Revision of the Framework for Australian clinical quality registries and the development of a CQR quality Standard

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE
Acknowledgement of Country

I would acknowledge the Gadigal People of the Eora Nation as the traditional custodians of this land.

We acknowledge and honour the aboriginal elders of the Gadigal people of the Eora Nation-those who once lived here and first walked this land where we stand today and to their descendants who maintain their spiritual connections and traditions.

We acknowledge that the Gadigal people occupied and cared for this country over countless generations, and we celebrate their continuing contribution to the life of this region.
The Commission

The Australian Commission on Safety and Quality in Health Care (the Commission) was established in 2006 to lead and coordinate safety and quality improvements nationally. The functions of the Commission are specified in the National Health Reform Act 2011 and include:

- Formulating standards, guidelines and indicators relating to healthcare safety and quality matters
- Advising health ministers on national clinical standards
- Monitoring the implementation and impact of these standards
- Formulating model national schemes that provide for the accreditation of organisations that provide healthcare services and relate to healthcare safety and quality matters
- Collecting analysing, interpreting and disseminating information relating to healthcare safety and quality matters.
Use of safety and quality information to improve the delivery of care

- Australian Health Performance Framework
- Public reporting of safety and quality indicators for public and private hospitals
- Work under the National Health Reform Agreement; the Addendum and the future agreement (2020-2025): integration of funding and pricing signals for safety and quality
- Reporting on antimicrobial resistance, use and prescribing - AURA report
- Reporting on patient safety and quality - State of patient safety and quality in Australian hospitals 2019
Safety and quality indicator options - hospital indicator development

The Commission has developed reproducible indicators of safety and quality for use by clinicians and hospital administrators at the local hospital level:

• Core hospital based outcome indicators (CHBOIs)
  o hospital standardised mortality ratio (ACM-HSMR)
  o death in low mortality diagnosis related groups (DRGs)
  o condition specific mortality measures for stroke, acute myocardial infarction, pneumonia, and fractured neck of femur

• Australian Hospital Patient Experience Question Set (AHPEQS)

• Hospital acquired complications

• Indicators to support clinical care standards (e.g. stroke, acute myocardial infarction, venous thromboembolism, colonoscopy, cataracts)

• Sentinel events for national monitoring.
The Commission’s work on patient reported measures (PROMs and PREMs)

- Australian Hospital Patient Experience Question Set (AHPEQs) – developed and specified for consistent reporting
- PROMs – information platform on the Commission’s website
- Work with the OECD
  - Patient Reported Indicator Survey – PaRIS
  - Two parts: (1) international analysis of existing PROMs in three areas: mental health hip and knee surgery and breast cancer (2) international survey of management of people with chronic disease in the community
Other indicator and analytical work underway

- Clinical incident reporting systems – consistent national taxonomy – acute and primary care
- Potentially preventable hospitalisations – supporting improvement of the management of chronic disease
- Patient safety culture measurement(s)
Health data to report on safety and quality

- Administrative databases take information from health records in a standardised and coded form using a combination of local, national and international standards (e.g. the International Classification of Diseases).

- Data are used for several purposes including monitoring health system activity and performance, disease epidemiology, identifying service gaps, reporting regulation, program administration (including health care) and managing financial transactions.

- Report what happened and to whom in terms of pathways and outcomes for key performance measures, for pricing purposes and to measure against policy variation.

Administrative health information is considered a national resource to be managed for public purposes
Limitations of administrative data

• Lack of contextual/background information and inflexibility in making changes or adding detail to what they contain.

• System-wide focus and use of established standards, so varying the data contained with them often involves substantial negotiation, prioritisation and long lead times (there is potential for change over time with increased digitisation and more flexible ICT systems).

Until recently, administrative data collections have been unable to facilitate the granularity of data and feedback to a broad range of stakeholders within a quality framework, in a timely manner.
Registry data capture

• Often admin datasets don’t contain the specific and detailed data required for monitoring variation in treatment practices and patient outcomes

• Australian researchers have developed alternative sources of evidence, via registries and clinical audits

• The primary data source are components of health records that provide insights into specific aspects of clinical care and outcomes (for example, timely reperfusion following an acute myocardial infarction, prescription of evidenced-based therapies and patient reported outcome measures), combined with demographic information and other factors such as clinical history.
Clinical groups and researchers have greater direct control over the specifications of the data to be collected and the indicators to be reported.

CQR organisations generally ensure the registry is built on a foundation of well-constructed theories and methods and provide greater flexibility in terms of developing performance benchmarks and returning information to participating clinicians.

CQRs are costly to establish, being ‘bespoke’ in nature, and require substantial time and effort from leading clinicians.

