AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Logical Design

Australian Clinical Quality Registries

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1 Overview

1.1 Purpose

The purpose of the logical design for Australian clinical quality registries (CQR) is to provide pragmatic guidance to organisations wishing to develop and support a new CQR, or upgrade an existing CQR. This document proposes a logical application and infrastructure design that is intended to provide a standardised starting point for the physical design and implementation of an Australian clinical quality registry.

1.2 Intended audience

This consultation draft is provided for comment and review. The intended audience for this document is organisations and individuals who are revising existing, or building new, national clinical quality registries.

1.3 Scope

This document presents the logical design for a national clinical quality registry. Section 3 describes the generic business functions of a CQR that are supported by the design. Section 4 proposes an information design, providing a data model and data dictionary for common aspects of CQRs with guidelines for how CQR-specific aspects can be modelled for consistency.

Section 5 describes a technology agnostic design of the application components that constitute a CQR system. Section 6 presents the infrastructure design needed to support the deployment of CQR applications.

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

1.4 Questions and feedback

The Australian Commission on Safety and Quality in Health Care and the Architecture Development Programme with the National E-Health Transition Authority values your feedback on the content contained in this document. Please direct your questions or feedback to feedback.CQR@nehta.gov.au

2 Introduction

Clinical quality registries (CQRs) are clinical databases that systematically collect longitudinal health-related information on the quality of care provided to individuals. They focus on conditions and procedures where outcomes are thought to vary and where improvements in quality have the greatest capacity to improve quality of life and/or reduce costs. They potentially provide a strong evidence base for determining the efficacy, safety and quality of providers, interventions, medications, devices and treatments.

The purpose of clinical quality registries is to monitor the safety and quality of health care provided to patients by systematically gathering, analysing and making widely available what is being done and the results of that clinical activity. Clinical quality registries build on data collected from events in daily health care and use this information to assess the appropriateness (process) and effectiveness (outcomes) of health care and support quality improvements where required.

Currently, reliable national data to support reporting of clinically specific variations against best practice or guidelines (appropriateness of care) and to map outcomes (effectiveness of care) are scant. Where data to support such measurement are not available from existing national health information sets, this gap can be addressed by the development and operation of a number of Australian CQRs.

In November 2010, the Australian Health Ministers Advisory Council (AHMAC) endorsed Strategic Principles and Operating Principles for the evaluation of Australian clinical quality registries (refer to Appendix B: Strategic and Operating Principles). They also noted that the Australian Commission on Safety and Quality in Health Care (the Commission) would draft national arrangements, including data and clinical governance for Australian clinical quality registries, and prepare costed options for best-practice technical infrastructure to be provided to Health Ministers in 2011.

In October 2011, the National E-Health Transition Authority and the Commission developed a set of requirements, Reference Architecture and Costing Options for Australian Clinical Quality Registries. That work forms the basis for this logical design document.

2.1 Purpose

The purpose of the logical design for Australian clinical quality registries is to provide pragmatic guidance to organisations wishing to embark on developing or upgrading a clinical quality registry. Specifically, the design has been developed to:

- reduce the time and cost of developing future clinical quality registries through the provision of a generalisable and reusable design
- promote standardised approaches to registry designs that support the strategic and operating principles for a national approach to Australian clinical quality registries (refer to Appendix B:)
- deliver efficiencies and interoperability in data collection and exchange
- standardise data elements and definitions to facilitate benchmarking, comparisons, and data exchange wherever possible.

The logical design presented in this document can be applied when developing a single registry that will be hosted on dedicated infrastructure or when developing a registry that will be hosted with other registries on shared infrastructure (e.g. Centre of Excellence). Section 7 includes specific design considerations in relation to the latter scenario, that is, multiple registries hosted on shared infrastructure.

3 Business Functions

This section presents the high level functions ordinarily undertaken by clinical quality registries. Figure 1 illustrates the set of high level business functions for 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.

This section, which details a description of the business functions, provides context for the information, application and infrastructure designs.

A list of key stakeholders in the governance, operation and use of information produced by Australian clinical quality registries is included in Appendix C:.

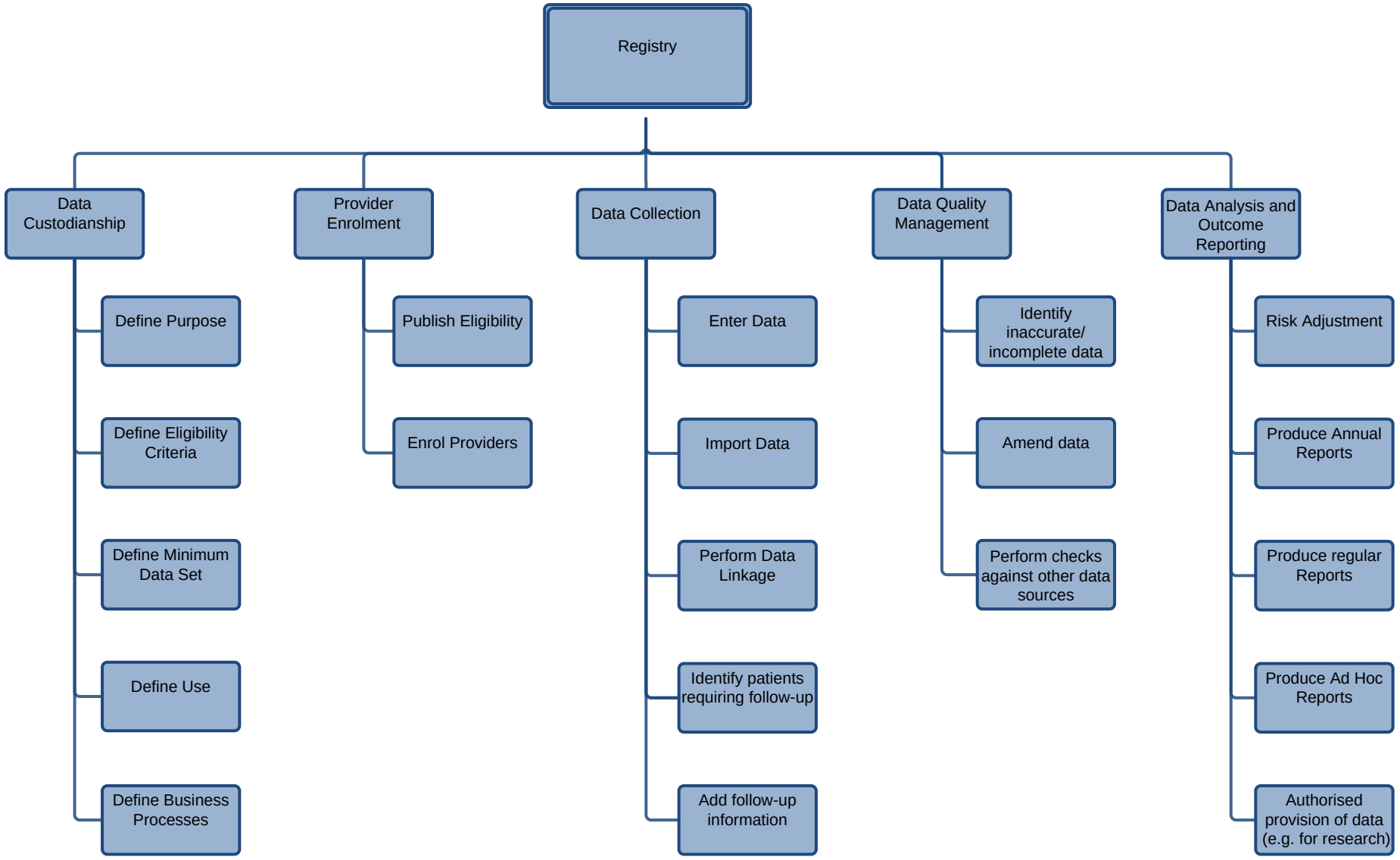

Figure 1: High level clinical quality registry functions

3.1 Data Custodianship

Australian clinical quality registries should be developed with a clear and precisely defined purpose that relates to questions the registry stakeholders want answered through the registry, both immediately and in the future. Formal governance structures must be established to oversee the registry's operation and ensure that the corporate and clinical goals of the registry are met.

Australian clinical quality registries should make clear, publically available statements of data ownership and data custodianship (refer to Operating Principle 27, in Appendix B:). Data custodianship relates to the establishment of data access and reporting policies which must take into account requirements imposed by ethics committees, legislation and reguation.

3.1.1 Define purpose

To provide maximum value to the health system, Australian clinical quality registries must be developed with clear and precisely defined purposes aimed at improving the safety and/or quality of health care (refer to Operating Principle 1, in Appendix B:). Note also, that a CQR's purpose is to complement inpatient data by filling a gap in the collection of information on the appropriateness and effectiveness of health care within specific clinical domains, thereby informing improvements in quality of care.

3.1.2 Define Eligibility Criteria

Clinical quality registries need to clearly define the eligibility criteria, or common circumstance, that determines inclusion in the registry. Registries should publish patient eligibility criteria on a publicly accessible website (refer to Operating Principle 12 in Appendix B:).

3.1.3 Define Minimum Data Set

Clinical quality registries need to define the minimum data set required to meet their core purpose. Data collected by the registry should be confined to items that relate to a specific case definition (refer to Operating Principles 2 and 3 in Appendix B:).

Registry systems support the maintenance of their minimum data set 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 are deactivated and no longer collected,
- Date stamp business rules,
- 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.

Registry data sets should 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 registries and other healthcare organisations.

[1] http://meteor.aihw.gov.au/content/index.phtml/itemId/181162

3.1.4 Define Use

Australian clinical quality registries should make clear statements of data ownership and data custodianship and make data access and reporting policies publicly available (refer to Operating Principles 27 and 28 in Appendix B:).

3.1.5 Define Business Processes

Clinical quality registries need to develop and define processes and procedures for data collection, lodgement, storage and management. Procedures and methods for reporting on quality of care that include processes for addressing outliers of unexplained variance must be documented (refer to Operating Principle 40 in Appendix B:).

3.2 Provider enrolment

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

3.2.1 Publish Eligibility

The publication of eligibility criteria on a public website enables prospective participating institutions or participating clinicians to identify the purpose of the registry and enables others to approach the registry in relation to undertaking analysis or data linkage (refer to Operating Principle 12, in Appendix B:).

3.2.2 Enrol Providers

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

Clinical quality registries will use a hierarchical model of enrolment, whereby registries 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 registry governing bodies, registries 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.

3.3 Data collection

Data capture for use by a registry should be performed as close as possible in time to the relevant care event to maximise the completeness and accuracy of data (refer to Operating Principle 9 in Appendix B:). Missing data items are difficult to capture retrospectively.

For Australian clinical quality registries to ensure good quality data, meticulous attention must be given to ensuring that complete data are collected on all patients and that all eligible patients within a defined clinical population are included in the registry. If registries collect an incomplete set of patient data, strong biases in the data may occur.For example, if a unit were only to record information in relation to patients with a favourable outcome this would create selection bias, thereby diminishing the power of the registry to inform improvements in healthcare.

Outcome determination is the most fundamental requirement of an Australian clinical quality registry and should be undertaken at a time when the clinical condition has stabilised so that outcome information can be accurately ascertained.

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

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

3.3.1 Enter Data

Australian clinical quality registries currently use a range of data capture options.Increasingly, however, best practice points to the use of electronic forms through which participating institutions / clinicians / staff may directly enter data through a registry portal, or use offline forms which are uploaded securely to the registry in a batch.

3.3.2 Import Data

Other data capture options for clinical quality registries 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 and , patient administration systems) and receipt of information through messages (e.g. HL7 pathology reports).

Information imported to a clinical quality registry 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 complex computations). Registry users will have the ability to add missing data or amend incorrect information identified through automated validity checks during data import.

In addition, registries 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.

3.3.3 Perform Data Linkage

In some registries, there is considerable value to be gained by linking data from different sources (refer also to Operating Principle 14 in Appendix B:). For example, linkages with the National Death Index provide a powerful tool to assess longer term outcomes which 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 registries provide information that could not have been derived from the registry 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.

3.3.4 Identify patients requiring follow-up

It is important for registries to 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 an Australian clinical quality registry and should be undertaken at a time when the clinical condition has stabilised so that outcome information can be accurately ascertained (refer to Operating Principle 5 in Appendix B:).

To support this requirement, registry systems will enable registry staff to define the period in which an individual's record should 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.

3.3.5 Add follow-up information

Ideally, registries 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 registry staff with the participating institution or clinician to obtain outcome information.

Clinical quality registry systems 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 (refer to 3.3.1 Enter Data and 3.3.2 Import Data).

3.4 Data quality management

The potential use of Australian clinical quality registry data for benchmarking outcomes, assessing compliance with best practice guidelines etc. mandates the need for registry data to be accurate and reliable in order to maintain the confidence of providers and recipients of registry information. Australian clinical quality registries must have a robust quality assurance plan and be able to demonstrate its effectiveness. 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 Australian clinical quality registries.

Registries inform improvements in health care, in part by providing clinicians with information about how their outcomes benchmark with standards and other clinical outcomes. Data output from registries must be regarded as credible by clinicians if it is to drive change in practice. 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.

3.4.1 Identify inaccurate/incomplete data

Completeness of data fields should be determined on a regular and frequent basis and be fed back to data collectors to enable them to retrieve outstanding data items. Reports on the performance of individual data collectors should be provided to individuals to improve data collection accuracy and reliability.

Data entry errors are not infrequent and may result from systematic errors (e.g. unclear definitions, programming errors, violation of data collection protocols) or random errors (e.g. inaccurate transcription and typing, illegible handwriting on paper forms). Strategies for reducing such errors include incorporating range and consistency checks (front-end logic checks) in the data collection process and performing a range of back end data cleaning activities such as field audits that match reported data with clinical records in a random sample of cases.

The accuracy of data entry from paper-based forms should also be regularly monitored using strategies such as double entry of a random sample of cases.

Registry systems should 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

3.4.2 Amend data

When inaccurate or incomplete data are identified, registry users will be able to amend the data in accordance with their user access rights.

3.4.3 Perform checks against other data sources

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

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

3.5 Data analysis and outcome reporting

Registries have a fundamental requirement to report without delay on information they collect to institutions, clinicians and to the broader community, including State and Territory governments, funders and consumers (refer to Operating Principles 34 to 40 in Appendix B:).

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

Registries 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, clinical registries must be able to provide reports as soon as possible after episodes of care. Delayed reporting lessens the clinical value of registry data, because over time the relevance of the findings to contemporary clinical care are reduced.

3.5.1 Risk Adjustment

In determining whether quality of care differs across health care settings, CQRs need to adjust for variation in patient outcomes that result from differences in patient characteristics that are outside the control of the healthcare providers. When outcomes are compared amongst institutions or when attempts are made to investigate poor outcomes, it may be appropriate that these factors are taken into account by applying appropriate statistical adjustments. Risk adjustment is the statistical process of identifying and adjusting for variation in outcomes resulting from differences in patient characteristics or risk factors.

