance, and provide better insights. At the same time, domain experts and specialists can leverage the domain-specific CQRs to continuously monitor and set the standard of care quality in each clinical area.

4. Information design

This section describes a logical information design that provides a standardised starting point for the design and implementation of a CQR.

Standardising the information model and design guidelines across all CQRs provides benefits by:

- Reducing the time and cost of developing CQRs through the provision of a generalisable and reusable design
- Promoting standardised approaches to registry designs that support the strategic and operating principles for a national approach to CQRs (refer to the Framework)
- Delivering efficiencies and interoperability in data collection and exchange
- Standardising data elements and definitions to facilitate benchmarking, comparisons, and data exchange wherever possible.

It is anticipated that the information design for CQRs will continue to evolve over time. As more CQRs are modelled and implemented, further common requirements may be identified and incorporated into the core information model.

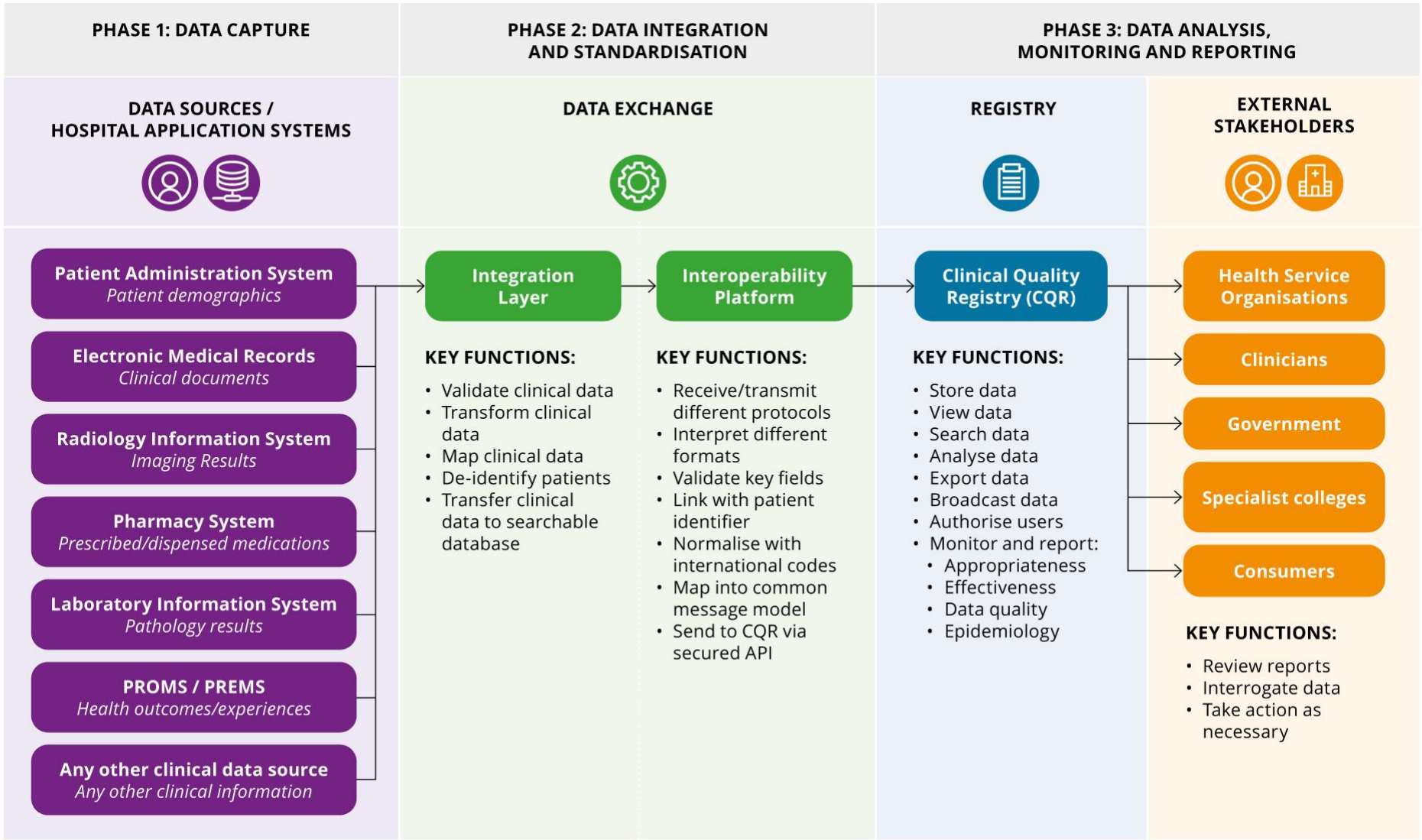
Over the long term, CQRs may develop Data Set Specifications (DSS)[2] under the umbrella of the National Health Information arrangements. DSSs are metadata sets that are not mandated for collection but are recommended as best practice. The development of metadata standards improves quality, relevance, consistency and the availability of information about the health of Australians. Key benefits of metadata standards include consistency of content and definition; reduced duplication and diversity of solutions; and reductions in the costs of data development through avoiding the need for each registry to have to start from scratch.[3]

4.1 Information data flow view

Figure presents a high-level conceptual view of a CQR Information Model data flow to provide context for the logical model that follows.

Please see following page for Figure 7.

Figure 7: Phases of CQR data capture and reporting



The data sources of the CQR represented on the left side of the diagram are where all core data elements are captured at the point of care on each of the respective systems.

The core data categories consist of data that will be defined in a consistent way across all CQR designs. These include patient demographic data, healthcare event data, and clinical documents (including health outcomes).

Although these data categories will represent a small subset of the data collected by a CQR, it is important to establish a consistent model to ensure that interoperability and record linking can be performed as efficiently and easily as possible.

Core data categories	Examples
Patient demographic data	• Family name • Given name(s) • Date of birth • Gender Identity (however, gender identity will not come from the HL7 message directly) • Personal Identifiers such as Medicare identifier, Department of Veteran Affairs (DVA) identifier, state and territory identifier, Registry identifier or Individual Health Identifier (IHI) • Sex • Age • Country of birth • Indigenous status • Residential postcode and locality
Healthcare event	• Date of event • Any relevant condition-specific data • Participating organisation, institution or facility name • Organisation or facility identifiers such as Health Provider Identifier – Organisation (HPI-O) • Healthcare provider identifier (HPI-I)

A CQR will also collect data across the following categories: disease or condition data, comorbidities, intervention data and outcome data. This data will represent the majority of the data that a CQR collects, but there will be a high degree of variability between the clinical details collected by individual CQRs. The definition of data to be captured related to the clinical condition shall be informed by best practice, such as the indicators identified within the Clinical Care Standards developed and published by the Australian Commission on Safety and Quality in Health Care.[4] As such, the definitions of the data within these categories may not be consistent across multiple CQRs as they may vary by condition. Data in these categories will be referred to as condition-specific data.

Condition data categories	Examples
Disease or condition data	• Principal diagnosis • Results of key diagnostic tests • Severity • Postcode or locality of incident
Risk factors and comorbidities	• Diabetes • Hypertension • Previous history of cancer
Intervention	• Principal treatments (e.g. beta-blockers) • Intensive care unit (ICU) admission • Elements of clinical care provided
Outcomes	• Survival time • Length of stay in hospital • Time from initial procedure to first revision procedure • Re-admission • Patient reported outcome measures
Medications	• Current medications • Dispensed medications

The condition-specific data will link to the core data via the health service event and follow-up event. Specific disease and condition, comorbidities, intervention and outcome data will be collected by the CQR at one or more health service events and, in most cases, one or more follow-up events.

Both the core and condition-specific data elements represented in the logical design diagram are concerned with how CQR data are stored once collected for a patient. The means by which the data are physically collected (e.g. paper forms, electronic data forms, direct feed from other systems) is not important when considering this information model.

The condition-specific analysis and reporting data categories represent physical structures that have been designed and optimised for the unique output requirements of a CQR. A data transformation process will allow the CQR to determine clinical-focused outcomes, such as appropriateness of care and effectiveness of care. The CQR will also generate business-focused outcomes, such as determining data quality.

Conceptual data categories	Examples
Appropriateness of care	• Proportion of patients admitted to a specific type of unit • Proportion of patients who received a specific type of test • Treatment at the acute phase
Effectiveness of care	• Joint replacement revision

	• Complication rates
Data quality	• Determine completeness of data via comparison with external data sources (e.g. admitted patient data).

External to the CQR Information Model is a set of other data sources that may provide supplementary data and allow a CQR to perform data quality and data completeness analysis. All interaction with other data sources will be performed with due regard to information security and confidentiality.

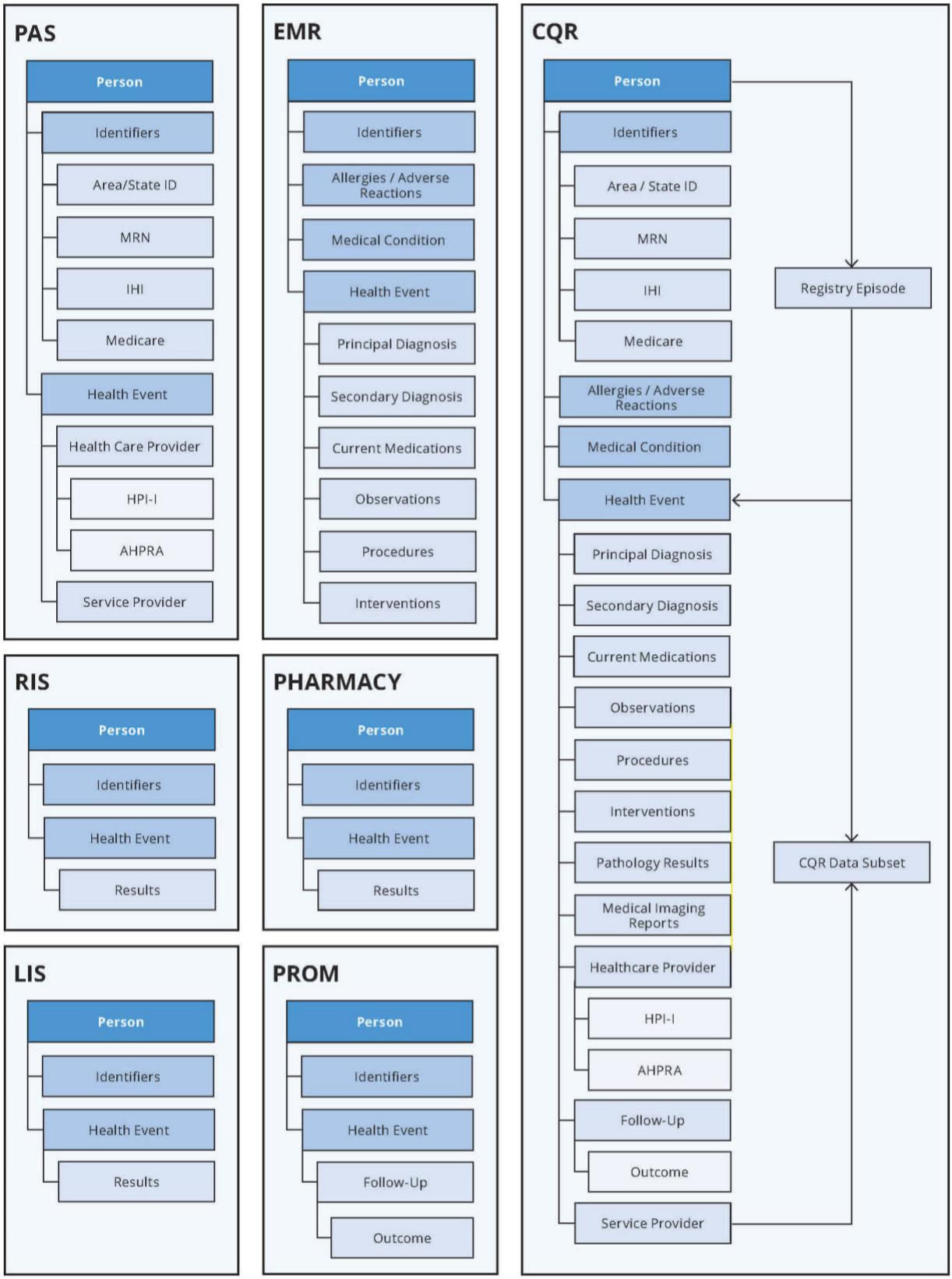
4.2 Conceptual representation of the core data

The core data model (Figure 8) outlines the storage of and relationships between the basic patient, provider, organisation and service event information that is common to all CQRs. Where possible, the objects and data elements within the core data model should align with METEOR, as the Australian metadata standards for health information and data.[5]

It is important that the core data model provides maximum flexibility so it is a suitable foundation for all CQRs, regardless of their specific data collection and reporting purposes.