Their establishment and ongoing development often also requires complex negotiation and governance obligations at the level of individual health services.
Issues with both

• Lacking or poor quality metadata; missing or erroneous data; data quality and data governance issues and changes to administrative procedures and definitions

• Variation in practice across clinical sites can often mean that the scope of capture or the ‘real meaning’ of a particular data set also varies

• Timeliness in reporting outcomes to clinicians and others is an issue for both administrative and clinical registries

• The work involved in ensuring accurate re-abstraction of clinical data in a format that can be used for comparative purposes is substantial and often involves multiple levels of data quality cross checking and verification.
CQRs

CQR feedback loop

Data recorded by clinicians

Data transferred to registry

Data compiled and analysed

Regular reports that include benchmarks and outliers

Clinical care

Improvement in clinical care

Regular feedback is provided to clinicians, patients, hospital administrators, stakeholders and Government
Commission lead work in CQRs

- Tested and validated *Operating Principles and Technical Standards for Clinical Quality Registries* - endorsed by Health Ministers in 2010
- Developed the *Framework for Australian Clinical Quality Registries* in 2014 which incorporated the endorsed Operating Principals and Technical Standards
- Developed a Prioritised List of Clinical Domains for Clinical Quality Registry Development in 2016
- Completed an Economic Evaluation of Clinical Quality Registries in 2016
- Continued work to support developing registries, 2014 to date
- National Register of clinical registries, 2019

*Working in close collaboration with the Department on the National CQR Strategy*
Economic evaluation of CQRs

• Evaluation of economic impact of five well implemented and mature CQRs in Australia:
  o Victorian Prostate Cancer Registry (Victorian PCR)
  o Victorian State Trauma Registry (VSTR)
  o Australia and New Zealand Intensive Care Adult Patient Database (ANZICS APD)
  o Australia and New Zealand Dialysis and Transplantation Database (ANZDATA)
  o Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).

Well implemented and mature CQRs have delivered significant value for money:
  o Benefit to cost ratios ranged from 2:1 to 7:1
  o Return on investment could range from $4, if national coverage was achieved by all five CQRs

• Not every CQR will be cost-effective due to issues such as low coverage, inadequate collection of information about patient outcomes and inadequate reporting.
1. **Identifying a short-list of diseases, conditions and procedures**
   Identified a manageable list for further analysis based on:
   - Burden of disease (44 identified)
   - Cost to the health system (36 identified)
   - Survey of key stakeholders (21 identified)

2. **Application of the threshold criteria:**
   Short-listed diseases, conditions and interventions assessed against the threshold criteria of:
   - Evidence based sequence of care (Criterion 1.2)
   - Ability to identify and address variation from the sequence of care (Criterion 1.3)
   - Suitability of the domain to clinical quality registry data collection (Criterion 2.1)
   - Ability to meet the information requirements for a successful registry (Criterion 1.2)

3. **Grouping of diseases, conditions and interventions into clinical domains**
   The remaining short-listed diseases, conditions and interventions were systematically grouped into clinical domains.

4. **Prioritisation of clinical domains**
   These groups were assessed against the prioritisation crania of:
   - Serious consequence for the patient (Criterion 1.1)
   - High cost to the health system (Criterion 1.4)
   - Clinician support (Criterion 2.2)
<table>
<thead>
<tr>
<th>Priority</th>
<th>Clinical domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ischemic heart disease</td>
</tr>
<tr>
<td></td>
<td>Musculoskeletal disorders</td>
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<tr>
<td>2</td>
<td>Trauma</td>
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<tr>
<td></td>
<td>Adult critical care</td>
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<tr>
<td>3</td>
<td>Stroke</td>
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<td></td>
<td>Renal disease</td>
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<td>4</td>
<td>Neonatal critical care</td>
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<td></td>
<td>Mental health</td>
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<td>5</td>
<td>Maternity</td>
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<td>6</td>
<td>Dementia</td>
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<tr>
<td>7</td>
<td>Major burns</td>
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<td></td>
<td>Diabetes</td>
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</tbody>
</table>
The Framework for Australian Clinical Quality Registries, 2014

- Specifies national arrangements under which peak clinical groups and healthcare organisations can partner with governments to systematically monitor and report on healthcare quality.