3.5.2 Produce Annual Reports

Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings (refer to Operating Principle 38 in Appendix B:).

3.5.3 Produce Regular Reports

Having good quality data is not, in itself, sufficient to improve quality of care. Systems must be in place to ensure that data is analysed in a timely manner with clinical interpretation on findings, and then fed back to appropriate personnel/bodies to ensure that appropriate action occurs.

Registries routinely analyse data and provide timely reports to clinicians and relevant stakeholders. Outputs from CQRs might include warning signals which identify when performance falls below pre-determined levels to enable proactive monitoring of the provision of care. Data need to be analysed to identify unexplained variance and outliers. Often such data are presented graphically to aid in interpretation of findings.

Analysis and reporting of CQR data may include:

- The proportion of eligible patients participating in the registry against a target indicator
- Descriptive reporting of process or outcome variance
- Benchmarking
- Assessment of outcome data against minimum procedure volume
- Post-market surveillance of devices and of new and existing technology
- Cost-benefit, cost-utility and cost effectiveness assessment.

Much of this type of analysis is generally complex and often undertaken using specialist statistical software packages.

To support reporting requirements, registry staff shall be able to generate routine standard reports that can be sent to identified institutions and clinicians, or made available to authorised users through a secure portal.

In addition, registries may allow authorised users in participating units/institutions and jurisdictions to produce centrally configured reports of their own unit's/institutions/jurisdiction's data through selection from available reports, parameters and pre-set frequencies.

Registries will enable authorised users to print reports and or save them in HTML and PDF formats.

3.5.4 Produce ad hoc reports

The provision of full access to a contributor's own data and the associated reports (e.g. via real-time web-based data access) can act as a strong incentive for participation in a registry. Accordingly, clinical quality registry systems will enable participating units/hospitals to undertake ad hoc analyses of their own unit's/patient's data. Authorised users will be able to define parameters, such as date ranges, filter criteria, and sort criteria. Secure access for authorised users to this ad hoc reporting function will be via a secure web interface.

Authorised users will be able to print reports and or save the results in HTML and PDF formats.

3.5.5 Authorised provision of data

Registries shall be able to export unit record data for approved purposes e.g. to support secondary use of data for research once necessary approvals have been obtained, or for use in statistical software packages to support complex data analysis. Registry systems will be able to record authorisation details when providing identifiable information to external parties and the purpose for which the information is to be used.

4 Information Design

This section proposes a logical information design that is intended to provide a standardised starting point for the physical design and implementation of an Australian clinical quality registry (CQR).

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

- reducing the time and cost of developing future clinical quality registries 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 Australian clinical quality registries (refer to Appendix B:);
- delivering efficiencies and interoperability in data collection and exchange; and
- standardising data elements and definitions to facilitate benchmarking, comparisons, and data exchange wherever possible.

It is anticipated that the information design for Australian clinical quality registries will evolve over time. As individual CQRs are modelled and implemented, further aspects of commonality may be identified and incorporated into the core information model. Furthermore, it is anticipated that communities of CQRs with similar data collection requirements may be able to share and standardise their information models.

Over the long term, clinical quality registries may develop Data Set Specifications (DSS) under the umbrella of the National Health Information Management 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 national 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[2].

4.1 Conceptual view

Figure 2 presents a high level conceptual view of a CQR Information Model to provide context for the logical model that follows.

[2] <http://meteor.aihw.gov.au/content/index.phtml/itemId/276533>

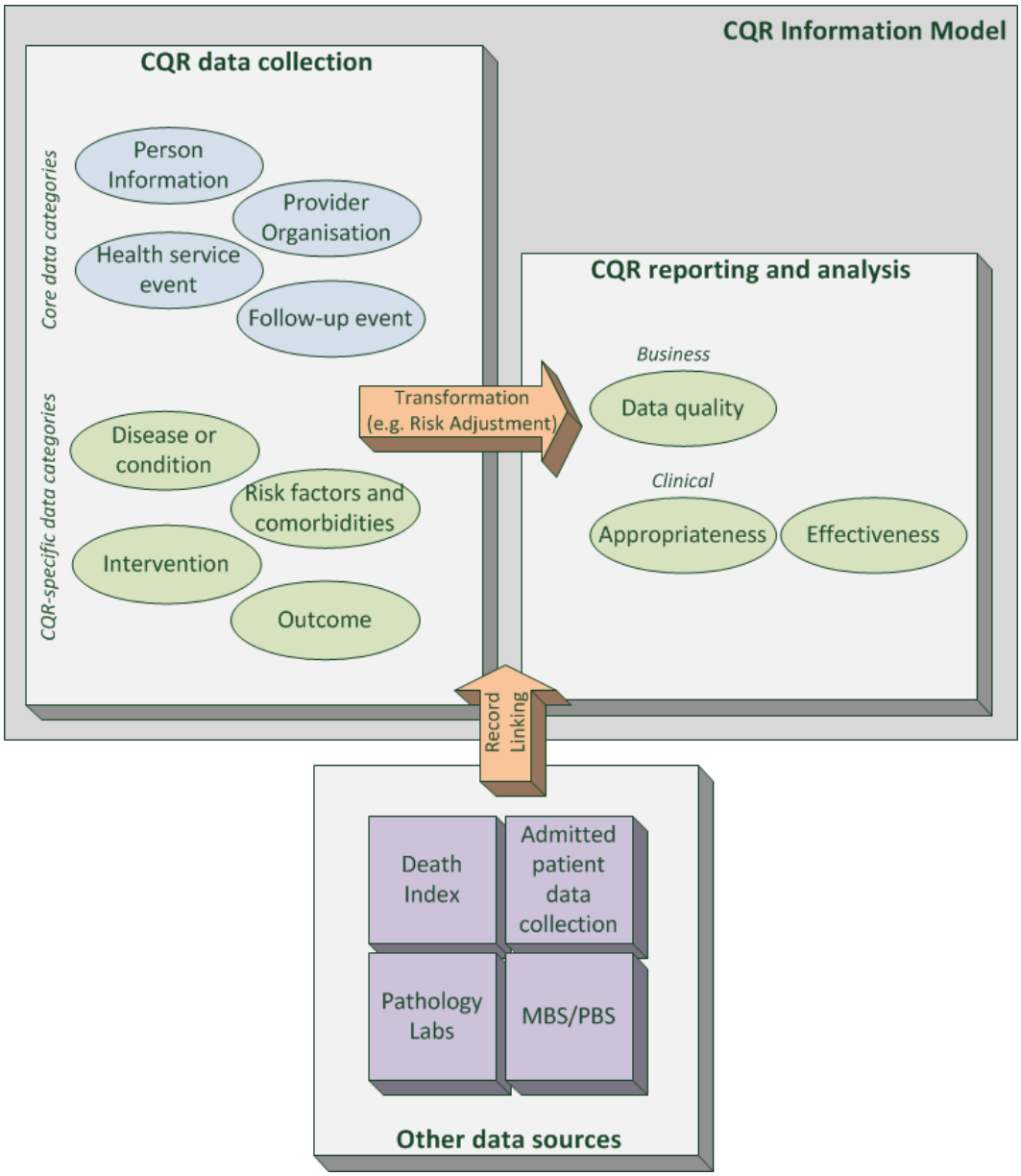

Figure 2: Conceptual View

The CQR Information Model is represented in two parts: the data collection categories (represented on the left side of the diagram) and the data reporting and analysis categories (represented on the right side of the diagram).

Within the data collection categories there are two sub-groupings: the core data categories (the upper half) and the CQR-specific data categories (the lower half).

The core data categories consist of data that will be defined in a consistent way across all CQR designs. These include patient identification data, health care provider data, health care event data and follow-up event data.

Conceptual data categories	Examples
Patient identification data (including demographic data)	- Family name - Given name(s) - Date of birth - Personal Identifiers (could include Medicare identifier, DVA identifier, State identifier, Registry identifier or Individual Health Identifier (IHI)) - Sex - Age - Country of birth - Indigenous status - Residential postcode and locality
Health care provider organisation data	- Participating organisation, institution or facility name - Organisation or facility identifiers (such as Health Provider Identifier - Organisation (HPI-O))
Health care event	- Date of event - Any relevant CQR-specific data
Follow-up event	- Date of event - Any relevant CQR-specific data

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.

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. As such, the definitions of the data within these categories will not be consistent across multiple CQRs. Data in these categories will be referred to as CQR-specific data.

Conceptual 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 (beta-blockers) - 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

The CQR-specific data will link to the core data via the Health service event and Follow-up event. That is, 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 CQR-specific data represented in the conceptual diagram are concerned with how CQR data is stored once it has been collected for a patient. The means by which the data is physically collected (e.g. paper forms, electronic data forms, direct feed from other systems) is not important when considering this information model.

The CQR-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 which 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 Logical representation of the core data

The proposed core logical data model that will form the basis of all CQR implementations is represented in the UML diagram below (Figure 3).

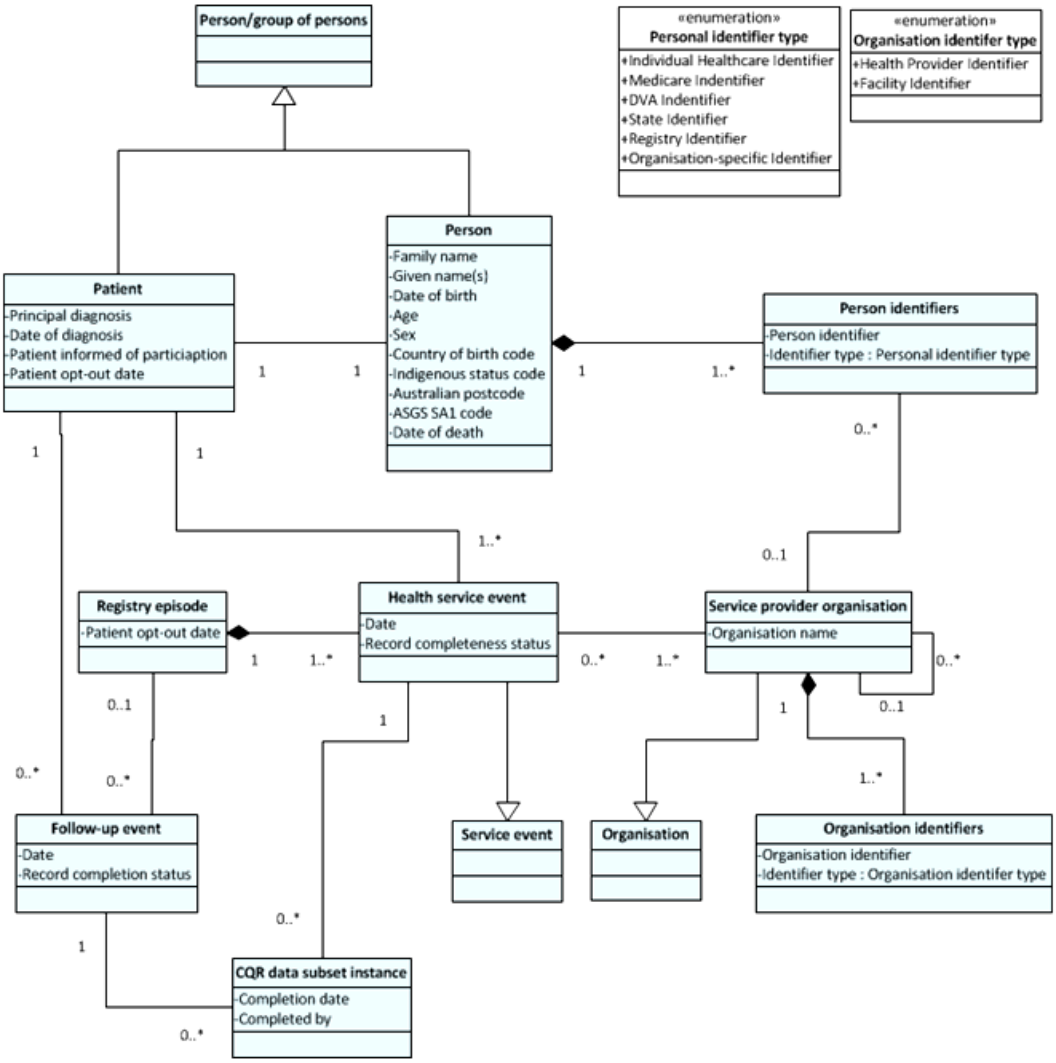

Figure 3: UML class diagram of the core data model

The core model is responsible for storing and relating 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 have been mapped to the National Health Data Dictionary (NHDD)[3].

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

Person

For consistency with the NHDD, the Patient and Person records are modelled as separate object classes. The set of data elements associated with a Patient/Person record allow for basic identification and demographic information to be collected.

[3] <http://meteor.aihw.gov.au/>

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 identifier or Individual healthcare identifier (IHI)[4]) or may be allocated by the CQR.

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.

Health service event

A Health service event represents an interaction between one or more health care 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.

Registry episode

A Registry episode defines a period of time from diagnosis through the period in which patient receives health care which is relevant to the CQR, to the final measurement of outcomes specified in the regsitry 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.

Follow-up event

The Follow-up event is an event where additional data is collected about a patient following an initial Health service 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 Health service 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 Health service events) or it may be related directly to the patient (indicating that the follow-up data is relevant across all registry episodes, if this applicable for a CQR).

CQR data subset instance

The CQR data subset instance represents the data collected for a patient at a single Health service event or Follow-up event. The CQR data subset instance is analogous to an instance of a 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.

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.

[4] <http://www.nehta.gov.au/connecting-australia/healthcare-identifiers>

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 CQR-specific data categories (that is, disease or condition data, comorbidities, intervention data and outcome data). The following section presents guidelines for how CQR-specific data elements should be defined in a logical information model.

4.3 Design guidelines for CQR-specific data

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

The guidelines provide a basis for:

- how CQR-specific data elements can be categorised in the model for consistency,
- how CQR-specific data elements will link to the core information model,
- how CQR-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 CQR-specific data elements

When the CQR's minimum dataset has been determined (refer to Operating Principle 2 in Appendix B:), all CQR-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 CQR-specific data elements into these categories will provide the basis for achieving a practical level of consistency across CQR logical information models.

The diagram in Figure 4 shows the categorisation of a very small subset of data elements from the National Breast Cancer Audit full dataset collection form (January 2011)[5] to illustrate this concept.