Please see following page for Figure 8.

Figure 8: The core data model



4.2.1 Person

A **person** record can have one or more **person identifiers**. Person identifiers may be associated with a **service provider organisation** (such as the person identifier within a Patient Administration System), a national or state authority (such as Medicare identifier, DVA identifier, state or territory identifier, or Individual Healthcare Identifier (IHI)[6]) or may be allocated by the CQR.

Person may also be an individual **healthcare provider**; in this case the HPI-I serves as the relevant identifier. HPI-O shall also be included, if available, and shall be linked to existing available services.

4.2.2 Service provider organisation

A **service provider organisation** represents a hospital, institution, or other organisation that provides healthcare services. A hierarchical structure of organisations is supported. Organisations can be identified by one or more identifiers, one of which could be a Healthcare provider identifier – organisation (HPI-O), if available.

4.2.3 Health service event

A **health service event** represents an interaction between one or more healthcare providers with one or more persons for assessment, care, consultation, and/or treatment. Across CQRs, a health service event could represent a wide variety of events, such as a surgical procedure (e.g. Australian Orthopaedic Association National Joint Replacement Registry), diagnostic testing (e.g. National Breast Cancer Audit) or a hospital admission (e.g. Australian & New Zealand Intensive Care Society Adult Patient Database). At each health service event, the CQR will record relevant observations and clinical data for the patient.

4.2.4 Registry episode

A **registry episode** defines a period of time from diagnosis through to the period in which the patient receives health care, to the final measurement of outcomes specified in the registry dataset. A registry episode will consist of one or more health service events (e.g. a diagnostic consultation event, and a therapeutic intervention). The data model supports the definition for one or more episodes for a patient.

4.2.5 Follow-up event

The **follow-up event** is an event where additional data are collected about a patient following the initial event. The data model supports the definition of one or more follow-up events. Some CQRs will collect follow-up data at set intervals after an initial event for a pre-defined period of time, whereas other CQRs may collect follow-up data for the life of the patient. The follow-up event can relate to a patient via a particular registry episode (indicating that it is follow-up data for one or more preceding events) or it may be related directly to the patient (indicating that the follow-up data are relevant across all registry episodes, if this is applicable for a CQR).

Follow-up may also be recorded via PROMs data collections.

4.2.6 CQR data subset

The **CQR data subset** instance represents data collected for a patient at the initial event and follow-up event. The CQR Data Subset instance is analogous to an instance of a legacy data collection form template, which contains the values of observations and clinical details that were collected about a patient at a given point in time. This may correlate to an ‘episode’ in an electronic medical record.

The reason that the term 'subset' is used is to support the notion that of all possible observations a CQR is interested in collecting, some observations or clinical details might not be relevant in all cases. For example, a follow-up data collection form may not be identical to an initial consultation data collection form. By modelling the data collection subsets in this way, the CQR system will be able to streamline the data collection process for particular circumstances.

The set of observations included in a CQR data subset instance will consist of observations that can be classified across most, if not all, of the condition-specific data categories (that is, disease or condition data, comorbidities, intervention data and outcome data).

The following section presents guidelines for how condition-specific data elements shall be defined in a logical information model.

4.3 Design guidelines for condition-specific data

The following is a set of pragmatic guidelines that can be used when modelling the condition-specific aspects of the data model.

The guidelines provide a basis for:

- how condition-specific data elements can be categorised in the model for consistency
- how condition-specific data elements will link to the core information model
- how condition-specific reference sets should be modelled
- how data subsets can be defined to suit particular data collection scenarios, and
- how the completed data model should be formalised into a data dictionary.

In order to be applicable across all CQRs, these guidelines are intentionally high level and do not cover specific implementation details. However, by following these guidelines, a practical level of uniformity across CQR information designs can be achieved.

4.3.1 Logically categorising condition-specific data elements

When the CQR's minimum dataset has been determined (refer to *Operating principle 1: Organisation and governance* in the Framework), all condition-specific data elements can be logically categorised into one of the following:

- disease or condition data
- risk factor and comorbidity
- intervention
- outcome.

Even though different CQRs are unlikely to share specific data elements, modelling condition-specific data elements into these categories will provide the basis for achieving a practical level of consistency across CQR logical information models.

4.3.2 Linking condition-specific data elements to the core model

The majority of the condition-specific data elements will capture data about a patient at a particular moment in time. Therefore, the values recorded against these condition-specific data elements will relate to the patient via either a health service event or follow-up event in the core model.

Relating these data elements to a health or follow-up event will ensure that the observations are 'time stamped' and allow relevant facts about a patient to be compared and analysed over time.

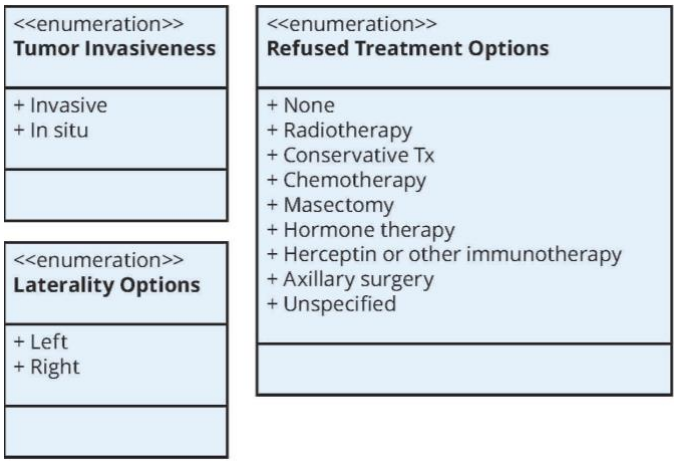
There may be instances where a CQR needs to collect additional static data about a patient for which comparison over time is not relevant. In these instances, the condition-specific data elements can be added directly to the patient object class in the core model.

4.3.3 Modelling reference sets

Standard definitions, terminology and specifications shall be used in CQRs wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other data sources (refer to *Operating principle 3: Data collection* in the Framework). In some cases, this may require using terminology services and reference datasets such as SNOMED CT-AU[7], the Australian Medicines Terminology (AMT)[8] and the National Product Catalogue (NPC).[9]

Where reference sets are used, whether from a published standard or unique to the CQR, they shall be defined in the information model to ensure that appropriate validation can be implemented. **Error! Reference source not found.** shows a representation of three example reference sets that would be included in an information model for the National Breast Cancer Audit registry.

Figure 9: Example reference sets for condition-specific data elements from the National Breast Cancer Audit



If the reference set of permissible values for a data element is large, such as a data element that represents a Principal diagnosis (ICD-10-AM), the external classification scheme should be referenced in the information model.

4.3.4 Defining data subsets

Within the CQR minimum dataset, a CQR can define one or more 'subsets' of data that represent the data elements that will be collected for a specific type of event (i.e. health services event or follow-up event) or patient diagnosis.

4.3.5 Formalising a data dictionary

Once the CQR information model has been defined, the publication of a data dictionary describing the model is an important step. This will ensure that multiple organisations and institutions can readily contribute to and use the CQR data.

A data dictionary must provide unambiguous definitions for all data elements, specify format, data-type information, usage guidelines and acceptable range or permissible values from a reference set, where applicable.

This logical design, including a data dictionary describing the core information model, will form part of the CQR data dictionary. This data dictionary is included in Section 6.3.

Ideally, the complete data dictionary will be published to a central national resource providing a single point of reference for all CQRs.

5. Definitions, acronyms and abbreviations

Term / Acronym / Abbreviation	Definition
ACPR	Australian Cardiac Procedures Registry
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADHA	Australian Digital Health Agency
AIHW	Australian Institute of Health and Welfare
AMT	Australian Medicines Terminology (AMT) – a national extension of SNOMED CT for use within information systems within Australia.
ANZICS	Australian and New Zealand Intensive Care Society
AOM	Adaptive Object Modelling
API	Application Programming Interface. A software intermediary that allows two applications to talk to each other. It consists of a set of commands, functions, and protocols that programmers can use when building software. It allows the use of predefined functions to interact with a system, instead of writing them from scratch.
Audit	An examination or review that establishes the extent to which a condition, process or performance conforms to predetermined standards or criteria. Audits may be carried out on the provision of care, compliance, community response and completeness of records.
AUSCR	Australian Stroke Clinical Registry
Benchmarking	Benchmarking is the process of measuring patient care and outcomes against other comparable healthcare organisations or practices[10]. Risk-adjusted models must be applied to the data.
Clinical governance	An integrated component of corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services. It is the set of relationships and responsibilities established by a health service organisation between its governing body, executive, clinicians, patients and consumers, to deliver safe and quality health care. Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe and high-quality health care[11].
Clinical Quality Registry	Clinical Quality Registries are a specific type of clinical registry focused on routinely collecting and analysing health outcome data, and generating risk-adjusted reports, for the purpose of driving ongoing improvements in safety and quality.