[5] <http://www.surgeons.org/media/450997/frm_2011-08-10_full_dataset_ba.pdf>

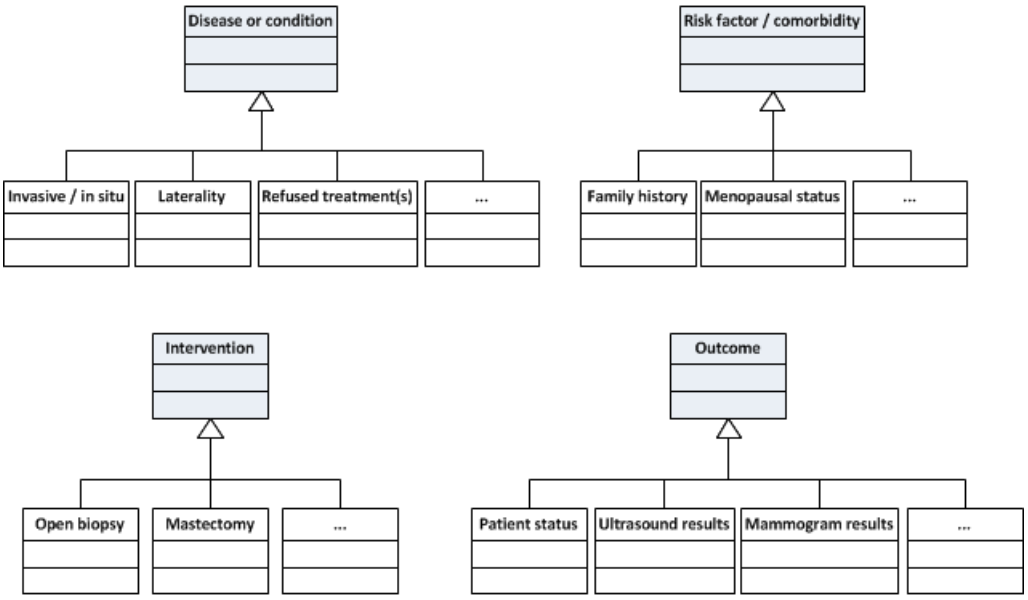

Figure 4: An example of standardised classification of data elements from National Breast Cancer Audit

In this diagram, UML notation is used to describe the logical categorisation of data elements into each of the four data categories.

It should be emphasised that this logical categorisation process does not place limitations on the way in which the underlying database structures in the physical implementation are defined. Nor does it impose any restrictions regarding the format or layout of the questions on a data collection form.

The categorisation process is simply a means of providing a reasonable logical data design pattern that can be applied across all CQR domains.

A data analyst viewing a CQR information model that is categorised in this way will be able to infer a certain amount of metadata from the model (this is, information describing the type of data being stored) even if they lack specific domain knowledge. This will assist in the process of data comparison with other data sources.

Within a specific CQR data model, CQR-specific data elements will be organised into a set of object classes and relationships between CQR-specific object classes will be defined.

4.3.2 Linking CQR-specific data elements to the core model

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

By relating these data elements to a health service or follow-up event, it 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 CQR-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 should be used in Australian 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 11 in Appendix B:). In some cases this may require the use of terminology services and reference data sets such as SNOMED CT-AU[6], the Australian Medicines Terminology (AMT)[7] and the National Product Catalogue (NPC)[8].

Where reference sets are used, whether they are from a published standard or unique to the CQR, they should be defined in the information model to ensure that appropriate validation can be implemented. Figure 5 shows a representation of three example reference sets that would be included in an information model for the National Breast Cancer Audit registry.

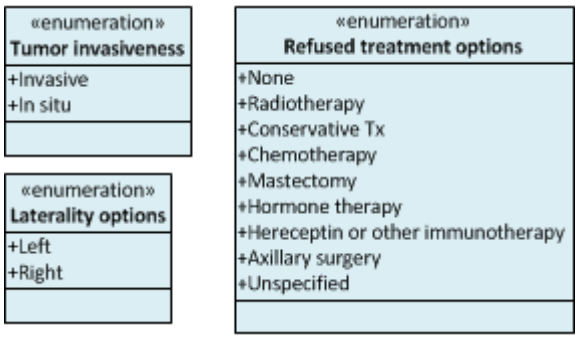

Figure 5: Example reference sets for CQR-specific data elements from the National Breast Cancer Audit

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 service event or follow-up event) or patient diagnosis.

By way of example, it would be appropriate for the National Joint Replacement Registry to define a data subset for patients receiving knee replacements[9] and another data subset definition for patients receiving hip replacements[10]. In this example, there will be some data elements common to both data subsets (e.g. whether the patient has osteoarthritis), and some elements unique to each data subset that relate specifically to the replacement type.

[6] <http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/snomed-ct-au>

[7] <http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology>

[8] <http://www.gs1au.org/services/gs1net/industry/npc/index.asp>

[9] <http://www.dmac.adelaide.edu.au/aoanjrr/documents/joint_forms/2009/knee_dc_form_2009.pdf>

[10] <http://www.dmac.adelaide.edu.au/aoanjrr/documents/joint_forms/2009/hip_dc_form_2009.pdf>

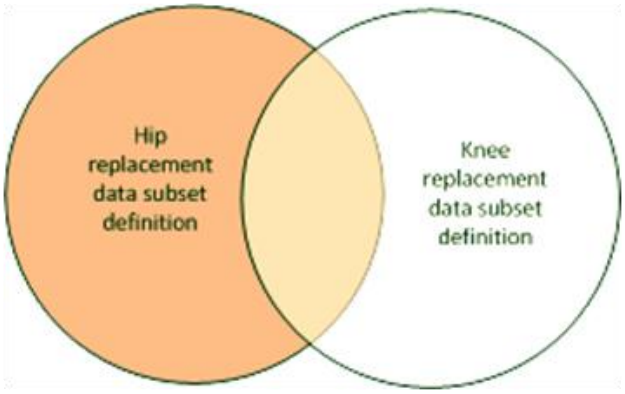

Figure 6: Example of overlapping data subset definitions from the National Joint Replacement Registry

In a similar way, it might be appropriate for a CQR to define one data subset representing the data elements collected for an initial consultation event and another data subset representing the data elements collected for a follow-up event.

This approach will ensure that data elements in the CQR minimal dataset are only defined once, but can be re-used across multiple data collection scenarios, where applicable.

The data subset definitions are essentially templates describing the questions that will be asked at a particular event. These are analogous to the master copy of a data collection form.

From these data subset definitions, 'instances' can be created. This is analogous to the act of producing a printed copy of the form to record details about a particular patient. The subset instances are related to a single health care event or a single follow-up event in the core information model. In cases where multiple values are allowed for a particular data element, the information model should define a separate object that is related to the subset instance object to record these values.

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.

The data dictionary contained in Section 4.5 describing the core information model will form part of the CQR data dictionary.

Ideally the complete data dictionary will be published to a central CQR portal (refer to Operating Principle 12 in Appendix B:).

4.4 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.

Data item	Sub-section
Person/group of persons	
Patient	4.5.10
Date of diagnosis	4.5.11
Patient informed of participation	4.5.12
Patient opt-out date	4.5.13
Principle diagnosis	4.5.14
Person	4.5.15
Person identifier	4.5.22
Family name	4.5.25
Given name	4.5.26
Date of birth	4.5.18
Age	4.5.16
Sex	4.5.23
Country of birth code	4.5.17
Indigenous status code	4.5.20
Australian postcode	4.5.24
Australian Statistical Geography Standard SA1 code	4.5.21
Date of death	4.5.19
Organisation	
Service provider organisation	4.5.27
Organisation name	4.5.30
Organisation identifier	4.5.31
Service event	
Health service event	4.5.7
Date	4.5.8

Data item	Sub-section
Record completion status	4.5.9
Follow-up event	4.5.4
Date	4.5.5
Record completion status	4.5.6
Service episode	
Registry episode	4.5.27
Patient opt-out date	0

4.5 Data dictionary

This section defines the object classes and data elements in alphabetical order.

4.5.1 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.

4.5.2 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

4.5.3 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

4.5.4 Follow-up event

Identifying and definitional attributes

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

4.5.5 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

4.5.6 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
Data type:	Boolean
Format:	N
Maximum character length:	1
Permissible values:	1 - Provisional 2 - Final 3 - Locked

4.5.7 Health service event

Identifying and definitional attributes

Metadata item type:	Object Class
METeOR identifier:	268979
Registration status:	Health, Standard 01/03/2005 Tasmanian Health, Proposed 28/09/2011
Definition:	An interaction between one or more health care providers with one or more persons for assessment, care, consultation and/or treatment.
Specialisation of:	Service/care event

4.5.8 Health service event - presentation date

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	270393
Registration status:	Health, Standard 01/03/2005 Tasmanian Health, Proposed 28/09/2011

Definition:	The date on which the patient/client presents for the delivery of a service.

Representational attributes

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

Related attributes

Data Element Concept:	Health service event - presentation date (METeOR: 269568)
Property:	Presentation date (METeOR: 269321)

4.5.9 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
Data type:	Boolean
Format:	N
Maximum character length:	1
Permissible values:	1 - Provisional 2 - Final 3 - Locked

4.5.10 Patient

Identifying and definitional attributes

Metadata item type:	Object Class
METeOR identifier:	268959

Registration status:	Health, Standard 01/03/2005
Definition:	A person for whom a health service accepts responsibility for treatment and or care.
Specialisation of:	Person/group of persons

4.5.11 Patient - diagnosis date

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	270544
Registration status:	Health, Standard 01/03/2005
Definition:	The date on which a patient is diagnosed with a particular condition or disease.

Representational attributes

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

Related attributes

Data Element Concept:	Patient - diagnosis date (METeOR: 269449)
Property:	Diagnosis date (METeOR: 269392)

4.5.12 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 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

4.5.13 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 should not be included in the Clinical Quality Registry reports.

Representational attributes

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

4.5.14 Patient - principal diagnosis

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	433356
Registration status:	Health, Standardisation pending 14/11/2011
Definition:	The diagnosis established after study to be chiefly responsible for occasioning a patient's service event or episode, as represented by a code.

Representational attributes

Classification scheme:	ICD-10-AM [11]

[11] Refer to <http://meteor.aihw.gov.au/content/index.phtml/itemId/391301> (ICD-10-AM) for the classification scheme.

Representation class:	Code
Data type:	String
Format:	ANN{.N[N]}
Maximum character length:	6

Related attributes

Data Element Concept:	Patient - principal diagnosis (METeOR: 433351)
Property:	Principal diagnosis (METeOR: 269186)

4.5.15 Person

Identifying and definitional attributes

Metadata item type:	Object Class
METeOR identifier:	268955
Registration status:	Community Services, Standard 01/03/2005 Housing assistance, Standard 01/03/2005 Health, Standard 01/03/2005 Early Childhood, Standard 21/05/2010 Homelessness, Standard 23/08/2010 Tasmanian Health, Proposed 28/09/2011
Definition:	A human being, whether man, woman or child.
Specialisation of:	Person/group of persons

4.5.16 Person - age

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	303794

Registration status:	Community Services, Standard 29/04/2006 Housing assistance, Standard 10/02/2006 Health, Standard 08/02/2006 Early Childhood, Standard 21/05/2010 Tasmanian Health, Proposed 28/09/2011
Definition:	The age of the person in (completed) years at a specific point in time.

Representational attributes

Representation class:	Total
Data type:	Number
Format:	N[NN]
Supplementary values:	999 - Unknown/not stated
Maximum character length:	3

Related attributes

Data Element Concept:	Person - age (METeOR: 290402)
Property:	Age (METeOR: 269152)

4.5.17 Person - country of birth

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	370943
Registration status:	Community Services, Standard 02/06/2008 Housing assistance, Standard 24/11/2008 Health, Superseded 22/11/2011 Homelessness, Standard 23/08/2010 Tasmanian Health, Proposed 28/09/2011
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)

4.5.18 Person - date of birth

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	287007
Registration status:	Community Services, Standard 25/08/2005 Housing assistance, Standard 20/06/2005 Health, Standard 04/05/2005 Early Childhood, Standard 21/05/2010 Homelessness, Standard 23/08/2010 Tasmanian Health, Proposed 28/09/2011
Definition:	The date of birth of the person.

Representational attributes

Representation class:	Date
Data type:	Date/Time
Format:	DDMMYYYY

[12] Refer to <http://meteor.aihw.gov.au/content/index.phtml/itemId/370931> (SACC 2008) for the classicisation scheme.

Maximum character length:	8

Related attributes

Data Element Concept:	Person - date of birth (METeOR: 269565)
Property:	Date of birth (METeOR: 269318)

4.5.19 Person - date of death

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	287305
Registration status:	Community Services, Standard 30/09/2005 Health, Standard 04/05/2005 Tasmanian Health, Proposed 28/09/2011
Definition:	The date of death of the person.

Representational attributes

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

Related attributes

Data Element Concept:	Person - date of death (METeOR: 287299)
Property:	Date of death (METeOR: 287292)

4.5.20 Person - Indigenous status

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	291036

Registration status:	Community Services, Standard 25/08/2005 Housing assistance, Standard 15/04/2010 Health, Standard 04/05/2005 Early Childhood, Standard 21/05/2010 Homelessness, Standard 23/08/2010 Tasmanian Health, Proposed 30/09/2011
Definition:	Whether a person identifies as being of Aboriginal or Torres Strait Islander origin, as represented by a code. This is in accord with the first two of three components of the Commonwealth definition.

Representational attributes

Representation class:	Code
Data type:	Number
Format:	N
Permissible values:	1 - Aboriginal but not Torres Strait Islander origin 2 - Torres Strait Islander but not Aboriginal origin 3 - Both Aboriginal and Torres Strait Islander origin 4 - Neither Aboriginal nor Torres Strait Islander origin
Supplementary values:	9 - Not stated/inadequately described
Maximum character length:	1

Related attributes

Data Element Concept:	Person - Indigenous status (METeOR: 269618)
Property:	Indigenous status (METeOR: 269161)

4.5.21 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

4.5.22 Person - person identifier

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	290046
Registration status:	Community Services, Standard 25/08/2005 Health, Standard 04/05/2005

[13] <http://www.abs.gov.au/websitedbs/D3310114.nsf/home/Australian+Statistical+Geography+Standard+(ASGS)>

[14] <http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/7CAFD05E79EB6F81CA257801000C64CD?opendocument>

Definition:	Person identifier unique within an establishment or agency.

Representational attributes

Representation class:	Identifier
Data type:	String
Format:	XXXXXX[X(14)]
Maximum character length:	20

Related attributes

Data Element Concept:	Person - person identifier (METeOR: 287172)
Property:	Person identifier (METeOR: 269369)

4.5.23 Person - sex

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	287316
Registration status:	Community Services, Standard 25/08/2005 Housing assistance, Standard 10/02/2006 Health, Standard 04/05/2005 Early Childhood, Standard 21/05/2010 Homelessness, Standard 23/08/2010
Definition:	The biological distinction between male and female, as represented by a code.

Representational attributes

Representation class:	Code
Data type:	Number
Format:	N

Permissible values:	1 - Male 2 - Female 3 - Intersex or indeterminate
Supplementary values:	9 - Not stated/inadequately described
Maximum character length:	1

Related attributes

Data Element Concept:	Person - sex (METeOR: 269716)
Property:	Sex (METeOR: 269231)

4.5.24 Person (address) - Australian postcode

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	287224
Registration status:	Community Services, Standard 25/08/2005 Housing assistance, Standard 10/02/2006 Health, Standard 04/05/2005 Early Childhood, Standard 21/05/2010 Homelessness, Standard 23/08/2010 Tasmanian Health, Proposed 28/09/2011
Definition:	The numeric descriptor for a postal delivery area, aligned with locality, suburb or place for the address of a person.

Representational attributes

Classification scheme:	Postcode data file [15]
Representation class:	Code
Data type:	Number
Format:	{NNNN}

[15] Refer to <http://meteor.aihw.gov.au/content/index.phtml/itemId/270561> for the classification scheme.

Maximum character length:	4

Related attributes

Data Element Concept:	Person (address) - Australian postcode (METeOR: 269894)
Property:	Australian postcode (METeOR: 269316)

4.5.25 Person (name) - family name

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	286953
Registration status:	Community Services, Standard 25/08/2005 Housing assistance, Standard 20/06/2005 Health, Standard 04/05/2005 Tasmanian Health, Proposed 28/09/2011
Definition:	That part of a name a person usually has in common with some other members of his/her family, as distinguished from his/her given names, as represented by text.

Representational attributes

Representation class:	Text
Data type:	String
Format:	X[X(39)]
Maximum character length:	40

Related attributes

Data Element Concept:	Person (name) - family name (METeOR: 269711)
Property:	Family name (METeOR: 269355)

4.5.26 Person (name) - given name

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	287035
Registration status:	Community Services, Standard 25/08/2005 Housing assistance, Standard 20/06/2005 Health, Standard 04/05/2005 Tasmanian Health, Proposed 28/09/2011
Definition:	The person's identifying name within the family group or by which the person is socially identified, as represented by text.

Representational attributes

Representation class:	Text
Data type:	String
Format:	[X(40)]
Maximum character length:	40

Related attributes

Data Element Concept:	Person (name) - given name (METeOR: 269709)
Property:	Given name (METeOR: 269222)

4.5.27 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

4.5.28 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 should not be included in the Clinical Quality Registry reports.

Representational attributes

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

4.5.29 Service provider organisation

Identifying and definitional attributes

Metadata item type:	Object Class
METeOR identifier:	269022
Registration status:	Community Services, Standard 01/03/2005 Housing assistance, Standard 01/03/2005 Health, Standard 01/03/2005 Early Childhood, Standard 21/05/2010 Homelessness, Standard 23/08/2010 Tasmanian Health, Proposed 30/09/2011
Definition:	An organisation that provides services and/or care.
Specialisation of:	Organisation

4.5.30 Service provider organisation (name) - organisation name

Identifying and definitional attributes

Metadata item type:	Data Element
METeOR identifier:	288917

Registration status:	Community Services, Standard 30/09/2005 Health, Standard 04/05/2005 Early Childhood, Standard 07/06/2011
Definition:	The appellation by which an establishment, agency or organisation is known or called, as represented by text.

Representational attributes

Representation class:	Text
Data type:	String
Format:	[X(200)]
Maximum character length:	200

Related attributes

Data Element Concept:	Service provider organisation (name) - organisation name (METeOR: 288903)
Property:	Organisation name (METeOR: 288901)

4.5.31 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

5 Application Design

This section presents the logical application components common to clinical quality registries. The application design presents an agnostic technology (physical implementation) design view that describes the structure and behaviour of applications used in a clinical quality registry and how they interact with each other and with users.

The proposed application design is based on IT-industry software and architecture standards and best-practice.

5.1 Logical Application Layers

It is recommended that CQR systems be designed using a layered application architecture. In this architecture, logical layers are used to group functionality by "areas of concern" so that each layer is responsible for a performing a specific role.

A high level view of a generic layered application architecture is shown in Figure 7.

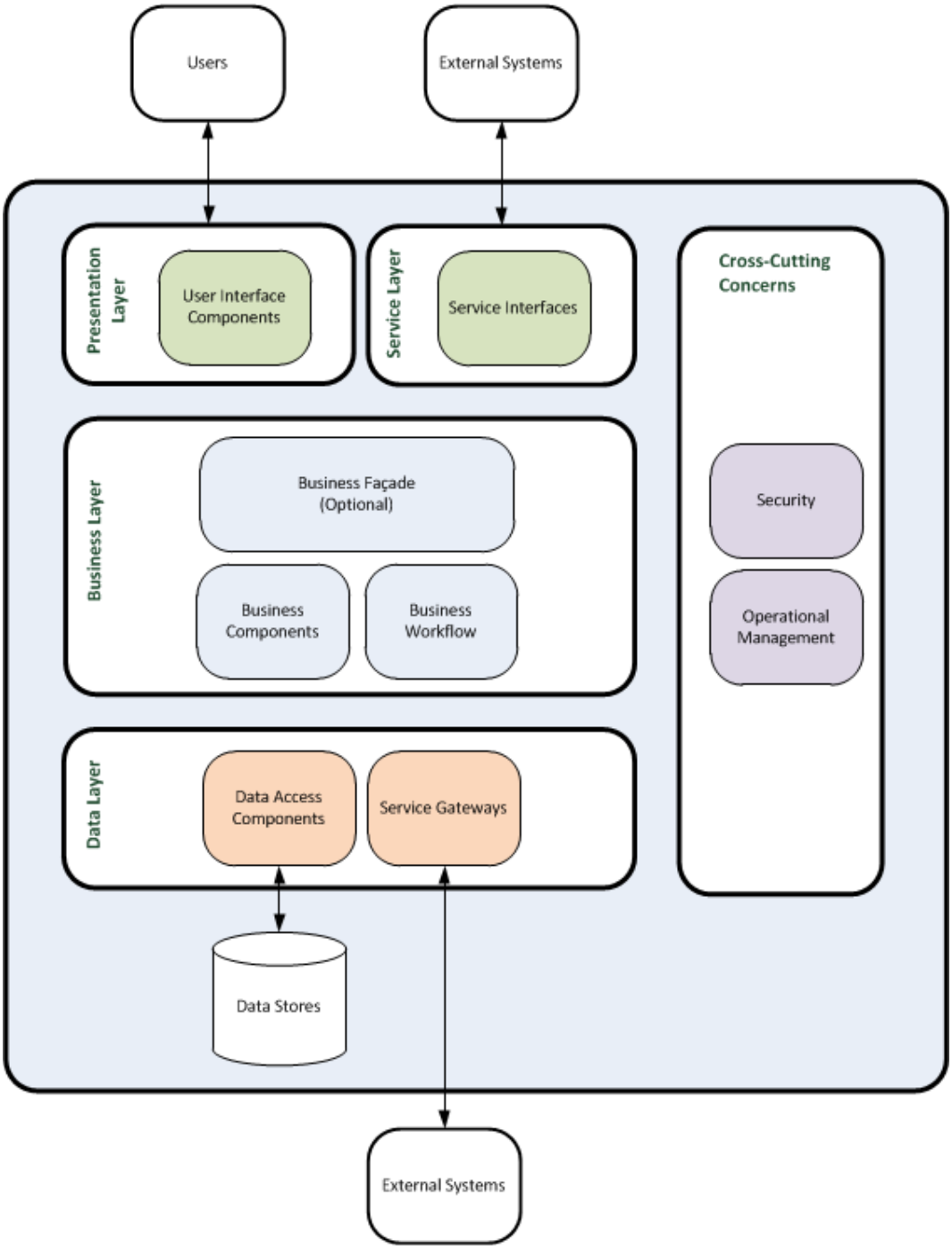

Figure 7: Generic logical application architecture

The main logical layers in this application architecture are:

- the presentation layer (which deals with user interface functionality)
- the services layer (which exposes interfaces for external systems)
- the business layer (which defines business logic and processing rules)
- the data layer (which supports retrieving/storing data from/to the database)

The business façade is an optional sub-layer within the business layer that provides a simplified interface for presentation and service layer components to the business logic components. In this way, a complex set of related business operations can be encapsulated by a single façade operation.

The layered application architecture also caters for components that provide functionality across all logical layers. These are referred to as cross-cutting concerns in the application architecture.

The logical application layers are stacked vertically such that components within a layer can only communicate with components in the same layer or in the layer directly below.

The internal details of how components within each layer perform their particular tasks are sheltered from other components. Communication is therefore loosely-coupled and performed through well-defined programming interfaces.

The logical layers described in the Figure 7 are not concerned with how the components are physical deployed. Deployment considerations are covered in Section 6.

5.1.1 Benefits

Following the basic design principles of a layered application architecture when implementing a CQR system will bring a number of benefits.

1. The design of individual software components within each layer is simplified because they have a specific and focused role. For example, a user interface component is only responsible for rendering data in an appropriate format to the user. It does not need to worry about how that data will be retrieved from the database or what processing rules should be performed when the user interacts with the data. Those areas of concern will be handled by software components in other application layers.
2. Because components communicate via interfaces, maintenance of the system is simplified as changes to components within an application layer will have a very limited, or zero, impact to the overall system.
3. Because lower layers do not have any direct dependency on higher layers and inter-component communication is performed using well-defined interfaces, functionality performed by components in lower layers can be more easily re-used across the system.
4. The layered application approach supports a high degree of flexibility when it comes to determining how the components of the system can be deployed onto physical infrastructure (refer to Section 6.2).

5.1.2 Responsibilities of each layer

This sub-section will describe the responsibilities of each logical layer.

Presentation layer

The presentation layer is responsible for managing how end users interact with the system. This layer will contain user interface components that use visual elements to present data to users and receive input from users.

The presentation layer components communicate with the business layer to perform operations in response to user actions.

In the proposed CQR application design, it is recommended that the user interface components consist of web controls delivered via the end user's web browser.

There are a number of technology choices and design patterns that a CQR can utilise to implement the web-based user interface controls. One common design pattern, known as Model-View-Controller[16], uses a level of abstraction within the presentation layer to separate the technology-specific user interface controls (the view) from the user interface processing logic (the controller). In this way the same processing logic can be re-used by different user interface implementations (such as mobile devices, if required).

[16] Patterns of Enterprise Application Architecture, Martin Fowler, page 330. <http://martinfowler.com/books.html#eaa>

Service layer

The service layer is responsible for providing application interfaces that will be consumed by external systems. The services layer interacts with business layer components and where applicable re-uses business logic that is also used by the presentation layer.

In the context of CQR systems, an external system using the service layer could be a clinical information system or patient administration system that provides relevant clinical data for patients that qualify under the CQR's eligibility criteria.

Business layer

The business layer is responsible for performing all business logic, such as processing rules, validation and managing workflow tasks.

Business workflow components are responsible for managing the execution of business processes. For a CQR system, a workflow could involve a data approval process, or a background process that triggers and escalates reminders to users if patient data is incomplete.

Data layer

The data layer is responsible for providing an abstraction between the business layer and the physical data storage. The data components shelter the business components from the technology-specific details of how data is physically retrieved from the data store and saved to the data store.

A data component will be defined for each data entity in the system which will typically expose methods that support create, read, update, delete and search functionality for the data entity.

By implementing a data layer to separate the business layer components from the physical database, the data retrieval functionality can be easily re-used throughout the business layer (as opposed to being implemented directly across multiple business components). Furthermore, because the technology-specific functionality for interacting with the database is restricted to one logical layer (and ideally implemented in a base class that all data components can share), the physical database platform can be replaced with a different product without impacting any other layer.

The logical data layer can also contain one or more service gateways (or service agents) that are responsible for managing the semantics of interacting with externally hosted systems or data stores. A service gateway may provide services such as data caching or offline support for a particular external system.

Cross-cutting concerns

The cross-cutting concerns contain common functionality that spans all application layers. Examples of these areas of functionality are security and operational management.

Security functionality covers authentication (determining who the user is) and authorisation (determining what the user is allowed to do in the system).

Operational management covers aspects such as configuration management, exception management, state management and logging.

5.2 CQR Application Design

In this section, the required CQR services are mapped to logical components in the proposed layered application architecture. The responsibilities of each logical component are then described. Finally, a set of vertical slices through the application layers will show the main interactions between logical components in each layer.

5.2.1 CQR Logical Architecture

The conceptual system services that fulfil the business requirements of a CQR are presented in Figure 8.

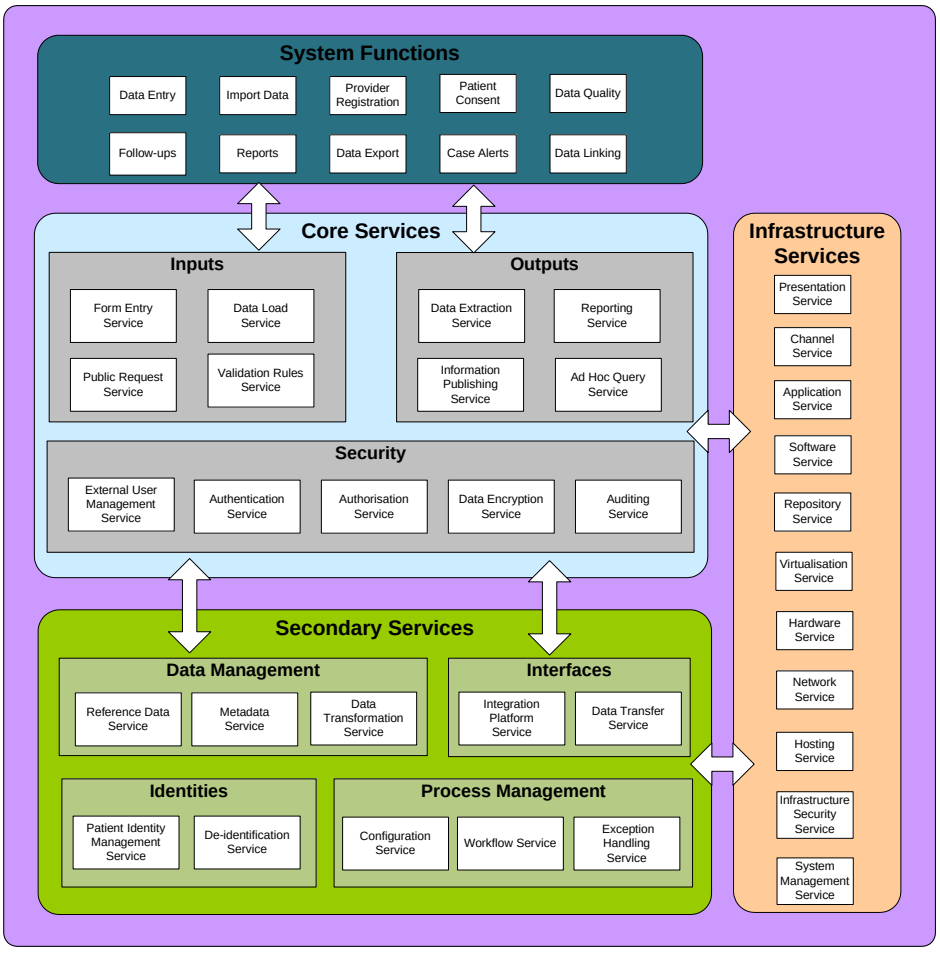

Figure 8: CQR conceptual system services[17]

In Figure 9, the CQR conceptual services and business functions are mapped to logical components within the proposed layered application architecture.