Clinical trial	Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.
Clinician	A health professional whose practice is based on direct observation and treatment of a patient, as distinguished from other types of health workers, such as laboratory technicians and those employed for research.
CQR	Clinical Quality Registry
CSV	Comma Separated Values
DMZ	De-Militarised Zone. Computer or small subnetwork that is present between a trusted internal network and untrusted external network(s). Adds an additional layer of security to an organisation's local area network (LAN).
FHIR	Fast Healthcare Interoperability Resource
Firewall	Device(s) designed to prevent unauthorised transmission to or from a private network based on a set of rules. Used to protect networks from unauthorised access while permitting legitimate communications to pass through
Guideline	A formal statement about a defined task or function. In the terminology developed by the European Community, directives are stronger than recommendations, which are in turn stronger than guidelines.
HI Services	Healthcare Identifier Services. Also see HPI and IHI.
HL7 **HL7 ORU**	Health Level Seven (HL7) is an all-volunteer, not-for-profit organisation involved in development of international healthcare standards. HL7 is also used to refer to some of the specific standards created by the organisation. An HL7 Observation Result (ORU) message contains information about a patient's clinical observations and is used in response to an order generated in a clinical system (HL7 ORU message). ORU messages are most commonly used within the context of EKG studies, laboratory results, imaging studies, and medical interpretations. They have also been used to communicate order and results information for the purpose of clinical trials (e.g. drug development). It is important to note that ORU messages do not natively contain images, but use a combination of text, codes and numbers to communicate results.
HPI	Healthcare Provider Identifier – for both individual providers (HPI-I) and for provider organisations (HPI-O)
ICD10	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
ICD10-AM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification
IHI	Individual Healthcare Identifier – a unique identifier for users of health care.
ISO	International Organization for Standardization

LAN	Local area network (LAN) – computer network that interconnects computers in a limited area such as an office building providing high data transfer rates
METeOR	Metadata Online Registry – Australia's repository for national data standards for health, housing and community services statistics and information.
Minimum dataset	A widely agreed on and generally accepted set of terms and definitions constituting core data acquired for medical records and employed for developing statistics suitable for diverse types of analyses and users.
NASH	National Authentication Service for Health
National Health Data Dictionary (NHDD)	The national metadata standards for the health sector are published in the National Health Data Dictionary by the Australian Institute of Health and Welfare. The data dictionary is a reference of standardised, accepted terms and protocols used for data collection in the health sector.
NBCA	National Breast Cancer Audit
NHMRC	National Health and Medical Research Council
NJRR	National Joint Replacement Registry
NMDS	National Minimum Data Set
NPC	National Product Catalogue
OCR	Optical Character Recognition
OMG	Object Management Group – a consortium, originally aimed at setting standards for distributed object-oriented systems, focused on modelling (programs, systems and business processes) and model-based standards.
PBS	Pharmaceutical Benefits Scheme
Quality of care	A level of performance or accomplishment that characterises the health care provided. Ultimately, measures of the quality of care always depend on value judgements, but there are elements and determinants of quality that can be measured objectively. These elements and determinants can be classified into measures of structure (staff, facilities), process (diagnostic and therapeutic procedures) and outcome (mortality rates, disability rates, level of patient satisfaction).
Record linkage	A method of bringing together the information contained in two or more records – e.g. in different sets of medical charts, and in vital records such as death certificates – and a procedure to ensure that each individual is identified and counted only once. Record linkage makes it possible to relate significant health events that are remote from one another in time and place or to bring together records of different individuals, e.g. members of a family.
Register	The file of data concerning all cases of a particular disease or other health-relevant condition in a defined population such that the cases can be related to a population base. With this information, incidence rates can be calculated. If the cases are followed up, information on remission, exacerbation, prevalence and survival can also be obtained.

Registry	See Clinical Quality Registry
Reverse proxy	Reverse proxy takes requests from the internet and forwards them to servers in an internal network. Those making requests connect to the proxy and the details/dispersion in the internal network is hidden.
Smart forms	Forms that provide for electronic data entry without having to be synchronously connected to an application. Smart forms can be developed without programming knowledge to: validate data; perform calculations; check for errors; bind form fields to XML schemas, databases or web services; use digital signatures.
SNOMED-CT	Systematised Nomenclature of Medicine, Clinical Terms
Standard	Something that serves as a basis for comparison; a technical specification or written report drawn up by experts based on the consolidated results of scientific study, technology and experience aimed at optimum benefits and approved by a recognised and representative body.
TOGAF	The Open Group Architecture Framework – a framework for Enterprise Architecture providing a comprehensive approach to the design, planning, implementation, and governance of an enterprise information architecture.
UML	Unified Modelling Language – a standardised general-purpose software engineering modelling language. UML includes a set of graphical notation techniques to create abstract models of specific systems, referred to as UML model.
Validity (study)	The degree to which the inference drawn from a study, warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn. Two varieties of study validity are distinguished: internal validity and external validity (generalisability).
Validity measurement	An expression of the degree to which a measurement measures what it purports to measure. Several varieties are distinguished, including construct validity, content validity, and criterion validity (concurrent or predictive validity).

6. Software industry standards and common information model

6.1 Standards

This section aims to direct readers to the established standards relevant to the development of the CQR. Instead of redefining these standards within this document, we aim to provide a clear and concise reference to existing standards, which can be found on the Australian Digital Health Agency (ADHA) website. The inclusion of these references is crucial as it underlines the importance of using a recognised standard in the development of the CQR. Adhering to these standards ensures consistency, reliability, and quality in the CQR data management and reporting.

Standards Map – a listing or mapping of the various technical standards that may be relevant to a CQR. It is recognised that varying levels of technical sophistication may be required depending on a given CQR's scope and purpose. The Standards Map identifies the different standards that may apply for each level in the following areas:

- Interoperability
- Clinical communications
- Unique healthcare identifiers
- Identity management
- Secure messaging.

Some of the technical standards referred to in this section are industry-neutral and not specific to the health sector. They do, however, have application or relevance for CQRs and can be considered as best practice technology standards that can be applied to e-health and to CQRs.

6.1.1 Interoperability and Clinical Communications

Interoperability standards are vital for the CQR as they ensure consistent, reliable, and efficient data exchange across different healthcare systems. These standards facilitate the integration of diverse source systems into the CQR, crucial for accurate and comprehensive registry content. Interoperability allows for effective communication between various technological platforms used in health care, enhancing the CQR's functionality and its ability to support healthcare providers. In addition, adhering to these standards is essential for maintaining data integrity. It ensures that the CQR's information is accurate and up-to-date, which is crucial for informed decision-making in health care.

For detailed information about interoperability and digital health standards, see the ADHA website.

6.1.2 Unique Healthcare Identifiers

The Healthcare Identifiers Service (HI Service) is integral to the CQR as it provides a system for uniquely identifying individuals, healthcare providers and organisations. This precision ensures the correct association of health information with the appropriate individuals at the point of care. For the CQR, such accurate identification is crucial as it underpins the integrity and reliability of the data linkage within the registry, ensuring consistency across various healthcare settings and supporting effective data analysis and improved CQR reporting.

For detailed information about the HI Service, see the ADHA website.

6.1.3 Identity management

Identity management makes sure that users only gain access to the information they are entitled to view. Identity management (IdM) can be regarded as an integrated system of policies, processes and technologies which allow organisations to facilitate and control users' access to applications and information while protecting confidential personal and business information from unauthorised users.

A number of standards are pertinent to identity management for CQRs. These include:

- National eHealth Security and Access Framework
- National Authentication Service for Health (NASH)
- OASIS eXtensible Access Control Markup Language (XACML) TC V3.0
- OASIS Security Services (SAML) TC v2.0
- OpenId.

6.1.4 Secure messaging

Secure messaging ensures source system data are transported securely between healthcare organisations and the CQR. Relevant standards, developed in collaboration with various industry partners and Standards Australia, can facilitate the protected and efficient communication of sensitive health information. Secure messaging is essential for the CQR as it underpins the confidentiality of the health data being shared, and maintains the trust and privacy standards expected in healthcare communications.

For detailed information please visit ADHA Secure Messaging website.

6.2 Core information model data dictionary

This section documents the data dictionary for the core information model for CQRs.

6.2.1 Data item index

The following table describes the hierarchy of object classes and data elements that constitute the core CQR collection dataset. The sub-section column refers to the appropriate entry for the data item in the data dictionary.

Please see following page for table.

Data item	Data entry
Patient	
	Date of diagnosis
	Principle diagnosis
Person	
	Person identifier
	Family name
	Given name
	Date of birth
	Age
	Sex recorded at birth: Male Female Another term
	What is your gender: Male Female Non-binary Another term (please specify) Prefer not to answer
	Country of birth code
	Indigenous status code
	Australian postcode
	Australian Statistical Geography Standard SA1 code
	Date of death
Service provider organisation	
	Organisation name
	Organisation identifier
Health service event	
	Date
	Record completion status
Follow-up event	
	Date
	Record completion status
Registry episode	

6.3 Data dictionary

This section defines the object classes and data elements in alphabetical order. Where the object or data element is specified in METeOR, a link is provided to the METeOR entry.

6.3.1 CQR data subset instance

Identifying and definitional attributes

Metadata item type	Object Class
Definition	An instance of a data subset that will be used to collect clinical data values for a particular health service event or follow-up event

6.3.2 CQR data subset instance – completion date

Identifying and definitional attributes

Metadata item type	Data Element
Definition	The date on which the information was recorded about the patient

Representational attributes

Representation class	Date
Data type	Date/Time
Format	DDMMYYYY
Maximum character length	8

6.3.3 CQR data subset instance – completed by

Identifying and definitional attributes

Metadata item type	Data Element
Definition	The user identifier of the person who entered the data collection form into the system

Representational attributes

Representation class	Identifier
Data type	String
Format	X(20)
Maximum character length	20

6.3.4 Follow-up event

Identifying and definitional attributes

Metadata item type	Object Class
Definition	An interaction between one or more healthcare providers with one or more persons for assessment, care, consultation and/or treatment

6.3.5 Follow-up event – date

Identifying and definitional attributes

Metadata item type	Data Element
METeOR identifier	N/A
Registration status	N/A
Definition	The date on which the follow-up data was collected about a patient

Representational attributes

Representation class	Date
Data type	Date/Time
Format	DDMMYYYY
Maximum character length	8

6.3.6 Follow-up event – record completion status

Identifying and definitional attributes

Metadata item type	Data Element
Definition	Whether the record has been completed, as represented by a code

Representational attributes

Representation class	Code
Format	N
Maximum character length	1
Permissible values	1 – Provisional 2 – Final 3 – Locked

6.3.7 Health service event

Identifying and definitional attributes

Metadata item type	Object Class
METeOR link	Health service event (aihw.gov.au)

6.3.8 Health service event – presentation date

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Health service event—presentation date, DDMMYYYY (aihw.gov.au)

6.3.9 Health service event – record completion status

Identifying and definitional attributes

Metadata item type	Data Element
Definition	Whether the record has been completed, as represented by a code

Representational attributes

Representation class	Code
Format	N
Maximum character length	1
Permissible values	1 – Provisional 2 – Final 3 – Locked

6.3.10 Patient

Identifying and definitional attributes

Metadata item type	Object Class
METeOR link	Patient (aihw.gov.au)
Registration status	Health, Standard 01/03/2005
Definition	A person for whom a health service organisation accepts responsibility for treatment and or care
Specialisation of ...	Person/group of persons

6.3.11 Patient – diagnosis date

Identifying and definitional attributes

Metadata item type	Data Element
METeORlink	Patient – diagnosis date (aihw.gov.au)

6.3.12 Patient – informed of participation

Identifying and definitional attributes

Metadata item type	Data Element
METeOR identifier	N/A
Registration status	N/A
Definition	Whether the patient has been informed that their records will be included in Clinical Quality Registry reports, as represented by a code

Representational attributes

Representation class	Code
Data type	Boolean
Format	N
Maximum character length	1
Permissible values	1 – Yes 2 – No