Refer to Conceptual Services Traceability in Appendix D: for a traceability table showing how the conceptual services map to logical components.

[17] This diagram is taken from the CQR Reference Architecture document.

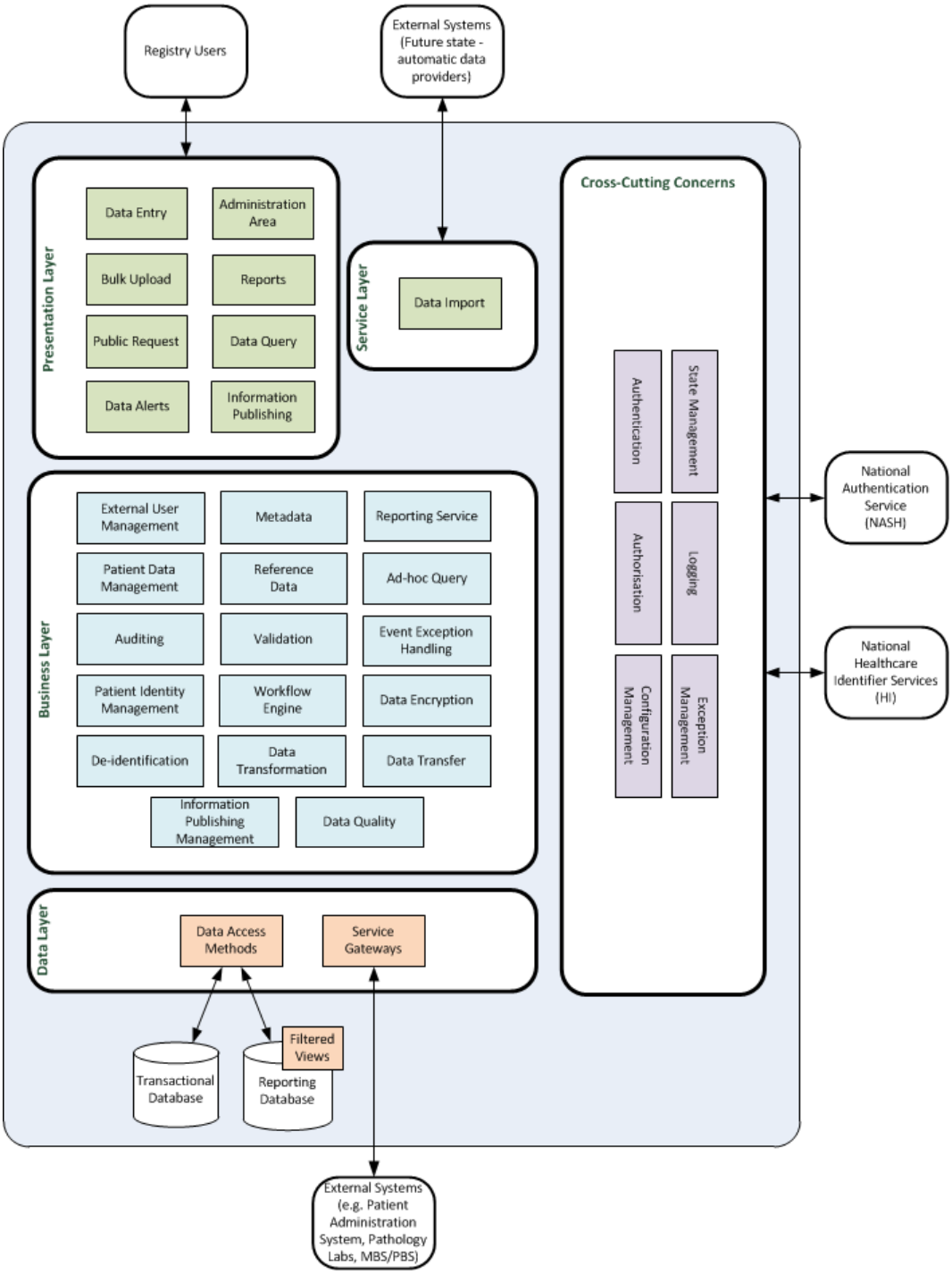

Figure 9: Proposed CQR application architecture

The following table describes each of the logical components in the proposed application architecture using definitions from the CQR Reference Architecture, where applicable.

Presentation Layer	
Data Entry	Provides user interface functionality for authorised users to submit patient data to the registry. The recommended input method is the use of web-based user interface controls presented to the user via a web browser. The implementation of these controls should take into consideration any accessibility requirements and minimum browser compatibility requirements of the CQR and the anticipated users. Depending on requirements for a particular CQR, it may be appropriate to implement smart-form data entry (whereby forms can be completed off-line and automatically submitted to the registry at a later time[18]) or the ability to scan paper forms using Optical Character Recognition (OCR) technology as alternative means for data entry. Refer to Figure 10 for a diagram identifying the related business and data layer components that delivers this functionality.
Bulk Upload	Allows bulk upload of patient data to be submitted to the registry by authorised users. This will involve uploading flat files containing the relevant data via a web form. The supported file format(s) are anticipated to be XML or CSV formats (in isolated cases, HL7[19] message formats might be required). It is likely that data contributors will have established schemas for data that is exported from their systems. In which case, the CQR may need to implement data transformation logic for each input format required (refer to Data Transformation service in the Business Layer). Refer to Figure 10 for a diagram identifying the related business and data layer components that delivers this functionality.
Administration Area	Provides user interface functionality for administration users to register and manage data provider details, login information, manage metadata, reference sets and initiate data transfers. Refer to Figure 11 for a diagram identifying the related business and data layer components that delivers this functionality.
Reports	Provides user interface functionality for authorised users to execute pre-defined reports and export the results to different formats. Refer to Figure 13 for a diagram identifying the related business and data layer components that delivers this functionality.

[18] This pattern is referred to as the store-and-forward pattern.

[19] < http://www.hl7.org.au/>

Data Query	Provides user interface functionality for authorised "power" users to author their own reports using ad-hoc data queries. This functionality may be provided via an interface to a third-party reporting tool that securely integrates with the CQR reporting database. Refer to Figure 13 for a diagram identifying the related business and data layer components that delivers this functionality.
Data Alerts	Provides user interface controls to allow personalised alerts and notifications to be delivered to the user. Alerts will be generated by the system in response to events such as data validation errors or when data quality issues are identified (refer to Event Exception Handling service in the Business Layer). Refer to Figure 14 for a diagram identifying the related business and data layer components that delivers this functionality.
Public Request	Provides user interface functionality for authorised users to request registration forms, consent forms or data collection forms. The forms may be electronic web forms or downloadable paper-based forms (PDF documents). These components can be classified as 'input' components because they respond to user requests for documents. Refer to Figure 15 for a diagram identifying the related business and data layer components that delivers this functionality.
Information Publishing	Provides a means of publishing data, reports and forms in response to Public Requests. Information published via this component will include CQR eligibility criteria, public reports, metadata and data dictionary. The output will be in the form of static documents (expected to be HTML or PDF documents). These components can be classified as 'output' components because they provide a mechanism for the CQR to publish documents for user consumption. Refer to Figure 15 for a diagram identifying the related business and data layer components that delivers this functionality.
Service Layer	

Data Import	Provides an application interface for an authorised administration or clinical systems to submit patient data to the CQR. The patient data may be sent to the CQR as a single record at a time or a bulk import of multiple patient records. The authorised healthcare system will be responsible for ensuring that only patients matching the CQR's eligibility criteria are submitted. The physical design of the web service interface will need to implement adequate security in order to protect patient data being transferred in accordance with Secure Messaging Delivery Specifications[20] (published by Standards Australia). Refer to Figure 12 for a diagram identifying the related business and data layer components that delivers this functionality.
Business Layer	
Patient Data Management	Provides functionality for managing the input and retrieval of patient identifying data, patient clinical data and patient consent. The data elements managed by this component will consist of Core data categories (person information, heath service information, and follow-up event information) and CQR-specific data categories (disease/condition information, risk factors/comorbidities, interventions and outcome information).
Patient Identity Management	Provides functionality to manage multiple identifiers for patients. This component will support probabilistic matching of identifying data, searching for patients, linking/merging of duplicate patient records and unlinking of records that have been incorrectly merged.
De-identification	Provides functionality to remove identifying information from medical records to protect patient privacy and conform to relevant Privacy legislation and requirements. De-identification may be necessary for data exports and reports.
Metadata	Provides functionality to maintain the CQR metadata across the CQR-specific data categories. Metadata will draw on standard definitions from prescribed sources such as SNOMED CT-AU[21], the Australian Medicines Terminology (AMT)[22] and the National Product Catalogue (NPC)[23] where applicable.

[20] < http://www.nehta.gov.au/connecting-australia/secure-messaging>

[21] <http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/snomed-ct-au>

[22] <http://www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology>

Reference Data	Provides functionality to manage reference data for elements of the data model to assist with data entry and validation. Reference Data may be sourced from external data sources and definitions.
Validation	Provides functionality to validate data entered by users or loaded from external sources. Validation rules may be declared within the application code, or if a higher degree of flexibility is required, a flexible validation rules engine can be implemented that will allow administration users to dynamically edit and add validation rules.
Event Exception Handling	Provides functionality to capture and notify relevant users of data issues that require manual intervention. This will include prompts for patient consent, alerts when clinical data gaps are identified and alerts when particular data items fall outside configured thresholds. Issues identified by this service that remain unresolved will be escalated and managed by the Workflow Service.
Workflow Engine	Provides functionality to automate and manage business processes. Examples of CQR workflows include approval processes, escalations or reminders.
Auditing	Provides functionality to track the activity of authorised users within the CQR system. User information that might be audited could include login timestamps, source IP address, screens accessed, functions performed, data changed and reports executed.
Data Transformation	Provides functionality to map data structures provided by external sources into data structures that can be used by the registry. The Data Transformation components will also map the registry data structures to structures required by external systems when exporting data (see Data Transfer).
External User Management	Provides administration functionality to authorise provider organisations and clinical users that will contribute data to the registry.
Data Transfer	Provides functionality to export CQR data to a flat file or transferred to an external destination. The CQR data will be exported in pre-determined data formats, which could include HL7 or custom formats as required by the destination system. This service will utilise the Data Transformation service to map data structures into required formats and the Data Encryption service to ensure that data being transmitted is secure.

[23] <http://www.gs1au.org/services/gs1net/industry/npc/index.asp>

Data Encryption	Provides functionality to ensure that incoming and outgoing data and messages cannot be intercepted by third parties. Data encryption must be implemented in accordance with the Secure Message Delivery Specifications (published by Standards Australia).
Reporting Service	Provides functionality to define and host parameterised reports that can be executed by authorised users. The Report Service will deliver report functionality to allow users to determine data quality, risk adjusted outcomes, clinical condition stabilisation and confidence intervals. The reports will allow analysis of data contributed by an individual provider as well as comparison of aggregated data between an individual provider and other sources. The data returned in reports will be filtered to ensure that the user executing the report can only see data that they are authorised to see (as determined by the Authorisation Service).
Ad-hoc Query	Provides advanced functionality to authorised CQR users to perform ad-hoc analysis of their data by authoring and executing queries. This functionality may be provided by third-party reporting tools that securely integrate directly with the CQR reporting database.
Data Quality	Provides functionality to analyse the registry data to determine if there are data quality issues. This component will use data linking and cross-checking with external data sources.
Information Publishing Management	Provides version control functionality for published information, such as metadata and data dictionary. Workflow functionality will be utilised to manage the document staging and release approval process.

Data Layer	
Data Access Methods	Provides a set of data access methods (typically create, read, update, delete and search) for each logical entity in the system. It is common to utilise a data access framework (such as an Object-Relational Mapping tool) or custom-defined code templates to automatically generate data access methods based on either a physical database design or logical data model definition.
Service Gateway	Provides an abstraction layer between the business layer and externally hosted services. It is common to utilise an application tool to generate a service proxy and data class based on the service contract definition. From a CQR perspective, externally hosted services that may be accessed include Patient Administration Systems or Pathology labs, to name a few. Access to externally hosted services may be synchronous or asynchronous depending on CQR requirements. In some cases, access to externally hosted data sources may be facilitated using off-line extracts that are manually loaded into the CQR database.
Filtered Views	A set of logical views across one or more physical tables that can be used to simplify data retrieval and enforce data-level authorisation for the user.
Cross-cutting concerns	
Authentication	Provides a security mechanism to ensure that only authenticated users are able to contribute and access patient data. It will be necessary for each individual that requires access to the CQR system to be assigned their own login credentials. The National E-Health Security and Access Framework (NESAF[24]) should be used to determine the specific authentication requirements based on an assessment of the CQR's risk profile. The National Authentication Service for Health (NASH[25]) and national Healthcare Identifiers Service (HI Service[26]) Service are emerging national infrastructure components that could be utilised to implement a CQR authentication solution.

[24] < http://www.nehta.gov.au/media-centre/nehta-news/942-nehta-releases-ehealth-information-security-and-access-framework-to-strengthen-patient-records-protection>

[25] < http://www.nehta.gov.au/connecting-australia/nash>

[26] < http://www.nehta.gov.au/connecting-australia/healthcare-identifiers>

Authorisation	Provides functionality to manage and control the parts of the CQR system an authorised user can access. The authorisation solution will control page-level and report-level access in the presentation layer, function level access in the business layer and data level access in the data layer. Access control will be managed using role-based and group-based permissions.
Configuration Management	Provides functionality to manage the storage and retrieval of user, application and environmental settings.
State Management	Represents functionality provided by the application platform for managing the intermediate state of the application, either within a single web page or between a related series of web pages. Depending on the physical deployment requirements, application state will either be stored in server memory or in a database hosted on a separate server.
Logging	Provides functionality for logging system and business critical events to a centralised location.
Exception Management	Implements a strategy for detecting and handling unexpected or erroneous conditions that occur within the system. The exception management functionality will ensure that exception information is augmented with extra information so that the cause of the exception can be investigated by application support staff (however, exception information must not contain patient identifiable data). Exception management components will utilise the common Logging components to store exception information in a centralised location. Monitoring mechanisms must be in place to ensure that appropriate notifications are sent to application support staff based on the severity of the exception.

5.2.2 Interactions of logical components

A number of vertical slices through the logical application layers are presented in Figure 10 to Figure 15 to demonstrate how the logical presentation components interact with the logical components in the lower layers.

Figure 10 identifies the business and data components that support the Data Entry and Bulk Upload functionality by Registry Data Entry staff.

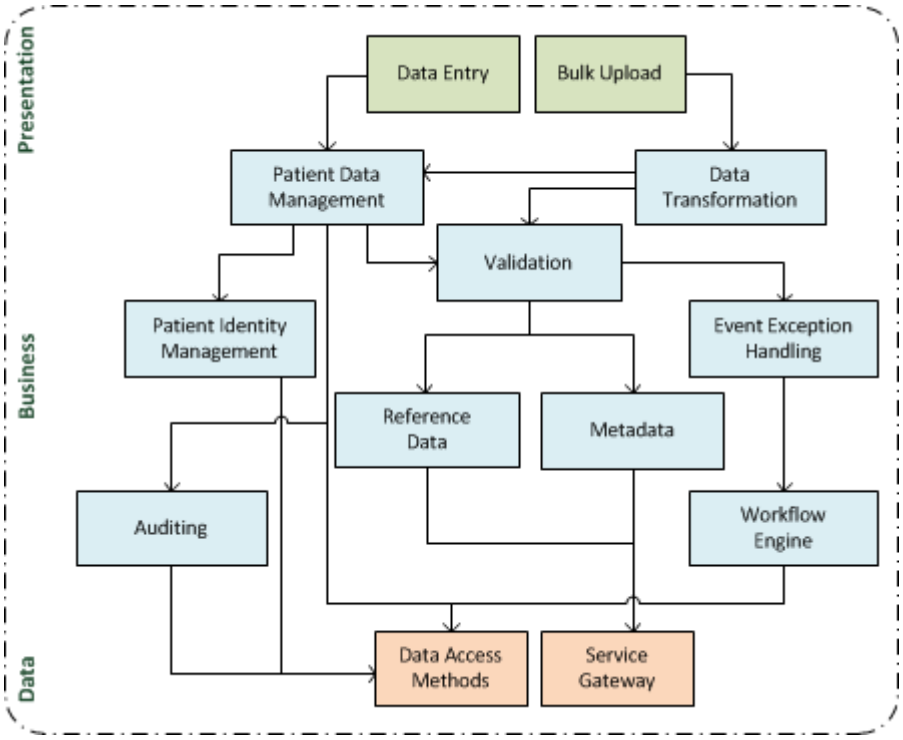

Figure 10: Component interactions for data entry functionality

Figure 11 identifies the business and data components that support the Administration functionality.

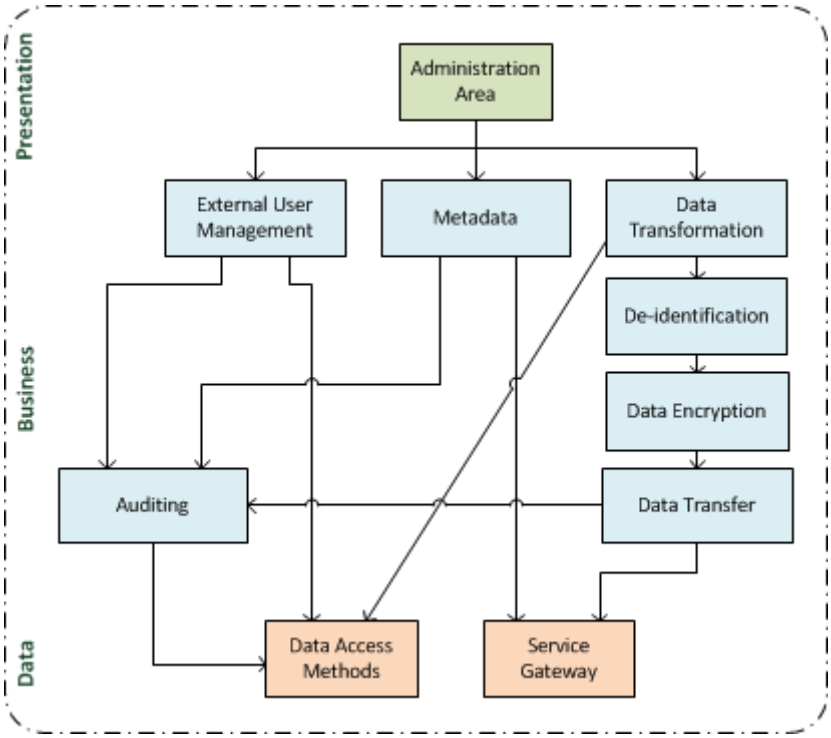

Figure 11: Component interactions for administration functionality

Figure 12 identifies the business and data components that support the Data Import functionality.

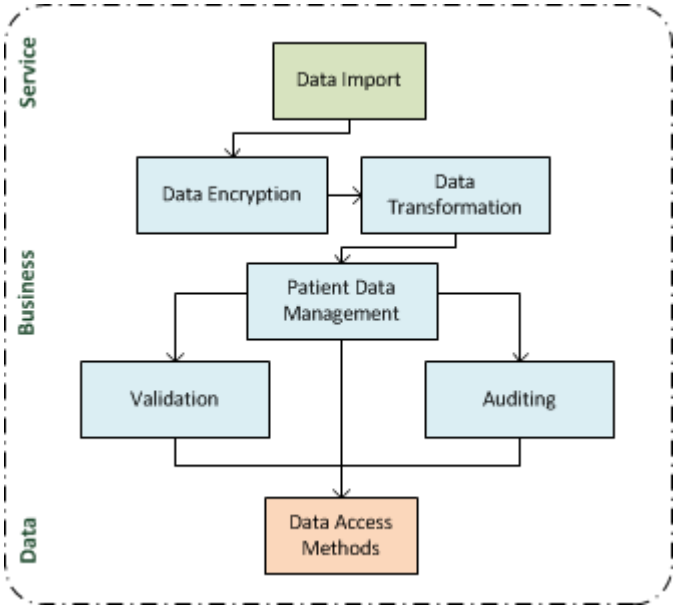

Figure 12: Component interactions for data import functionality

Figure 13 identifies the business and data components that support the Reporting functionality.

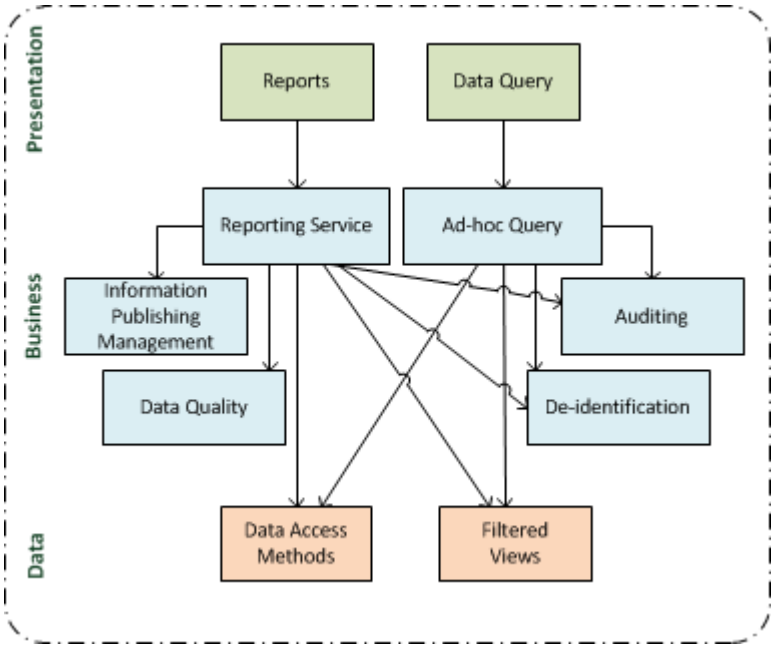

Figure 13: Component interactions for reporting functionality

Figure 14 identifies the business and data components that support the Data Alerts functionality.

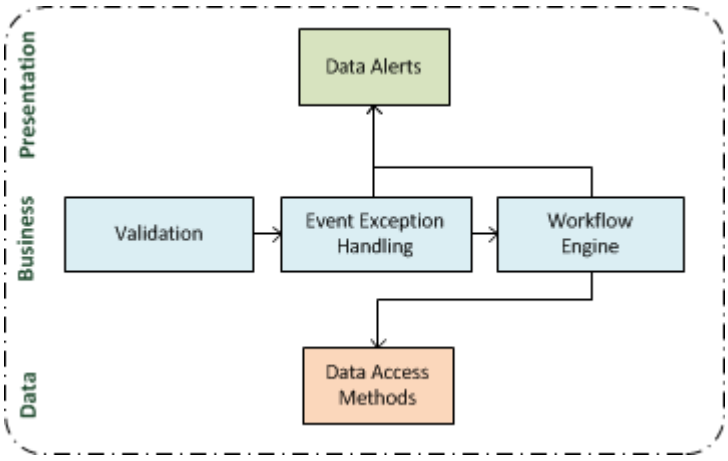

Figure 14: Component interactions for data alert functionality

Figure 15 identifies the business and data components that support the Information Publishing functionality.

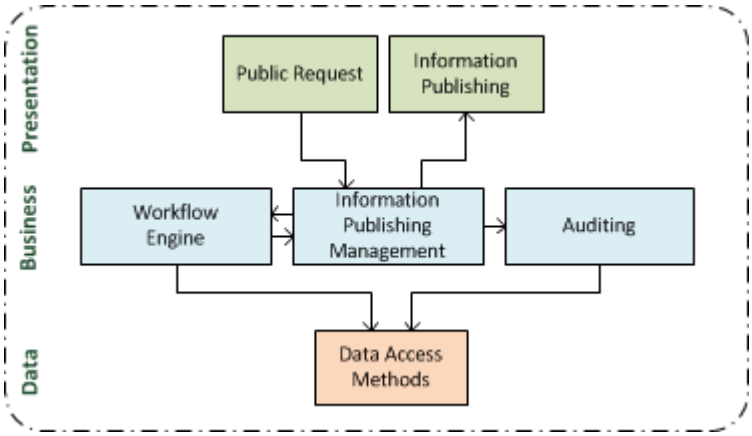

Figure 15: Component interactions for information publishing functionality

6 Infrastructure Design

This section describes the hardware, software and network infrastructure and capabilities needed to support the deployment of CQR applications. It defines the main logical infrastructure components based on the overarching drivers and principles for the logical design.

6.1 3-Tier Model

In Section 5, logical layers were used to separate CQR application components into distinct areas of concern. This section will show how the logical layers can be deployed across physical tiers.

The proposed deployment of CQR systems will follow a distributed 3-tier deployment, as shown in Figure 16.

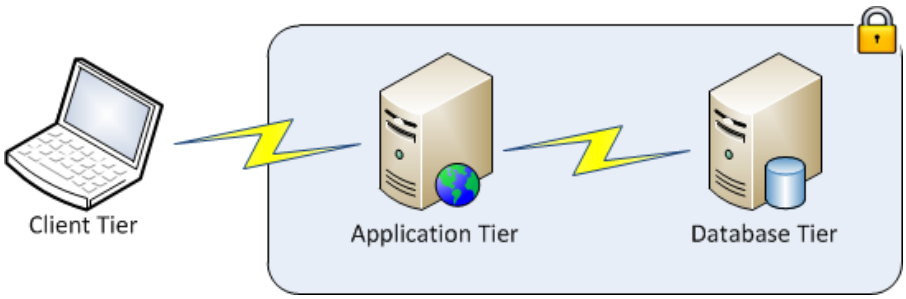

Figure 16: Generic 3-tier distributed deployment

In this model, the Client tier represents the end user's web browser. The Application and Database tiers represent groups of servers within the CQR secured data centre that host the CQR application and database, respectively.

Section 5.1.2 described the responsibilities of each logical application layer. Table 1 shows how the CQR logical application layer components (from Figure 9) will be deployed across the physical tiers.

Physical Tier	Logical Layer
Client tier	Delivers the Presentation Layer components to the end users via a web browser.
Application tier	Hosts the Service Layer, Business Layer, Data Layer and Cross-cutting components.
Database tier	Hosts the physical Transactional and Reporting Databases.

Table 1: Physical tier and logical application layer mappings

6.2 Production Environment

For improved robustness and reliability it is common to deploy the application and database tier components across multiple servers (referred to as a web farm and database cluster, respectively) in a production environment. The use of multiple servers supports:

- Sharing of the transaction load
- Continued operation of the system in the event of one server failing.

The CQR infrastructure design proposes the use of two web farms to host the application tier. One web farm will host the service, business and data layer components, and a separate web farm will host the reporting service components. This strategy will ensure that the process-intensive reporting functionality does not adversely impact the performance of the data entry and data management functionality.

It is recommended that at least two servers be allocated to each web farm in order to gain benefits of continued operation in the event of server failure, but additional servers can be utilised to support high levels of transactional load, as required.

Incoming web traffic from external users or provider systems will be distributed to one of the application tier servers in the appropriate web farm by a load balancer.

The use of web farms to host the reporting and web components ensures that server upgrades and software releases can be performed without causing a system outage. When a server requires a maintenance task to be performed, the load balancer can be reconfigured on the fly to remove the server from the farm so that no incoming web traffic is redirected to it. After the maintenance task has been completed, the load balancer can be reconfigured to add the server back into the web farm.

Similarly, it is recommended that the database be deployed across a cluster of two servers. Typically the database files are located on a shared storage device and accessed by both database servers. One database server in the cluster is configured to be the active node and the other server is the passive node. When a maintenance task is required or an error condition is encountered on the active node, the database host process can either manually or, in the case of an error condition, automatically swap the active and passive nodes so that new incoming data requests are not interrupted.

Figure 17 represents the logical deployment and infrastructure design across 3-tiers.