6.3.13 Patient – opt-out date

Identifying and definitional attributes

Metadata item type	**Data Element**
Definition	The date on which a patient elected that all their associated records shall not be included in the Clinical Quality Registry reports

Representational attributes

Representation class	Date
Data type	Date/Time
Format	DDMMYYYY
Maximum character length	8

6.3.14 Patient – principal diagnosis

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Patient – principal diagnosis (aihw.gov.au)

6.3.15 Person

Identifying and definitional attributes

Metadata item type	Object Class
METeOR identifier	268955
Registration status	Refer to the online registration by clicking the following link
Definition	A human being
Specialisation of ...	Person/group of persons

6.3.16 Person – age

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person – age, total years (aihw.gov.au)

6.3.17 Person – country of birth

Identifying and definitional attributes

Metadata item type	Data Element
METeOR identifier	370943
Registration status	Refer to the online registration by clicking the following link
Definition	The country in which the person was born, as represented by a code

Representational attributes

Classification scheme	**SACC 2008**[12]
Representation class	Code
Data type	Number
Format	NNNN
Maximum character length	4

Related attributes

Data Element Concept	Person – country of birth (METeOR: 269686)
Property	Country of birth (METeOR: 269206)

6.3.18 Person – date of birth

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person – date of birth (aihw.gov.au)

6.3.19 Person – date of death

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person – date of death (aihw.gov.au)

6.3.20 Person – Indigenous status

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person – Indigenous status (aihw.gov.au)

6.3.21 Person – Australian Statistical Geography Standard – SA1 code

Identifying and definitional attributes

Metadata item type	Data Element
Definition	A geographical region defined within The Australian Statistical Geography Standard (ASGS).[13] SA1 regions generally have a population of 200 to 800 persons, and an average population of about 400 persons. SA1s closely bound small rural towns with a population of 180 persons or more.

Representational attributes

Representation class	Code
Data type	Number
Format	NNNNNNN[NNNN]
Permissible values	SA1 Coding Structure: Identified either by an 11-digit fully hierarchical code, or by a truncated 7-digit code comprising the S/T, SA2 and SA1 identifiers. The SA1 identifier is a 2-digit code, assigned within an SA2. An SA1 code is only unique within an S/T when it is preceded by the S/T identifier.[14]
Maximum character length	11

6.3.22 Person – person identifier

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person – person identifier (aihw.gov.au)

6.3.23 Person – sex

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person – sex, code N (aihw.gov.au)

6.3.24 Person (address) – Australian postcode

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person (address) – Australian postcode (aihw.gov.au)

6.3.25 Person (name) – family name

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person (name) – family name (aihw.gov.au)

6.3.26 Person (name) – given name

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Person (name) – given name (aihw.gov.au)

6.3.27 Registry episode

Identifying and definitional attributes

Metadata item type	Object Class
Definition	A period of time during which a patient receives health care which is relevant to a Clinical Quality Registry
Specialisation of ...	Service episode

6.3.28 Registry episode – opt-out date

Identifying and definitional attributes

Metadata item type	Data Element
Definition	The date on which a patient elected that all the associated records for a particular episode shall not be included in the Clinical Quality Registry reports

Representational attributes

Representation class	Date
Data type	Date/Time
Format	DDMMYYYY
Maximum character length	8

6.3.29 Service provider organisation

Identifying and definitional attributes

Metadata item type	Object Class
METeOR link	Service provider organisation (aihw.gov.au)

6.3.30 Service provider organisation (name) – organisation name

Identifying and definitional attributes

Metadata item type	Data Element
METeOR link	Service provider organisation (name) – organisation name (aihw.gov.au)

6.3.31 Service provider organisation (name) – organisation identifier

Identifying and definitional attributes

Metadata item type	Data Element
Definition	The identifier for an organisation allocated by an establishment or agency

Representational attributes

Representation class	Text
Data type	String
Format	X(20)
Maximum character length	20

Appendix A: Detailed requirements traceability matrix

Section	Identifier	Summary	Detail
2.1 Data Custodianship			
2.1.1 Define purpose	B09	Identifying information to support CQR purpose	CQRs shall collect sufficient patient-identifying information to support the registry's stated purpose.
	B22	Public information about CQR purpose	CQRs shall make access to information about the quality improvement benefits or value of each registry readily available to the public.
2.1.2 Define scope	B01	Publicly accessible eligibility criteria	CQRs shall make scope and eligibility criteria publicly accessible. A history of changes to eligibility criteria changes shall be available to support analysts and researchers.
	B03	Entire eligible population	CQRs shall have the ability to collect complete registry data from the entire eligible population.
	B04	Right to opt-out	CQRs shall support and enable the right of patients to opt-out.
	B05	Voluntary participation	CQRs shall provide participants (eligible population) with the option not to participate.
	B35	Transparency to data extract logic	Where business rules or other advanced data query techniques are used to identify eligible participants, the CQR must make those rules and techniques available for review on request.
	F26	Eligibility criteria	CQRs shall be able to provide eligibility criteria in a computer processable form. This will allow systems that provide information to the registry via direct feed to identify eligible patients based on patient events.
	F27	Automatic updates to eligibility criteria and data specifications	When data automatically fed from administrative systems in participating facilities, registries shall provide automatic updates to those systems when changes to eligibility criteria or data specifications occur.

2.1.3 Define minimum dataset	B02	Publicly accessible data specifications	CQRs shall make data specifications publicly accessible. Previous versions shall also be publicly accessible.
	B08	Publication of metadata, data dictionaries and indicators	CQRs shall publish metadata, data dictionaries and indicators to make them publicly accessible.
	F08	Multiple unique healthcare identifiers	CQRs shall record the minimum number of unique healthcare identifiers for an individual patient to meet its primary and secondary purposes.
	F09	Unique identifiers for patients, providers and products	CQRs shall be able to allocate a unique identifier for patients, providers and products where the National Healthcare Identifier is not consistently available.
	F78	Use of Individual Healthcare Identifiers	CQRs that require individually identifiable data shall have the capability to use national Individual Healthcare Identifiers.
	F80	Record that patient has been informed of participation	CQRs shall be able to record that the patient has been informed of the inclusion of their data in the registry.
	F82	Data definitions	CQRs shall maintain data definitions and descriptions for each data element and its usage.
	F83	Retire data elements	CQRs shall be able to retire registry data elements to ensure information that is no longer relevant or required for relevant analysis is deactivated (and no longer collected).
	F84	Time variant data	CQRs shall maintain data in such a way that enables the time of data capture to be identified.
	F85	Manage business rules	CQRs shall have the ability to determine which business rules were active at a particular date/time.
	F86	Reference data integrity	CQRs shall support 'ageing of metadata' by maintaining accurate links with reference data over time.

	F89	Support for data retrieval	CQRs shall store data in a retrievable form with data descriptions and data structures.
	F90	Reference data sources	CQRs shall clearly identify sources of reference data as well as reference data currency in their data dictionary.
2.1.4 Define use	B21	Availability of policies	CQRs shall make data access and reporting policies available to registry users.
2.1.5 Define business processes	B30	Manage registry lifecycle	CQRs shall have in place processes that periodically consider the value that the registry is providing, plan for continuous improvement, and manage the controlled decommissioning of the registry and appropriate treatment of registry data when the registry is no longer used. These reports shall be available to all stakeholders.
	B31	Develop and manage registry roadmap	CQRs shall develop roadmaps that communicate the plan to develop the maturity of the registry. The roadmap shall outline the key activities, time line, risks and roles responsible for executing the plan.
	B32	Assess registry against the Framework	CQRs shall perform a self-assessment to determine where improvements are required. (These improvements will be represented on the registry roadmap.)
	B33	Advise originating organisations of data errors	CQRs shall advise participating organisations of data errors or omissions to provide those organisations with the opportunity to correct the data at source.
	B34	Develop, document and maintain processes and procedures	CQRs shall develop, document and maintain processes and procedures for data governance collection, lodgement, storage and management.
2.1.6 Comply with legislation and standards	B19	Manage data in accordance with legislation and standards	CQRs shall collect, store and transmit data in accordance with relevant legislation, regulation, standards and guidelines.
	B36	Maintain compliance register	CQRs shall maintain well-designed legislative compliance processes and incorporate a compliance register to ensure that the organisation's policies are regularly updated, and able to respond to

			regulatory changes and compliance issues.
2.2 Provide enrolment			
2.2.1 Publish Eligibility	B01	Publicly accessible eligibility criteria	CQRs shall make scope and eligibility criteria publicly accessible. A history of changes to eligibility criteria shall be available to support analysts and researchers.
2.2.2 Enrol providers	F01	Add participating institutions or clinicians	CQRs shall be able to add a new participating institution.
	F02	Associate groups	CQRs shall be able to create associations between clinicians with the institution/jurisdictions which they work for.
	F03	Central administration	CQRs shall have a central system administration group that shall be able to appoint participating group and participating institution level system administrators.
	F04	Group administration	CQRs shall enable defined groups to read and run reports on data within their hospitals, jurisdiction or clinical group.
	F05	Participating institution level administration	CQRs shall allow participating institution or clinical group level administrators to be appointed to allocate user rights within the institution or clinical group. This includes creating new user accounts and granting user privileges such as: create new records, read records, update records, edit records.
	F12	Access for international data providers	CQRs shall enable authorised users based outside of Australia to contribute and receive data to and from the registry via appropriately secure systems and processes.
2.3 Data collection			
2.3.1 Capture data	B06	Standardised data collection approaches	CQRs shall collect data using standardised and systematic approaches.
	B17	Determining client outcomes	Client outcomes shall be determined at a time when their clinical condition has stabilised and the outcome can be reasonably ascertained

	F07	Data capture	Where possible, CQRs shall access data utilising a direct feed from a hospital administrative or clinical information system, or another data repository (such as a state-based clinical repository). This access could be via messages (e.g. HL7 pathology reports), or via an API.
	F08	Multiple unique healthcare identifiers	CQRs shall record the minimum number of unique healthcare identifiers for an individual patient to meet its primary and secondary purposes.
	F09	Unique identifiers for patients, providers and products	CQRs shall be able to allocate a unique identifier for patients, providers and products where the National Healthcare Identifier is not consistently available.
	F10	Authorised contributors allowed to edit and add information	CQRs shall allow authorised contributors submitting information to review and revise (edit, add to) information they have posted to the registry.
	F13	Batch uploading	CQRs shall be able to receive batch uploads of information from a source system provided to the registry in a standardised format.
	F14	Establish criteria for rejecting or partially accepting records	CQRs shall be able to establish and publish criteria under which a record being imported will be rejected or accepted with a flag attached to enable it to be readily identified for review and follow-up.
	F15	Apply data validation checks during import	CQRs shall be able to apply automated data validation checks, including simple field validation, business rules (Boolean logic and clinical logic checks) and simple computations (e.g. assays) as part of the process of importing data.
	F16	Prompt if changes result from data import	CQR users shall be prompted if any data contained in existing records would be changed as a result of importing new data through an automated process.
	F17	Allow multiple episodes of care to be recorded	CQRs shall allow data relating to multiple episodes of care for a single patient to be imported.
	F18	Receipt of data from existing data sources	CQRs shall have the ability to receive/import data from existing data sources, including administrative data.