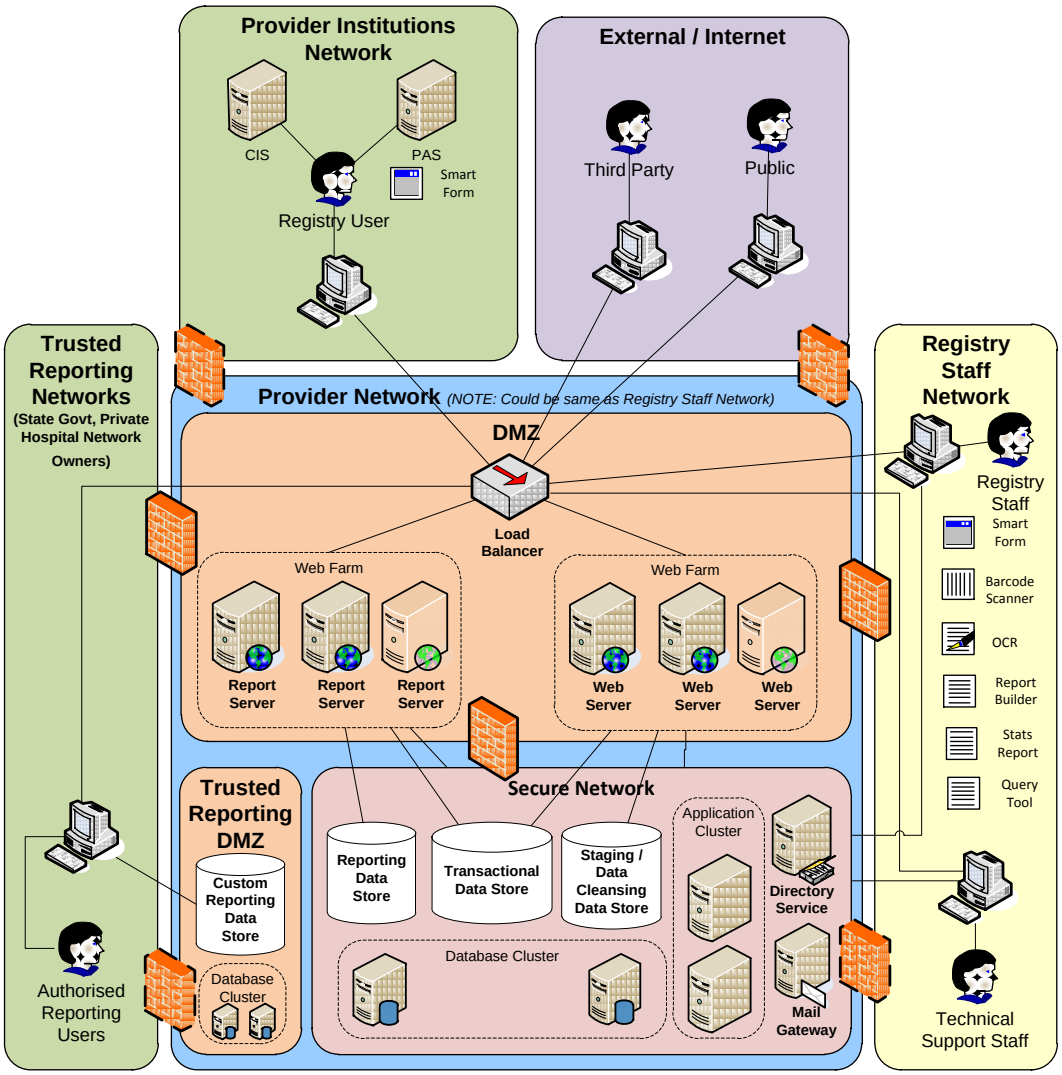

Figure 17: Proposed CQR logical deployment

The proposed logical infrastructure design advocates that the database tier and other infrastructure services (such as mail service and directory service) are hosted in a secure sub-network within the data centre. This sub-network cannot be accessed directly from external clients.

The web and reporting servers are hosted in a sub-network, known as a DMZ (de-militarised zone) or perimeter network, which acts as a security buffer between external clients and the secured sub-network.

A set of firewalls ensure that only servers within the DMZ can communicate with servers in the secured sub-network.

The registry staff users access the CQR servers from the Registry Staff Network. This network may be part of the DMZ sub-network, but in most cases will be a separate network.

To facilitate automatic contribution of data from authorised hospital systems, a trust relationship can be established between the External System's network and the CQR data centre via firewall configuration. Web server certificates can also be used to authenticate external contribution systems.

To support the direct connection from third-party reporting tools to the reporting database in a secure manner, a copy of the reporting database can be hosted in a Trusted Reporting DMZ sub-network. A firewall will be used to ensure that only authorised users and workstations are permitted to connect to the Trusted Reporting DMZ sub-network.

6.3 Non-production environments

The deployment model shown in Figure 17 represents the logical deployment of the CQR application in the production environment. In addition to a production environment, it is advised that other environments be established to support the full CQR application development life-cycle.

The other proposed environments are:

1. **Development and build environment**
2. **System testing environment**
3. **User acceptance testing environment**
4. **Training environment**

These environments will use scaled-down and lower-cost hardware and network infrastructure.

The databases in non-production environments should contain "dummy data", as opposed to actual production data. Dummy data should represent realistic values and data relationships similar to what would be found in production data, but must not contain actual patient name or identifying information.

Table 2 describes the main characteristics and usage of the non-production environments.

	Development and Build Environment	**System Testing**	**User Acceptance Testing**	**Training**
Purpose:	Used by software developers to develop the system and generate software installers that will be deployed onto other environments.	Used by testing resources to perform functional testing, regression testing and usability testing.	Used by a small number of nominated business user representatives to perform acceptance testing.	Used to host training sessions for new system functionality.
Advised physical architecture:	Generally consists of a single web server and single database server on a standalone PC for each member of the development team. It is recommended that a separate build server be used to generate the software installers.	Hosted on scaled down production technology with application server farm and clustered database.	Hosted on scaled down production technology with application server farm and single database server.	Hosted on scaled down production technology with application server farm and single database server.
Advised support requirements:	Daily backup. Administrative support as required.	Daily backup. Administrative support as required.	Daily backup. Administrative support as required.	Daily backup. Regular and defined Administrative support

Table 2: Recommended non-production environments

7 Implementation considerations for shared development and hosting

A number of options for the establishment of national clinical quality registries have been identified as part of the work currently being undertaken by the Australian Commission on Safety and Quality in Health Care. They include:

1. **Centralised** - A single entity to develop, support and centrally host all registries employing a standardised approach to the creation/hosting and support of each registry.
2. **Centre of Excellence** - A small set of entities (e.g. Universities) responsible for the standardised management of a discrete number of registries. Each of these "Centres" would employ a standardised approach to the creation / hosting and support of each registry under their control but this approach may vary from centre to centre.
3. **Standalone National Registries** - Each registry is responsible for the creation, hosting and support of its own solution. No standardisation is required across registries.

The CQR logical design presented in the preceding sections of this document can be applied when establishing CQRs for any of the above deployment options.

However when elaborating the logical design into a physical design for a Centralised or Centre of Excellence option, there are a number of implementation considerations that may provide efficiencies when establishing subsequent CQRs on a common platform.

7.1 Business Functions

The Business Functions of a CQR remain consistent regardless of the deployment options.

7.2 Information Design

While it would be possible to define individual CQR database models within separate database instances on a common database platform under the Centralised or Centre of Excellence options, consideration can be given to the use of a consolidated database instance that contains multiple CQR data models.

In this approach, all CQR systems utilise a common set of tables that represent the core data storage model, but define separate sets of CQR-specific tables in the one physical database instance. This is illustrated in Figure 18.

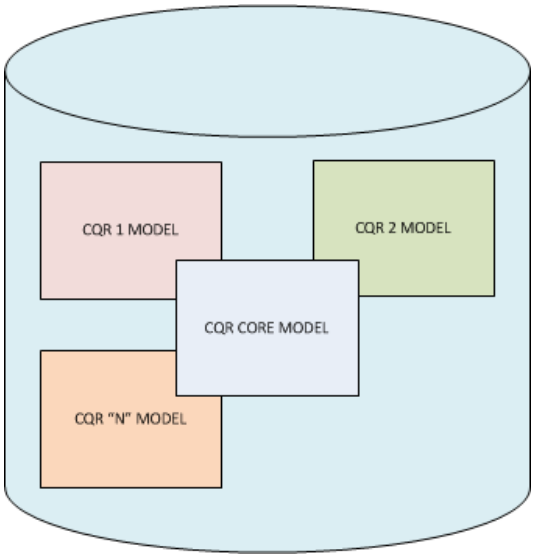

Figure 18: Single database instance approach

This approach may reduce the maintenance overhead of managing multiple database instances in a shared hosting environment. It may also ensure that the core data model remains consistent across all CQRs in the hosting environment.

The trade-off of this approach comes in the form of increased application complexity in managing data authorisation and ensuring that data stored for a single CQR is not accessed or used by another CQR. The application maintenance cycles under this approach will need to be carefully managed to ensure that changes to the database do not have adverse effects on other CQR systems hosted on the same platform.

Under this approach, it is anticipated that each CQR on the platform will require a dedicated reporting and analysis database since there will be no, or very little, areas of commonality between CQR reporting schemas.

7.2.1 Metadata-driven Model

As an extension to the single database approach described above, it may be beneficial to define CQR-specific aspects of the data model using a metadata-driven approach as opposed to defining concrete tables. The metadata-driven approach, also known as Adaptive Object Modelling (AOM)[27], utilises configuration tables to dynamically define data elements, data relationships and business rules.

This approach would allow the implementation of new registries to be fast-tracked without the need of a full-scale IT project team, since system administration staff would be able to configure the new data collection structures via user interface functionality.

This approach also has benefits in terms of reduced maintenance costs because changes to the data model and validation rules can be made by reconfiguring the metadata rather than requiring software developers to build and release new versions of the software and/or database.

Figure 19 illustrates how an adaptive object model can be used to define CQR-specific data elements and how these objects relate to the core data model.

[27] <http://adaptiveobjectmodel.com>

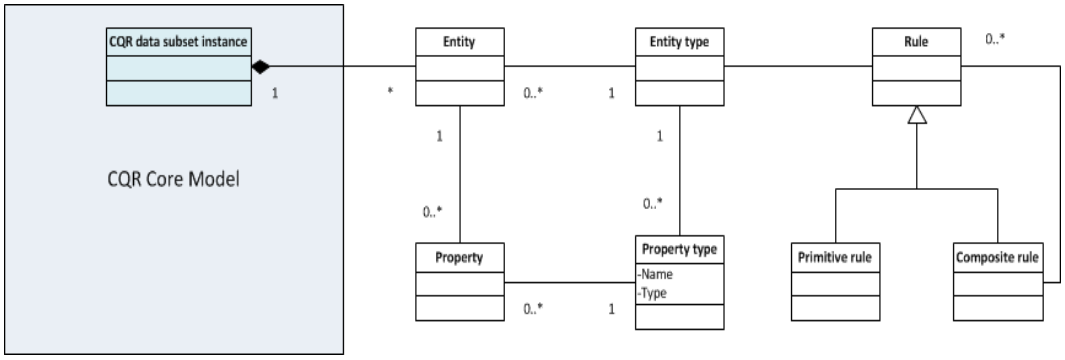

Figure 19: UML diagram describing a metadata-driven approach

There is an upfront effort impost to implementing this model for the first registry, with potential efficiency gains being realised as subsequent registries are implemented (which is consistent with the detailed costing options).

The resulting CQR system will be more complex in a metadata-driven approach. It will be necessary that experienced technical staff be used to establish the metadata administration and interpretation components to ensure that this approach delivers the intended benefits and does not become a technical overhead to the implementation of subsequent registries.

Additional information about implementing systems using an Adaptive Object Model approach, including an example of a medical application, is available here[28].

7.3 Application Design

When it comes to application design, the logical application components will be consistent across Standalone, Centre of Excellence and Centralised options. In other words, the logical view of a CQR system as presented in Section 5.2.1 will not differ based on the deployment approach.

Under the Centre of Excellence or Centralised options, there may be benefits in utilising a common application development framework, user interface libraries, base classes and code generation templates to decrease the development time of subsequent registries.

A common set of service components that provide data import functionality, integration with external services and authentication services (to name a few) should be developed and re-used across all CQRs in the hosting environment.

7.4 Infrastructure Design

Under the Centre of Excellence or Centralised options, a single provider network (consisting of the DMZ and secure sub-network) may be used to host multiple CQR applications.

The application and/or reporting web farms can be scaled vertically or horizontally, according to the load and capacity requirements of the combined CQR systems. Scaling the web farm vertically would involve adding memory and processing resources to each existing web server to allow more CQR systems to be hosted per server. Scaling the web farm horizontally would involve adding additional servers to the web farm to distribute the combined load of multiple CQR users across servers.

A separate Trusted Reporting DMZ sub-network may be established for each CQR, each containing a copy of one CQR's reporting database.

[28] <http://www.adaptiveobjectmodel.com/WICSA3/ArchitectureOfAOMsWICSA3.pdf>

Connectivity between the Registry Staff Networks and appropriate Provider Networks will be established for each CQR. In this scenario, it will be important that appropriate network security is implemented to ensure that provider systems and users are only granted access to their own CQR.

Figure 20 represents the logical deployment for a Centralised or Centre of Excellence model.

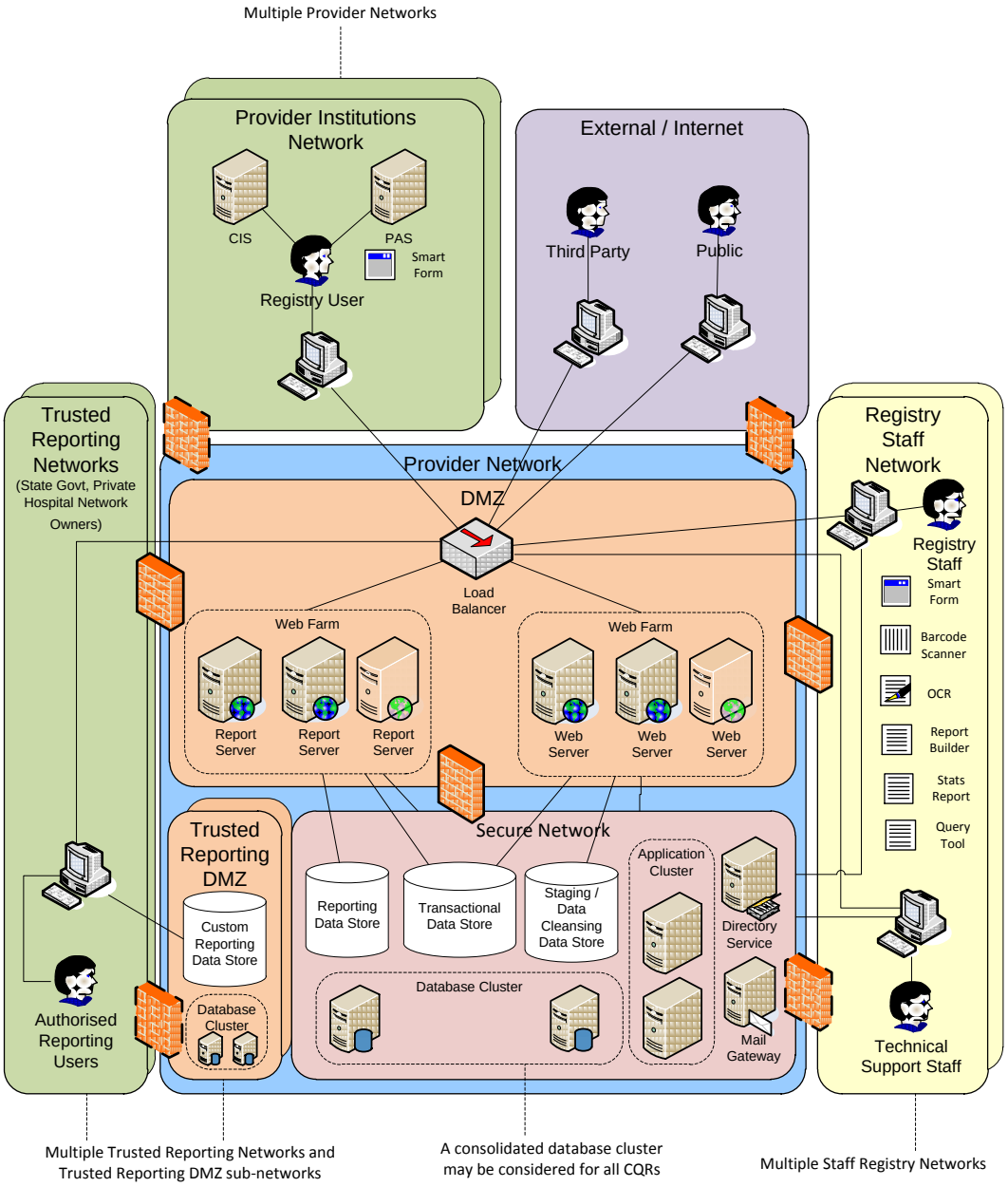

Figure 20: Logical deployment for multiple CQRs

8 Key References

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Appendix A: Definitions, Acronyms and Abbreviations