	F19	Access control for batch upload	CQRs shall use role-based access control to enable authorised users to perform batch uploads, and prevent unauthorised users from doing so.
	F20	Authorised system upload	CQRs shall enable authorised systems or users to upload batches of information to the registry.
	F21	Cross-check data being imported	CQRs shall be able to cross-check large quantities of records against another set of records as part of the process of importing data to avoid record duplication.
	F22	Alter records via data import	CQRs shall be able to use automated data import processes to append, modify, or discard patient records.
	F23	Mark mandatory fields	CQRs shall be able to identify which fields within a record are mandatory.
	F24	Correct errors identified through validation checks	CQRs shall provide users with the ability to add missing data or fix incorrect information identified through automated validity checks during data entry.
	F25	Data record rejection	In the case that records are rejected, a reason can be recorded against it.
	F26	Eligibility criteria	CQRs shall be able to provide eligibility criteria in a computer processable form. This will allow systems that provide information to the registry via direct feed to identify eligible patients based on patient events.
	F27	Automatic updates to eligibility criteria and data specifications	When data are automatically fed from administrative systems in participating facilities, registries shall provide automatic updates to those systems when changes to eligibility criteria or data specifications occur.
	F28	Scanning of simple data fields	CQRs shall allow for central or local scanning of simple data fields (e.g. checkboxes) in paper-based capture to convert information to an electronic format.
	F29	Barcode scanning	CQRs may facilitate barcode scanning of patient identification labels on paper forms.

	F30	Include automated data validity checks	CQRs shall use automated data validity checks supporting any required data entry such as drop-down selections, nested drop-downs, checkboxes, auto complete search clinical terminology, etc.
	F31	Download printable forms	CQRs shall enable users to download printable forms to aid manual data collection.
	F32	Offline forms	Users shall be able to download offline forms for data entry.
	F33	OCR in scanning	The CQR shall facilitate OCR in scanning of paper forms.
	F34	Logic checks and rules to guide efficient data entry	CQRs shall be able to define business rules and logic checks that increase the efficiency of any data entry required.
	F35	Storage of paper-based data sources	CQRs shall be able to store electronic copies of paper-based data collection forms.
2.3.2 Perform data linkage	B07	Use of standard terminology and data specifications	CQRs shall use standard definitions, terminology, data dictionaries and specifications (wherever possible) to enable meaningful comparisons and linkages (if approved by ethics committees) to other registries and databases.
	B18	Capacity to link or integrate with other registries	CQRs shall have the capacity to support linkage with other datasets.
	B29	Produce longitudinal patient outcome information through data linkage	CQRs shall be able to generate detailed longitudinal information about patient outcomes through the use of data linkage in order to monitor the effect of health care.
	NF42	Employ standard to support data linkage	CQRs shall employ technical and data information standards that support data linkage to, or eventual integration with, other disease and procedure registers or other databases.
	NF62	Audit trails to record data linkage details	CQRs shall record details of data export (for the purpose of data linkage) in comprehensive audit trails.

2.3.3 Identifying patients requiring follow-up	F14	Establish criteria for rejecting or partially accepting records	CQRs shall be able to establish and publish criteria under which a record being imported will be rejected, or accepted with a flag attached to enable it to be readily identified for review and follow-up.
	F36	Define period for record update	CQRs shall be able to define the period in which an individual's record shall be updated or completed.
	F37	Prompt when record incomplete	CQRs shall prompt a user when a record remains incomplete past the permitted duration for data collection/record update.
	F81	Record patient decision to opt-out	CQRs shall be able to record that the patient has opted-out of participating in the CQR at both a global and episodic level.
	F87	Record opt-out notification	CQRs shall alert users that a patient has opted-out each time that patient's eligibility identifies them for recruitment.
	F88	Flag when patient has opted-out	When the patient has opted-out, CQRs shall follow the process approved by their governing HREC.
2.3.4 Add follow-up information	F12	Access for international data providers	CQRs shall enable authorised users based outside of Australia to contribute and receive data to and from the registry via appropriately secure systems and processes.
	F38	Report of incomplete record	CQRs shall be able to produce a report that identifies records that are incomplete past the permitted duration for data collection/record update.
	F39	Download follow-up forms	CQRs shall enable users to download printable or offline forms to aid the collection of follow-up information.
	F40	Lock record at case completion	CQRs shall be able to lock a record (to prevent it from being edited by local users) at the point of case completion once it has passed audit checks.
	F41	Authorised users can unlock records	CQRs shall enable authorised users to unlock records.
	F42	Workflows	CQRs shall support the use of generic automated workflows.
2.3.5 Manage data capture	B10	Avoid data collection burden	CQRs shall collect data in such a way that it is not an unreasonable burden on

conditions and metadata requirements			consumers, in terms of the time and cost involved in participation.
	B11	Timely capture of data	CQRs shall capture data as close as possible to the time and place of care.
	B15	Collect covariates for risk adjustment	CQRs shall collect objective, reliable covariates for risk adjustment to be taken into account by the use of appropriate statistical adjustments.
	B23	Avoid redundant data capture	CQRs shall only record individual data elements once to avoid redundant data capture and entry.
	B24	Trained data collectors	CQRs shall use appropriately trained data collectors to capture data. This shall include training materials which are available to registry users.
	B25	Use of existing data	CQRs shall use data from existing sources (including administrative data) where they meet the data requirements.
	B26	Adequate sample sizes for data accuracy checks	CQRs shall ensure that the sample size used for data accuracy checks is sufficient to provide reliable measures of data completeness and accuracy.
	B27	Specific case definition	CQRs shall collect information related to a specific case definition.
	B28	Considerations in determining time to outcome assessment	CQRs shall cost and consider the burden and cost of data collection together with the likelihood of loss to follow-up in determining the time to outcome assessment. The summary of the costing analysis shall consider additional data collection, processing and time required by healthcare staff. This shall be balanced against the improvements to the quality of care which can be delivered.
2.4 Data quality management			
2.4.1 Identify inaccurate/ incomplete data	B12	Monitor quality in accordance with plans	CQRs shall monitor the completeness and accuracy of the data collected in accordance with quality assurance plans.
	B13	Prompt identification of data quality lapses	CQRs shall ensure that data accuracy checks are conducted frequently enough to enable prompt identification of data quality lapses.

	B33	Advise originating organisations of data errors	CQRs shall advise participating organisations of data errors or omissions to provide those organisations with the opportunity to correct the data at source.
	F43	Define logic checks	CQRs shall be able to define logic checks that constrain the information able to be entered into a field.
	F44	In-built data validation checks	CQRs shall incorporate in-built data validation checks such as data range and context sensitive validation.
	F46	Probabilistic matching	CQRs may support probabilistic matching of identifying information against existing registry data.
	F49	Audit for accuracy against source	CQRs shall check data accuracy in a sample of cases using audits against source records.
	F51	Identification of sample for audit	CQRs shall be able to identify a random sample of cases in which to conduct audits against source records.
	F53	Production of audit reports	CQRs shall be able to provide reports on the outcome of data audit checks by case, episode or facility.
	F54	Feedback on data entry error rates	CQRs shall be able to provide reports to users about their missing data rates. CQRs shall be able to produce reports which demonstrate case ascertainment when compared to other data sources and highlight missing cases for data entry. CQRs shall be able to produce reports which highlight cases where not all data elements have been completed, to improve case completeness.
	F72	Data extraction to be audited	CQRs shall only support data extraction of identifiable information, via the user interface, to enable auditing.
	F79	Specify when record is included in reports	CQRs shall be able to specify the stage of record completeness (e.g. provisional or final) at which the record can be included within reports.
2.4.2 Amend data	B14	Prompt actioning of incomplete data records	CQRs shall ensure that incomplete or inaccurate data identified through data completeness checks are actioned as soon as possible.

	B33	Advise originating organisations of data errors	CQRs shall advise participating organisations of data errors or omissions to provide those organisations with the opportunity to correct the data at source.
	F45	Record reason for overriding validity checks	CQRs shall allow users to override validity constraints and annotate the reason for this action, or allow 'other' responses where applicable.
2.4.3 Perform checks against other data sources	F48	Consistency of data from different sources	CQRs shall be able to produce reports on the consistency of data obtained through different sources, such as data entry versus checks against other data sources.
	F52	Feedback on data quality	CQRs shall be able to produce reports to users about the quality of data collected based on data quality standards.
2.4.4 Maintain searchability and data quality	F47	Search identifiers to reduce duplicate records	CQRs shall allow authorised users to search patient identifying information to reduce duplicates at the point of data entry.
	F50	Double entry to check accuracy	Users shall be able to double enter patient information to check the accuracy of data entry.
2.5 Data analysis and outcome reporting			
2.5.1 Risk adjustment	B15	Collect covariates for risk adjustment	CQRs shall collect objective, reliable covariates for risk adjustment to be considered by the use of appropriate statistical adjustments.
	B16	Timely reports that include risk adjusted analyses	CQRs shall report to healthcare staff, organisations and jurisdictions in a timely manner on risk-adjusted outcome analysis.
2.5.2 Manage identifiable information	B20	Provision of identifiable information	CQRs shall only provide identifiable information to external parties if consent has been obtained or if legislative or ethics approval allows for the provision of identifiable information.
2.5.3 Reporting	B37	Reporting	Generate benchmark reports on the appropriateness and effectiveness of health care.
	B38	Sharing reports	CQRs shall share reports with participating healthcare teams, hospitals, hospital groups and participating jurisdictions.

	B39	Public reporting	CQRs shall, at a minimum, publish an annual report within 12 months of the reporting year end. The annual report shall contain a hospital-level summary for each participating site benchmarking against national clinical care standards where available, and, optionally, CQR local indicators.
	B40	Data model	Publish the CQR data model to demonstrate the relationship between episodes of care, assessments, treatments and other tables of data. This will allow end users to build analytical queries more easily.
	B41	Documentation	A vignette outlining how a registry user may log in, export, transform and analyse data for the purposes of quality improvement shall be created.
	F55	Different report formats	Authorised users will be able to print reports, and/or save the results in HTML, PDF and other formats such as XML that support local analysis.
	F56	Access to restricted reports	CQRs shall implement business rules and special permissions relating to access for restricted reports.
	F57	Secure access to reporting from central registry	Authorised users shall be able to access reports from the central CQR, for which they have access rights, through a secure portal.
	F58	Record authorisation to provide identifiable data	CQRs shall be able to record authorisation details when providing identifiable information to external parties.
	F59	Web access to reports	CQRs shall provide secure access for authorised users to standard and ad hoc reports produced by registry staff via a secure web interface.
	F60	Patient summary	Users shall be able to produce an abstract of information included in the registry that pertains to an individual patient.
	F61	Generate standard reports	CQRs shall be able to generate scheduled/routine standard reports that may be reviewed by identified institutions and clinicians.

	F62	Scheduled reporting	CQRs shall enable authorised users to produce scheduled reports through selection from available reports, parameters and pre-set frequencies (for example, weekly).
	F63	Individual facility reports	CQRs shall be able to produce reports for a facility that contains only data that they have contributed. These reports may contain identified data.
	F64	Benchmark reports	CQRs shall be able to produce reports that enable comparisons of de-identified aggregated data against peer group benchmarks by facilities and by regions (including by jurisdiction and national level).
	F65	Clinical and epidemiological reporting	CQRs shall support clinical and epidemiological reporting.
	F66	Coverage of eligible population report	CQRs shall be able to produce a standard report on the proportion of eligible patients participating in the registry (by facility and region), against an indicator.
	F67	Contributing units can produce centrally configured reports	CQRs shall enable authorised users in participating units/institutions and jurisdictions to produce centrally configured reports of their own unit's/institution's/jurisdiction's data to enable monitoring of clinical care.
	F68	Export of unit record data	CQRs shall be able to export unit record data in delimited format for approved purposes.
	F69	Default format of unit record data export	CQRs shall export unit record data using de-identified data as the default format.
	F70	Ability to export data for research purposes	CQRs shall enable information to be exported for research purposes once the necessary approval has been obtained.
	F71	Ability to record purpose of data export	When information is exported for research purposes, CQR shall be able to record the purpose for which the information is to be used.
	F72	Data extraction to be audited	CQRs shall only support data extraction of identifiable information, via the user interface, to enable auditing.

	F73	Encrypt exported identifiable information	CQRs must encrypt identifiable information at the point of export.
	F74	Compatibility of data extracts with statistical packages	CQRs shall support the secure extract of data in formats compatible with major statistical packages.
	F75	Ad hoc data analysis available to participating units	CQRs shall enable participating units/hospitals to undertake ad hoc analyses of their own unit's/patient's data.
	F76	Define parameters for ad hoc reports	CQRs shall be able to define parameters, such as date ranges, filter criteria and sort criteria that are specific to a particular ad-hoc report.
	F77	Use report parameters to generate ad hoc reports	CQR users shall enter information into pre-defined report parameters to generate ad hoc reports.

Appendix B: Detailed requirements specification

CQR system and process recommendations

Identifier	Summary	Detail
B01	Publicly accessible eligibility criteria	CQRs shall make scope and eligibility criteria publicly accessible. A history of changes to eligibility criteria changes shall be available to support analysts and researchers.
B02	Publicly accessible data specifications	CQRs shall make data specifications publicly accessible. Previous versions shall also be publicly accessible.
B03	Entire eligible population	CQRs shall have the ability to collect complete registry data from the entire eligible population.
B04	Right to opt-out	CQRs shall support and enable the right of patients to opt-out.
B05	Voluntary participation	CQRs shall provide participants (eligible population) with the option not to participate.
B06	Standardised data collection approaches	CQRs shall collect data using standardised and systematic approaches.
B07	Use of standard terminology and data specifications	CQRs shall use standard definitions, terminology, data dictionaries and specifications (wherever possible) to enable meaningful comparisons and linkages (if approved by ethics committees) to other registries and databases.
B08	Publication of metadata, data dictionaries and indicators	CQRs shall publish metadata, data dictionaries and indicators to make them publicly accessible.
B09	Identifying information to support CQR purpose	CQRs shall collect sufficient patient-identifying information to support the registry's stated purpose (if it collects identified data).
B10	Avoid data collection burden	CQRs shall collect data in such a way that it is not an unreasonable burden on consumers, in terms of the time and cost involved in participation.
B11	Timely capture of data	CQRs shall capture data as close as possible to the time and place of care.
B12	Monitor quality in accordance with plans	CQRs shall monitor the completeness and accuracy of the data collected in accordance with quality assurance plans.

B13	Prompt identification of data quality lapses	CQRs shall ensure that data accuracy checks are conducted frequently enough to enable prompt identification of data quality lapses.
B14	Prompt actioning of incomplete data records	CQRs shall ensure that incomplete or inaccurate data identified through data completeness checks are actioned as soon as possible.
B15	Collect covariates for risk adjustment	CQRs shall collect objective, reliable covariates for risk adjustment to be considered by the use of appropriate statistical adjustments.
B16	Timely reports that include risk adjusted analyses	CQRs shall report to healthcare staff, organisations and jurisdictions in a timely manner on risk-adjusted outcome analysis.
B17	Determining client outcomes	Client outcomes shall be determined at a time when their clinical condition has stabilised and the outcome can be reasonably ascertained.
B18	Capacity to link or integrate with other registries	CQRs shall have the capacity to support linkage with other datasets.
B19	Manage data in accordance with legislation and standards	CQRs shall collect, store and transmit data in accordance with relevant legislation, regulation, standards and guidelines.
B20	Provision of identifiable information	CQRs shall only provide identifiable information to external parties if consent has been obtained or if legislative or ethics approval allows for the provision of identifiable information.
B21	Availability of policies	CQRs shall make data access and reporting policies available to registry users.
B22	Public information about CQR purpose	CQRs shall make access to information about the quality improvement benefits or value of each registry readily available to the public.
B23	Avoid redundant data capture	CQRs shall only record individual data elements once to avoid redundant data capture and entry.
B24	Trained data collectors	CQRs shall use appropriately trained data collectors to capture data. This shall include training materials which are available to registry users.
B25	Use of existing data	CQRs shall use data from existing sources (including administrative data) where they meet the data requirements.
B26	Adequate sample sizes for data accuracy checks	CQRs shall ensure that the sample size used for data accuracy checks is sufficient to provide

		reliable measures of data completeness and accuracy.
B27	Specific case definition	CQRs shall collect information related to a specific case definition.
B28	Considerations in determining time to outcome assessment	CQRs shall cost and consider the burden and cost of data collection together with the likelihood of loss to follow-up in determining the time to outcome assessment. The summary of the costing analysis shall consider additional data collection, processing and time required by healthcare staff. This shall be balanced against the improvements to the quality of care which can be delivered.
B29	Produce longitudinal patient outcome information through data linkage	CQRs shall be able to generate detailed longitudinal information about patient outcomes through the use of data linkage in order to monitor the effect of healthcare.
B30	Manage registry lifecycle	CQRs shall have in place processes that periodically consider the value that the registry is providing, plan for continuous improvement, and manage the controlled decommissioning of the registry and appropriate treatment of registry data when the registry is no longer used. These reports shall be available to all stakeholders.
B31	Develop and manage registry roadmap	CQRs shall develop roadmaps that communicate the plan to develop the maturity of the registry. The roadmap shall outline the key activities, time line, risks and roles responsible for executing the plan.
B32	Assess registry against the Framework	CQRs shall perform a self-assessment to determine where improvements are required. (These improvements will be represented on the registry roadmap.)
B33	Advise originating organisations of data errors	CQRs shall advise participating organisations of data errors or omissions to provide those organisations with the opportunity to correct the data at source.
B34	Develop, document and maintain processes and procedures	CQRs shall develop, document and maintain processes and procedures for data governance collection, lodgement, storage and management.
B35	Transparency to data extract logic	Where business rules or other advanced data query techniques are used to identify eligible participants, the CQR must make those rules and techniques available for review on request.
B36	Maintain compliance register	The CQR shall maintain well-designed legislative compliance processes and incorporate a

		compliance register to ensure that the organisation's policies are regularly updated, and able to respond to regulatory changes and compliance issues.
B36	Reporting	Generate benchmark reports on the appropriateness and effectiveness of health care.
B38	Sharing reports	CQRs shall share reports with participating healthcare teams, hospitals, hospital groups and participating jurisdictions.
B39	Public reporting	CQRs shall, at a minimum, publish an annual report within 12 months of the reporting year end. The annual report shall contain a hospital-level summary for each participating site benchmarking against national clinical care standards where available and, optionally, CQR local indicators.
B40	Data model	Publish the CQR data model, to demonstrate the relationship between episodes of care, assessments, treatments and other tables of data. This will allow end users to build analytical queries more easily.
B41	Documentation	A vignette outlining how a registry user may log in, export, transform and analyse data for the purposes of quality improvement shall be created.

CQR administrative recommendations

Identifier	Summary	Detail
F01	Add participating institutions or clinicians	CQRs shall be able to add a new participating institution.
F02	Associate groups	CQRs shall be able to create associations between clinicians with the institution/jurisdictions which they work for.
F03	Central administration	CQRs shall have a central system administration group that shall be able to appoint participating group and participating institution level system administrators.
F04	Group administration	CQRs shall enable defined groups to read and run reports on data within their hospitals, jurisdiction or clinical group.
F05	Participating institution level administration	CQRs shall allow participating institution or clinical group level administrators to be appointed to allocate user rights within the institution or clinical group. This

		includes creating new user accounts and granting user privileges such as: create new records, read records, update records, edit records.
F07	Data capture	Where possible, CQRs shall access data using a direct feed from a hospital administrative or clinical information system, or another data repository (such as a state-based clinical repository). This access could be via messages (e.g. HL7 pathology reports), or via an API.
F08	Multiple unique healthcare identifiers	CQRs shall record the minimum number of unique healthcare identifiers for an individual patient to meet its primary and secondary purposes.
F09	Unique identifiers for patients, providers and products	CQRs shall be able to allocate a unique identifier for patients, providers and products where the National Healthcare Identifier is not consistently available.
F10	Authorised contributors allowed to edit and add information	CQRs shall allow authorised contributors submitting information to review and revise (edit, add to) information they have posted to the registry.
F12	Access for international data providers	CQRs shall enable authorised users based outside of Australia to contribute and receive data to and from the registry via appropriately secure systems and processes.
F13	Batch uploading	CQRs shall be able to receive batch uploads of information from a source system provided to the registry in a standardised format.
F14	Establish criteria for rejecting or partially accepting records	CQRs shall be able to establish and publish criteria under which a record being imported will be rejected or accepted with a flag attached to enable it to be readily identified for review and follow-up.
F15	Apply data validation checks during import	CQRs shall be able to apply automated data validation checks, including simple field validation, business rules (Boolean logic and clinical logic checks) and simple computations (e.g. assays) as part of the process of importing data.
F16	Prompt if changes result from data import	CQRs users shall be prompted if any data contained in existing records would be changed as a result of importing new data through an automated process.
F17	Allow multiple episodes of care to be recorded	CQRs shall allow data relating to multiple episodes of care for a single patient to be imported.
F18	Receipt of data from existing data sources	CQRs shall have the ability to receive/import data from existing data sources, including administrative data.

F19	Access control for batch upload	CQRs shall use role-based access control to enable authorised users to perform batch uploads and prevent unauthorised users from doing so.
F20	Authorised system upload	CQRs shall enable authorised systems or users to upload batches of information to the registry.
F21	Cross-check data being imported	CQRs shall be able to cross-check large quantities of records against another set of records as part of the process of importing data to avoid record duplication.
F22	Alter records via data import	CQRs shall be able to use automated data import processes to append, modify, or discard patient records where possible.
F23	Mark mandatory fields	CQRs shall be able to identify which fields within a record are mandatory.
F24	Correct errors identified through validation checks	CQRs shall provide users with the ability to add missing data or fix incorrect information identified through automated validity checks during data entry.
F25	Data record rejection	In the case that records are rejected, a reason can be recorded against it.
F26	Eligibility criteria	CQRs shall be able to provide eligibility criteria in a computer processable form. This will allow systems that provide information to the registry via direct feed to identify eligible patients based on patient events.
F27	Automatic updates to eligibility criteria and data specifications	When data are automatically fed from administrative systems in participating facilities, registries shall provide automatic updates to those systems when changes to eligibility criteria or data specifications occur.
F28	Scanning of simple data fields	CQRs shall allow for central or local scanning of simple data fields (e.g. checkboxes) in paper-based capture to convert information to an electronic format where possible.
F29	Barcode scanning	CQRs may facilitate barcode scanning of patient identification labels on paper forms.
F30	Include automated data validity checks	CQRs shall use automated data validity checks supporting any required data entry such as drop-down selections, nested drop-downs, checkboxes, auto complete search clinical terminology, etc.
F31	Download printable forms	CQRs shall enable users to download printable forms to aid manual data collection.