Term/Acronym/Abbreviation	Definition
ACPR	Australian Cardiac Procedures Registry
ACSQHC	Australian Commission on Safety and Quality in Health Care
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	Set of commands, functions, and protocols which programmers can use when building software. Allows the use of predefined functions to interact with a system, instead of writing them from scratch.
Audit	An examination or review that established 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
Benchmark	A slang or jargon term, usually meaning a measurement taken at the outset of a series of measurements of the same variable, sometimes meaning the best or most desirable value of the variable. A standard or point of reference.
Clinical governance	A system through which health organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Term/Acronym/Abbreviation	Definition
Clinical Quality Registry	Clinical quality registries are clinical databases that systematically collect health-related information on the quality, safety and outcome of care provided to individuals who are: • treated with a particular surgical procedure, device or drug, e.g. joint replacement; • diagnosed with a particular illness, e.g. stroke; or • managed via a specific health care resource, e.g. treated in an intensive care unit.
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 for 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 present between a trusted internal network, and untrusted external network(s). Adds an additional layer of security to an organisation's LAN.
Firewall	Device(s) designed to prevent unauthorised transmission to or from a private network based upon 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.

Term/Acronym/Abbreviation	Definition
HL7	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.
HPI	Healthcare Provider Identifier – for both individual providers (HPI-I) and for provider organisations (HPI-O). Also see UHI.
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. Also see UHI.
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 data set	A widely agreed upon and generally accepted set of terms and definitions constituting as 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
NEHTA	National E-Health Transition Authority

Term/Acronym/Abbreviation	Definition
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 upon value judgements, but there are ingredients and determinants of quality that can be measured objectively. These ingredients and determinants can been classified into measures of structure (staff, facilities), process (diagnostic and therapeutic procedures) and outcome (fatality 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.

Term/Acronym/Abbreviation	Definition
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.
UHI	Unique Healthcare Identifier, see IHI and HPI.
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).

Term/Acronym/Abbreviation	Definition
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).

Appendix B: Strategic and Operating Principles

Strategic Principles for a National Approach to

Australian Clinical Quality Registries[29]

Principle 1: Consumers, clinicians, management and governments receive regular reports from Clinical Quality Registries on appropriateness of care (process and compliance with guidelines), and effectiveness of care (patient outcomes) to support ongoing improvement of health care in Australia.

Principle 2: Clinical Quality Registries, operating in close coordination with expert national clinical groups, provide an effective mechanism for:

- design of indicators of quality of care
- comprehensive data collection and analysis, and
- outlier management within a sound clinical governance framework.

Principle 3: National data governance arrangements and best practice infrastructure provide support for comprehensive reporting, monitoring and management of clinical practice variance.

Principle 4: Where existing data flows do not support analyses of quality of care, Australian Clinical Quality Registries are efficient and effective in providing consumers, clinicians, management and government with information for managing and improving delivery of health services.

Principle 5: Dedicated investment in Australian Clinical Quality Registries supports infrastructure, data cleansing, reporting and analysis of quality of care, based on succinct datasets captured routinely by clinicians at the point of care.

Principle 6: Australian Clinical Quality Registries have sound governance arrangements with strong clinical leadership and a demonstrated framework for quality improvement.

Principle 7: Prioritisation of Australian Clinical Quality Registry support is premised on gaps in existing data flows, the significance of the national burden of disease and the cost of interventions, the existence of variation in practice and outcomes, the ability to improve quality of care including reduction in practice variation, availability of national clinical leadership and consideration of existing data, and cost/benefit options.

Principle 8: Data governance for the collection, holding and analysis of patient-level, Australian Clinical Quality Registry information is managed as part of the national health information agenda, in a framework that protects patient privacy and complies with regulation. National data governance arrangements are essential to making the data collection, ethics approvals and reporting activities of Australian Clinical Quality Registries more efficient.

Principle 9: A secure, future-proof and scalable Australian Clinical Quality Registry design and infrastructure should support and host multiple Registries. Efficiency and best practice are best achieved through the operation of a small number of Australian Clinical Quality Registry systems or centres.

Principle 10: Australian Clinical Quality Registries must meet the requirements of national operating principles.

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[29] < http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-08_clinical1>

Operating principles for Australian Clinical Quality Registries

Attributes of Australian Clinical Quality Registries[30]

1. Australian Clinical Quality Registries must be developed with clear and precisely defined purposes aimed at improving the safety and/or quality of health care.

2. For Australian Clinical Quality Registries to provide the maximum value to the health system they must focus their core data collection on the essential elements required to serve their main purposes.

3. Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible, valid (including for risk adjustment) and related to a specific case definition;

4. Methods used to collect data in Australian Clinical Quality Registries must be systematic, with identical approaches used at the different institutions contributing information.

5. Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.

6. In determining the time to outcome assessment, Australian Clinical Quality Registries must consider the burden and cost of data collection together with the likelihood of loss to follow-up.

7. Australian Clinical Quality Registries must ensure that complete registry data are collected from the entire eligible population.

Data collection

8. The collection of data for an Australian Clinical Quality Registry should maintain an appropriate balance between the time and cost of data collection and the impact on patient care, particularly where clinicians are directly involved in data collection. The collection of data must not be an unreasonable burden on consumers, nor should it incur any cost to consumers.

9. Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors;

10. Data should be uniformly and easily accessible from the primary data source.

11. Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registrys and other databases (if approved by relevant ethics committees, etc.).

12. Australian Clinical Quality Registries must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. They need to publish eligibility criteria, metadata, data dictionaries, etc.;

13. To avoid duplicating data capture, Australian Clinical Quality Registries should use data from existing data sources, including administrative data, where they are of a satisfactory quality.

Data elements

[30] < http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-08_clinical1>

14. Australian Clinical Quality Registries should have the capacity to enhance their value through linkage to other disease and procedure registrys or other databases.

15. Australian Clinical Quality Registries must collect sufficient patient identifying information to support the registry's stated purpose. Most clinical quality registries would require individually identifiable data, for which use of national Individual Healthcare Identifiers is recommended.

16. Where patterns or processes of care have an established link to outcomes and process measures that are simple, reliable and reproducible, they should be considered for collection by Australian Clinical Quality Registries.

17. Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools.

Risk adjustment

18. Australian Clinical Quality Registries should collect objective, reliable co-variates for risk adjustment to enable factors outside the control of clinicians to be taken into account by the use of appropriate statistical adjustments.

Data security

19. To protect registry data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems.

20. The collection, storage and transmission of clinical registry data must be in line with relevant legislation, regulation, standards and guidelines.

Ensuring data quality

21. Australian Clinical Quality Registries must report as a quality measure the percentage of eligible patients recruited to the registry.

22. Australian Clinical Quality Registries must have a robust quality assurance plan which allows ongoing monitoring of the completeness and accuracy of the data collected.

23. Australian Clinical Quality Registry data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible.

24. Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks.

Organisation and governance

25. Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry.

26. Australian Clinical Quality Registries must establish policies to manage a range of contingencies arising from the analysis of data from the registry, which includes a formal plan ratified by the Registry Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately.

Data custodianship

27. Custodianship of clinical registry data must be made explicit in Contracts and/or Funding Agreements. Australian Clinical Quality Registries should make clear statements of data ownership and data custodianship publicly available.

28. Data access and reporting policies for Australian Clinical Quality Registries must be made available to persons wishing to use registry data. Australian Clinical Quality Registries should make data access and reporting policies publicly available.

29. Third parties wishing to access data and publish findings must seek approval from the Registry Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data is sought.

Ethics and privacy

With the exception of instances where data collection has been mandated through legislation or enabled through regulation or legislation:

30. Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry.

31. Registry personnel must be familiar with and abide by the requirements set out in relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

32. Participants or their next of kin must be made aware of the collection of registry data. They must be provided with information about the Australian Clinical Quality Registry, the purpose to which their data will be put and provided with the option to not participate. This must be at no cost to the registry participant.

33. Where projects are undertaken using registry data, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity.

Information output

34. Data from Australian Clinical Quality Registries must be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.

35. Australian Clinical Quality Registries must report without delay on risk adjusted outcome analyses to institutions and clinicians.

36. Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings.

37. Clinicians and/or staff at contributing units should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care.

38. Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings.

39. Australian Clinical Quality Registry reports should be produced according to a strict timeline and should demonstrate funding to enable this to occur.

40. Australian Clinical Quality Registries must have documented procedures, including methods employed, for reporting on quality of care, including addressing outliers or unexplained variance.

Resources and funds

41. Australian Clinical Quality Registries should demonstrate sufficient funding is allocated to allow data collection, reporting and the institution of strong quality assurance procedures.

Appendix C: Key Stakeholders

Stakeholder	Description
Funders of healthcare	Provide funding for the provision of healthcare with a concomitant interest in the quality of healthcare provision (e.g. Commonwealth, State and Territory governments, private healthcare organisations, and healthcare insurers).
Registry Management/ Governance Board	Establishes purpose and scope of registry, defines eligibility criteria, defines minimum data set, defines use of data, and oversees quality assurance activities.
Registry staff	Perform operational activities of registry including provider enrolment, support participating institutions/clinicians in data collection, performs data linkages, data quality management, follow-up patient outcome data, perform data analysis, support other authorised users in data analysis, produce reports.
ICT Technical staff	Provide ICT support within registries or provide support to registries through third party service arrangements.
Institutional Ethics Committee	Considers patient consent processes, requests for use of data for research purposes.
Participating Institution	Hospital or other organisation that identifies eligible patients for inclusion in CQR data collections, and provides and receives data to/from a CQR.
Participating Unit	May be a unit within a hospital (e.g. Intensive Care Unit, Stroke Unit). (Refer to Participating Institution).
Participating Clinicians	Healthcare provider/clinician that identifies eligible patients for inclusion in CQR data collections, and provides and receives data to/from a CQR.
Participating Staff	Administrative/support staff within a Participating Institution/Unit that assist in the collection of CQR data.
Eligible Population	All people within the community who meet the eligibility criteria of a specific Clinical Quality Registry.
Registry Participants	Patients/people from the eligible population who meet the eligibility criteria, consent to the provision of data to a CQR and have data recorded in a CQR.
Data Recipients	Individuals or organisations that receive data/reports from a CQR for the purpose of analysis and to influence improvements in clinical care. Recipients are inclusive of, but not limited to, clinicians, clinical colleges, quality assurance committees, insurers, government agencies (including State/Territory governments, Department of Health and Ageing), and funders of clinical care.
External registries/data collections	Provide data linkages to enhance the scope of data collection within a CQR and/or facilitate data quality checks.

Stakeholder	Description
Australian Commission on Safety & Quality in Health Care	Responsible for developing clinical quality measures.
Australian Institute of Health and Welfare (AIHW)	The principal health information agency in Australia responsible for collecting, analysing and reporting health care information. The AIHW develops performance indicators and targets for national agreements between the Commonwealth and State and Territory governments, builds capability in data linkage projects, develops and maintains national metadata standards.

Appendix D: Conceptual Services Traceability Table

Conceptual Service		**Logical Component**
System Functions	Data Entry	Presentation Layer - Data Entry
	Import Data	Presentation Layer - Bulk Upload
	Provider Registration	Presentation Layer - Administration Area
	Patient Consent	Presentation Layer - Public Request
	Data Quality	Presentation Layer - Reports
		Business Layer - Data Quality
	Follow-ups	Presentation Layer - Data Alerts
	Report	Presentation Layer - Reports
	Data Export	Presentation Layer - Administration Area
	Case Alert	Presentation Layer - Data Alerts
	Data Linking	Presentation Layer - Administration Area
Core Services - Input	Form Entry Service	Business Layer - Patient Data Management
	Data Load Service	Service Layer - Data Import
	Public Request Service	Presentation Layer - Public Request
		Business Layer - Information Publishing Management
	Validation Rules Service	Business Layer - Validation
Core Services - Output	Data Extraction Service	Business Layer - Data Transfer
	Reporting Service	Business Layer - Reporting Service
	Information Publishing Service	Presentation Layer - Information Publishing
		Business Layer - Information Publishing Management

	Ad Hoc Query Service	Presentation Layer - Data Query
		Business Layer - Ad Hoc Query
Core Services - Security	External User Management Service	Business Layer - External User Management
	Authentication Service	Cross Cutting Concerns - Authentication
	Authorisation Service	Cross Cutting Concerns - Authorisation
	Data Encryption Service	Business Layer - Data Encryption
	Auditing Service	Business Layer - Auditing
Secondary Services - Data Management	Reference Data Service	Business Layer - Reference Data
	Metadata Service	Business Layer - Metadata
	Data Transformation Service	Business Layer - Data Transformation
Secondary Services - Interfaces	Integration Platform Service	Data Layer - Service Gateways
	Data Transfer Service	Business Layer - Data Transfer
Secondary Services - Identities	Patient Identity Management Service	Business Layer - Patient Identity Management
	De-identification Service	Business Layer - De-identification
Secondary Services - Process Management	Configuration Service	Cross Cutting Concerns - Configuration Management
	Workflow Service	Business Layer - Workflow Engine
	Exception Handling Service	Business Layer - Event Exception Handling
Infrastructure Services		No logical application component mapping