F32	Offline forms	Users shall be able to download offline forms for data entry.
F33	OCR in scanning	The CQR shall facilitate OCR in scanning of paper forms.
F34	Logic checks and rules to guide efficient data entry	CQRs shall be able to define business rules and logic checks that increase the efficiency of any data entry required.
F35	Storage of paper-based data sources	CQRs shall be able to store electronic copies of paper-based data collection forms.
F36	Define period for record update	CQRs shall be able to define the period in which an individual's record shall be updated or completed.
F37	Prompt when record incomplete	CQRs shall prompt a user when a record remains incomplete past the permitted duration for data collection/record update.
F38	Report of incomplete record	CQRs shall be able to produce a report that identifies records that are incomplete past the permitted duration for data collection/record update.
F39	Download follow-up forms	CQRs shall enable users to download printable or offline forms to aid the collection of follow-up information.
F40	Lock record at case completion	CQRs shall be able to lock a record (to prevent it from being edited by local users) at the point of case completion once it has passed audit checks.
F41	Authorised users can unlock records	CQRs shall enable authorised users to unlock records.
F42	Workflows	CQRs shall support the use of generic automated workflows.
F43	Define logic checks	CQRs shall be able to define logic checks that constrain the information able to be entered into a field.
F44	In-built data validation checks	CQRs shall incorporate in-built data validation checks such as data range and context sensitive validation.
F45	Record reason for overriding validity checks	CQRs shall allow users to override validity constraints and annotate the reason for this action or allow ‘other’ responses where applicable.
F46	Probabilistic matching	CQRs may support probabilistic matching of identifying information against existing registry data.

F47	Search identifiers to reduce duplicate records	CQRs shall allow authorised users to search patient-identifying information to reduce duplicates at the point of data entry.
F48	Consistency of data from different sources	CQRs shall be able to produce reports on the consistency of data obtained through different sources, such as data entry versus checks against other data sources.
F49	Audit for accuracy against source	CQRs shall check data accuracy in a sample of cases using audits against source records.
F50	Double entry to check accuracy	Users shall be able to double enter patient information to check the accuracy of data entry.
F51	Identification of sample for audit	CQRs shall be able to identify a random sample of cases in which to conduct audits against source records.
F52	Feedback on data quality	CQRs shall be able to produce reports to users about the quality of data collected based on data quality standards.
F53	Production of audit reports	CQRs shall be able to provide reports on the outcome of data audit checks by case, episode or facility.
F54	Feedback on data entry error rates	CQRs shall be able to provide reports to users about their missing data rates. Registries shall be able to produce reports which demonstrate case ascertainment when compared to other data sources and highlight missing cases for data entry. Registries shall be able to produce reports which highlight cases where not all data elements have been completed, to improve case completeness.
F55	Different report formats	Authorised users will be able to print reports, and/or save the results in HTML, PDF and other formats such as XML that support local analysis.
F56	Access to restricted reports	CQRs shall implement business rules and special permissions relating to access for restricted reports.
F57	Secure access to reporting from central registry	Authorised users shall be able to access reports from the central CQR, for which they have access rights, through a secure portal.
F58	Record authorisation to provide identifiable data	CQRs shall be able to record authorisation details when providing identifiable information to external parties.

F59	Web access to reports	CQRs shall provide secure access for authorised users to standard and ad hoc reports produced by registry staff via a secure web interface.
F60	Patient summary	Users shall be able to produce an abstract of information included in the registry that pertains to an individual patient.
F61	Generate standard reports	CQRs shall be able to generate scheduled/routine standard reports that may be reviewed by identified institutions and clinicians.
F62	Scheduled reporting	CQRs shall enable authorised users to produce scheduled reports through selection from available reports, parameters and pre-set frequencies (for example, weekly).
F63	Individual facility reports	CQRs shall be able to produce reports for a facility that contains only data that they have contributed. These reports may contain identified data.
F64	Benchmark reports	CQRs shall be able to produce reports that enable comparisons of de-identified aggregated data against peer group benchmarks by facilities and by regions (including by jurisdiction and national level).
F65	Clinical and epidemiological reporting	CQRs shall support clinical and epidemiological reporting.
F66	Coverage of eligible population report	CQRs shall be able to produce a standard report on the proportion of eligible patients participating in the registry (by facility and region) against an indicator, where the denominator is known.
F67	Contributing units can produce centrally configured reports	CQRs shall enable authorised users in participating units/institutions and jurisdictions to produce centrally configured reports of their own unit's/institution's/jurisdictions' data to enable monitoring of clinical care.
F68	Export of unit record data	CQRs shall be able to export unit record data in delimited format for approved purposes.
F69	Default format of unit record data export	CQRs shall export unit record data using de-identified data as the default format.
F70	Ability to export data for research purposes	CQRs shall enable information to be exported for research purposes once the necessary approval has been obtained.
F71	Ability to record purpose of data export	When information is exported for research purposes, CQR shall be able to record the purpose for which the information is to be used.

F72	Data extraction to be audited	CQRs shall only support data extraction of identifiable information, via the user interface, to enable auditing.
F73	Encrypt exported identifiable information	CQRs must encrypt identifiable information at the point of export.
F74	Compatibility of data extracts with statistical packages	CQRs shall support the secure extract of data in formats compatible with major statistical packages.
F75	Ad hoc data analysis available to participating units	CQRs shall enable participating units/hospitals to undertake ad hoc analyses of their own unit's/patient's data.
F76	Define parameters for ad hoc reports	CQRs shall be able to define parameters, such as date ranges, filter criteria, sort criteria that are specific to a particular ad-hoc report.
F77	Use report parameters to generate ad hoc reports	CQR users shall enter information into pre-defined report parameters to generate ad hoc reports.
F78	Use of Individual Healthcare Identifiers	CQRs that require individually identifiable data shall have the capability to use national Individual Healthcare Identifiers.
F79	Specify when record is included in reports	CQRs shall be able to specify the stage of record completeness (e.g. provisional or final) at which the record can be included within reports.
F80	Record that patient has been informed of participation	CQRs shall be able to record that the patient has been informed of the inclusion of their data in the registry.
F81	Record patient decision to opt-out	CQRs shall be able to record that the patient has opted-out of participating in the CQR at both a global and episodic level.
F82	Data definitions	CQRs shall maintain data definitions and descriptions for each data element and its usage.
F83	Retire data elements	CQRs shall be able to retire registry data elements to ensure information that is no longer relevant or required for relevant analysis is deactivated (and no longer collected).
F84	Time variant data	CQRs shall maintain data in such a way that enables the time of data capture to be identified.
F85	Manage business rules	CQRs shall have the ability to determine which business rules were active at a particular date/time.

F86	Reference data integrity	CQRs shall support 'ageing of metadata' by maintaining accurate links with reference data over time.
F87	Record opt-out notification	CQRs shall alert users if a patient has opted-out each time that patient's eligibility identifies them for recruitment.
F88	Flag when patient has opted-out	When the patient has opted-out, CQRs shall follow the process approved by their governing HREC.
F89	Support for data retrieval	CQRs shall store data in a retrievable form with data descriptions and data structures.
F90	Reference data sources	CQRs shall clearly identify sources of reference data as well as reference data currency in their data dictionary.

CQR technical requirements

Identifier	Summary	Detail
NF01	Site branding	CQRs shall be able to support configurable branding (e.g. logos, colour themes, version numbering, copyright information).
NF02	User friendly	CQRs shall ensure that user interfaces are intuitive and easy to use.
NF03	Support for keyboard and mouse input navigation	CQRs shall support the use of keyboard and mouse input and navigation.
NF04	Windows navigation	CQRs shall use navigation aids (e.g. menus, tabs, breadcrumbs) to aid user navigation between windows and forms.
NF05	Web browser compatibility	CQRs shall be able to support multiple web browsers and will include backwards compatibility to popular browsers.
NF06	Interactive user support on each page	CQRs shall incorporate information to users in relation to each page to assist them in the use of the system.
NF07	Interactive user support for each field	CQRs shall incorporate information (e.g. tool tips, interactive pop-ups) to users in relation to each field to assist them in the use of the system.
NF08	Screen resolution	CQRs shall support a screen resolution on web pages equal to or higher than 1024x768.

NF09	Use of touch screens	CQRs shall support the use of touchscreen devices.
NF12	Usability for non-registry staff	CQRs shall support a level of usability for data entry/import functions that is suitable for 'familiar users' who use the same CQR often, as well as to casual users who only use the specific CQR once or twice.
NF13	Training expectations	CQRs users (participating data providers) performing data entry functions shall only require basic training.
NF14	Usability for registry staff	CQRs shall support a level of usability for registry staff that is suitable for expert users of the system who use the system on a frequent/daily basis.
NF15	Supported language	CQRs shall support the use of the English language.
NF16	Accessibility of publicly available information	CQRs shall move towards being accessible to people with physical impairments (such as colour blindness) by demonstrating to what level they comply with the Web Content Accessibility Guidelines (WCAG) 1.0.
NF17	Capacity – number of provider institutions	CQRs shall have the ability to support their total participating institution cohort.
NF18	Capacity – size of eligible population	CQRs shall have the ability to collect data in relation to their total eligible population.
NF19	Data entry peak transaction rate	CQRs shall have the ability to support expected data entry transactions for the size and data requirements of the registry.
NF20	Concurrent and logged in users	CQRs shall be able to support their total number of users including up to 20% of concurrent users at any one time.
NF21	Concurrent users	CQRs shall support their maximum concurrent registry staff users to support data entry/import functions, quality management, data analysis and internal report production.
NF22	Point to digital images	CQRs shall have the ability to provide the location of a stored image or scanned document.
NF23	Addition of data elements	CQRs shall be able to add data elements to the registry dataset either permanently or for a specified period of time.
NF24	Storage of digital images	CQRs shall be able to store digital images if required for their primary or secondary purpose.
NF25	Period of record retention	CQRs shall support the retention of active records for the period defined by the relevant Health Records

		Act to support longitudinal data analysis. After this time, records will be archived, but still be available for analysis.
NF26	Support for partially saved data	CQRs shall enable users to close a record that is being added or modified, save partially entered data and return the user to the record in a subsequent session.
NF27	Backup facilities and procedures	CQRs shall ensure that appropriate (relative to assessed risk) backup facilities are provided and backup procedures implemented.
NF28	Frequency of backup	CQRs shall be able to perform scheduled backups to meet availability requirements.
NF29	Backup retention	CQRs shall keep backups to support the requirements for: • NF25 Period of record retention • NF34 Recovery time • NF31 Loss of data following disaster recovery • NF30 Disaster recovery procedures and facilities
NF30	Disaster recovery procedures and facilities	CQRs shall develop appropriate disaster recovery procedures and associated infrastructure (e.g. failover and redundancy).
NF31	Loss of data following disaster recovery	CQRs shall tolerate the loss of not more than one hour of data loss following disaster recovery.
NF33	Flag to indicate data that does not meet business validation rules	CQRs shall flag items for follow-up where data were saved that did not meet business validation rules.
NF34	Recovery time	CQRs shall recover data entry and data import functions no later than 48 hours following a loss of system availability.
NF35	Availability for data entry	CQRs shall provide 24/7 system availability to participating data providers under normal conditions. In the event of failure, the requirements for: recovery time requirement (NF34); and turnaround time for critical production bug fixes (NF54); will apply.
NF36	System availability	CQR systems shall provide 24/7 system availability in relation to functions performed by registry staff, with peak usage expected between 9am and 5pm. In the event of failure, the requirements for: recovery time requirement (NF34); and turnaround time for critical production bug fixes (NF54); will apply.
NF37	Minimal impact of reporting on other registry functions	CQRs shall ensure that the use of reporting and data extraction (output) functions will have minimal impact on other registry functions such as data entry, data

		quality management, data analysis and other reporting functions.
NF38	Support for portable devices	CQRs shall support the use of portable devices.
NF39	Data centre standard	CQRs shall be housed in an environment that meets the requirements of a Tier 2 data centre (TIA-942 Telecommunications Infrastructure Standard for Data Centres).
NF40	Use of standards for demographic information	CQRs shall use the Provider and Individual Healthcare Identifier standard to support the interchange of participant demographic data between health information repositories where possible.
NF41	Metadata to support local system design	CQRs shall maintain and make accessible a catalogue of metadata to support software vendors in the design of local systems that interface and interact with registries. The catalogue shall include data element definitions and cross references to reference data.
NF42	Employ standard to support data linkage	CQRs shall employ technical and data information standards that support data linkage to, or eventual integration with, other disease and procedure registers or other databases.
NF44	Interfaces for receiving data	CQRs shall provide interfaces that enable external parties to 'push' data to the registry.
NF45	Interfaces to third-party sources	CQRs shall provide interfaces to third-party sources that enable registries to consume data 'pulled' from those sources.
NF46	Use of health industry standard terminologies	CQRs shall use Australian health industry standard terminologies (e.g. SNOMED CT) to support data import and export to other health information systems.
NF47	Health documents exchange	CQRs shall use the Clinical Document Architecture (CDA) to encode and structure clinical documents for exchange.
NF48	Use of standard data exchange mechanisms	CQRs shall adopt agreed ADHA interoperability standards for health care.
NF49	Data exchange agreements and contracts	Each data provider and consumer shall have a data exchange agreement and data exchange contract detailing the specific data being exchanged and how it interfaces.

NF51	Changing data requirements and standards	CQRs shall be able to change data elements and health information standards (e.g. ICD10) over the life of a registry.
NF52	Expected frequency of major upgrade	CQRs shall have the ability to support major upgrades of applications and databases when required.
NF53	Expected frequency of minor upgrade	CQRs shall have the ability to support minor upgrades of applications and databases when required.
NF54	Turnaround time for critical production bug fixes	CQRs shall have a turnaround time as per service/performance contracts to enable correction of critical bugs in production.
NF55	User acceptance testing	CQRs shall be able to perform user acceptance testing for system components that will be used by non-registry staff before changes are placed into production.
NF56	Administration support hours of operation	CQRs shall provide system administration support during weekday office hours (public holidays excluded).
NF57	Development and test environments	A CQR's IT infrastructure shall provide the ability to configure development and test environments as required.
NF58	Number of development licences	CQRs shall make provision for development software licences. The number of development licences will depend on the arrangements/resources/time frames for development, maintenance and support.
NF59	Training environments	A CQR's IT infrastructure shall provide the ability to configure a training environment as required.
NF60	Review security and access requirements against standards	CQRs shall review their security and access requirements annually against AS ISO 27799: *Information security management in health using ISO/IEC 27002* and emerging frameworks such as the National E-Health Security and Access Framework (currently in development).
NF61	Inclusion of audit processes in registry design	CQRs shall have audit processes inherent in their design. These will be automated where possible.
NF62	Audit trails to record data linkage details	CQRs shall record details of data export (for the purpose of data linkage) in comprehensive audit trails.

NF63	Ability to trace export of data	When information is exported for research or other purposes, CQRs shall be able to trace when the information has been exported in the system (audit trail).
NF64	Audit trails will track users and activity	CQR audit trails shall track all instances of record creation, reading, updating and deletion, and record who undertook the activity (e.g. who entered data from where; what records were viewed, altered; what reports were viewed/generated/issued).
NF65	Data extraction to be audited	CQRs shall in general only support data extraction of identifiable information via the user interface, to enable auditing.
NF66	Audit log to record data export and recipient details	CQRs shall have an audit log that records what records and fields were exported, the recipient of the exported data, when the data were received, and the authorisation code.
NF67	Use secure access controls	CQRs must use secure access controls to protect the privacy of participants and restrict access to those who are authorised.
NF68	Authenticate identity at each session	CQRs shall require individual users to authenticate their identity at the beginning of a session.
NF69	Individuals to authenticate themselves separately	CQRs shall ensure that individual users authenticate themselves separately to enable audit trails to identify each user who has interacted with the system
NF70	Log failed authentication attempts	CQRs shall log failed authentication attempts.
NF71	Terminate inactive sessions	CQRs shall terminate inactive sessions after a defined period of time.
NF72	Management of multiple identifiers for an individual	CQRs shall support the ability of an individual user to be assigned with different system privileges in different organisational settings.
NF73	Different permissions for subsets of data	CQRs shall support the setting and use of different permissions for different uses of subsets of registry data.
NF74	Use of authentication mechanisms across registries	CQRs shall use consistent authentication mechanisms such as multifactor authentication.
NF76	Selection of own passwords or pin codes	CQRs shall allow individual users to select their own passwords or pin codes.

NF77	Users can have password reset	CQRs shall provide users with the ability to have their password reset if it has been forgotten.
NF78	Encrypt passwords	CQRs shall ensure that passwords are stored in an encrypted form.
NF79	Strong password policies	CQRs shall employ strong password policies based on current standards.
NF80	Apply expiry dates to user access	CQRs shall enable expiry dates to be applied to user access.
NF81	Password changes	CQRs shall define the period after which user passwords must be changed if applicable.
NF82	Local user registration	CQRs shall allow for user registration to be undertaken by registry management staff such as allocating passwords and system privileges to users within the registry.
NF83	Expiration of user accounts	CQRs shall ensure that user accounts are reviewed by system administrators after a pre-defined period and extended if further access is required.
NF84	Agree to terms of registry participation	CQRs shall require users to agree to the terms and conditions of participating in a registry when they first authenticate themself to the system, when their password is reset, and when Terms and Conditions of participation change.
NF85	Lock account after unsuccessful authentication attempts	CQRs shall lock a user account for a defined period of time once a specified limited number of unsuccessful authentication attempts have been made by a user to access the system.
NF86	Use of DTO	CQRs shall use the National E-Authentication Framework in registry system design to determine an appropriate level of authentication.
NF87	Automatic logoff after inactivity	Users shall be automatically logged off after a pre-set period of inactivity.
NF88	IP address monitoring	CQRs shall automatically identify equipment to authenticate connections from specific locations and equipment.
NF89	Define period of inactivity	CQRs shall enable local system administrators to define the period of inactivity that can be permitted prior to terminating an inactive session.
NF90	Receive encrypted records when importing data	CQRs shall have the ability to accept encrypted records when importing data.

NF91	Use secure electronic transfer	CQRs must use secure electronic transfer and electronic messaging systems to protect the privacy of participant information when data are in transit (noting some CQRs use paper forms for various reasons).
NF92	Ability to receive secure electronic messages	CQRs shall be able to receive messages and information received through secure electronic messaging and secure electronic transfers.
NF93	Use of virus scanning	CQRs shall use virus scanning software to allow prevention, detection and/or removal the introduction of damaging or disruptive malware to the system.
NF94	Hosting location	CQRs shall be hosted in Australia and be subject to Australian law to fully comply with the *Privacy Act 1988* (Cth).
NF95	Information and records management standards	CQRs shall comply with the Australian and international standard for records management.

References

1. Australian Government Australian Institute of Health and Welfare. METeOR Metadata Online Registry. Canberra: AIHW. http://meteor.aihw.gov.au/content/index.phtml/itemId/181162 (accessed Feb 2024)
2. Australian Government Australian Institute of Health and Welfare. [METEOR] Data set specification (DSS). Canberra: AIHW. https://meteor.aihw.gov.au/content/237561 (accessed Feb 2024)
3. Australian Government Australian Institute of Health and Welfare. [METEOR] About metadata standards. Canberra: AIHW. https://meteor.aihw.gov.au/content/276533 (accessed Feb 2024)
4. Australian Commission on Safety and Quality in Health Care. Clinical Care Standards. Sydney: ACSQHC. https://www.safetyandquality.gov.au/standards/clinical-care-standards (accessed Feb 2024)
5. Australian Government Australian Institute of Health and Welfare. METEOR Metadata Online Registry. Canberra: AIHW. http://meteor.aihw.gov.au/content/index.phtml/itemId/181162 (accessed Feb 2024)
6. Australian Government Department of Health and Aged Care. Healthcare Identifiers and the Healthcare Identifier Service. Canberra: Dept of Health. https://www.health.gov.au/topics/health-technologies-and-digital-health/about/healthcare-identifiers (accessed Feb 2024)
7. Australian Government Australian Digital Health Agency. National Clinical Terminology Service (NCTS). Canberra: ADHA. https://developer.digitalhealth.gov.au/resources/services/national-clinical-terminology-service-ncts (accessed Feb 2024)
8. Australian Government Australian Digital Health Agency. National Clinical Terminology Service (NCTS). Canberra: ADHA. https://developer.digitalhealth.gov.au/resources/services/national-clinical-terminology-service-ncts (accessed Feb 2024)
9. GS1 Australia. National Product Catalogue. Melbourne: GS1 Australia. https://www.gs1au.org/services/data-and-content/national-product-catalogue (accessed Feb 2024)
10. Australian Commission on Safety and Quality in Health Care. Measurement for Improvement Toolkit B. Sydney: ACSQHC; 2006. https://www.safetyandquality.gov.au/sites/default/files/migrated/measurement-for-Improvement-toolkit-b.pdf (accessed Feb 2024)
11. Australian Commission on Safety and Quality in Health Care National Safety and Quality Health Service (NSQHS) Clinical Governance Standard
12. Refer to http://meteor.aihw.gov.au/content/index.phtml/itemId/370931 (SACC 2008) for the classicisation scheme.
    Australian Government Australian Institute of Health and Welfare. [METEOR] Standard Australian Classification of Countries 2008. Canberra: AIHW. https://meteor.aihw.gov.au/content/370931 (accessed Feb 2024)
13. Australian Bureau of Statistics. Australian Statistical Geography Standard (ASGS). Canberra: ABS; 2021–2023. https://www.abs.gov.au/statistics/statistical-geography/australian-statistical-geography-standard-asgs (accessed Feb 2024)
14. Australian Bureau of Statistics. 1270.0.55.001 - Australian Statistical Geography Standard (ASGS): Volume 1 - Main Structure and Greater Capital City Statistical Areas, July 2011. Canberra: ABS; 2011.

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au