- Provides assurance to jurisdictions, private health sector, patients and clinicians that data systems (data holdings), have satisfied minimum security, technical and operating standards.
The Framework – strengths

- National health information arrangements
- National infrastructure model
- Principles, guidelines and standards for CQR development
  - Operating principles and technical standards
- Prioritisation criteria for CQR development and operation
- Requirements specification
  - Infrastructure and technical standards
  - Logical architecture and design
  - Security compliance guideline
  - Reporting
Operating principles and technical standards

- Data collection
- Data elements
- Risk adjustment
- Data security
- Ensuring data quality
- Organisation and governance
- Data custodianship
- Ethics and privacy
- Information output
- Resources and funds
Ownership models

For the most part registries are undertaken as quality initiatives within a research framework. In Australia, there are principally three CQR ownership models:

1. Government owned, regulated and funded
2. Stakeholder-lead and government and stakeholder funded
3. Stakeholder-lead and funded

Government owned, regulated and funded CQRs (such as the cancer registries) operate within the public sector governance framework. Stakeholder-driven CQRs are largely self-governed by clinicians with additional input from key stakeholders.
Information needs:
- Public
- Patient
- Clinician
- Hospital
- Primary care service
- Private sector
- Jurisdiction / government
- Administrators and policy makers
- Funders
- Regulators
- Manufacturers

Data access and linkage
Clinical audit mechanisms
Outlier management / reduction in variation
- jurisdictional oversight
- community assurance
- AHPRA Professional Performance Framework
Integration with eMR - National Data Sets
- avoidance of duplicate data collections and data entry
- real time feedback

eHealth records
Value: patient outcomes, appropriateness and QA
- understanding what is being done to whom and their outcomes
The challenge is moving from this…

CQR feedback loop

- Data recorded by clinicians
- Data transferred to registry
- Data compiled and analysed
- Regular reports that include benchmarks and outliers
- Improvement in clinical care
- Regular feedback is provided to clinicians, patients, hospital administrators, stakeholders and Government

Clinical care
…to CQR enabled person-centred care

Value for:
- Public
- Patient
- Clinician
- Hospital
- Primary care service
- Private sector
- Jurisdiction / government
- Administrators and policy makers
- Funders
- Regulators
- Manufacturers and industry
Priority 4
Supporting health professionals to provide safe and high-quality care.
<table>
<thead>
<tr>
<th>2020-21</th>
<th>2021-22</th>
<th>2022-23</th>
</tr>
</thead>
</table>
| • Literature review and environmental scan  
• Draft guidance on governance arrangements for CQRs | • Update the logical architecture and design  
• Update requirements specification; infrastructure and technical standards; security compliance guideline and reporting guide. | • Pilot and implementation of the national Standard for clinical quality data collections and reporting as provided in the revised Framework. |
| • Update national health information arrangements  
• Reporting policy (CCS indicators qualified privilege and open disclosure)  
• Update technical and operating principles | • Second draft Revised Framework  
• National consultation | • Develop the Clinical Quality Data Collections Accreditation Scheme. |
| • First draft Revised Framework  
• Implementation of the Register of Australian Clinical Quality Registries | • Implementation of the Register of Australian Clinical Quality Registries as a web-based application | • Updated report on the ‘Register of Australian Clinical Registries’ via the Commission website |

- Model for national clinical quality data collections (underpinned by the updated Framework for Australian clinical quality registries with guidance on governance arrangements and Standard) in prioritised clinical domains using administrative and clinical datasets via the National Data Agreement.
National Clinical Quality Registry Strategy

**Vision**
National CQRs are integrated into Australia’s health care information systems and systematically drive patient-centred improvements in the quality and value of health care and patients outcomes, across the national health care system.

**Goals**
- Support effective partnerships with patients, their families & carers
- Co-design & standardise patient reported and experience measures
- Facilitate interactive CQRs for patients & clinicians
- Support clinician leadership
- Develop national minimum standards for feedback loop reporting
- Develop national outlier and reporting policies
- Harness legislation to support national CQRs

**Objectives**
1. National CQRs contribute to patient-centred care
2. National CQRs drive improvements in clinical practice and patient outcomes
3. National CQRs are quality assured, efficient and cost effective
4. National, prioritised CQRs are sustainably funded
5. National CQR information is accessible to a broad range of stakeholders
6. National CQR data is maximised through data linkage, interoperability and integration

**Purpose**
Develop a National CQR Strategy

**Foundation (ACSQHC)**
- 2016: Prioritised list of CQRs
- 2016: Economic Evaluation of CQRs
- 2019: Registry of registries
- 2020: Review CQR Framework
- 2021: CQR Standard
- 2022: CQR Accreditation
Project objectives

1. Provide guidance on governance arrangements for CQRs with updated National Health Information Arrangements (NIHA)

2. Provide contemporary reporting requirements and guidance on outlier management that take into account the conditions of qualified privilege and open disclosure

3. Provide a contemporary national standard for clinical quality data collections including: operating and technical principles; logical system architecture and design and security compliance

4. Progress the development of the Register of Australian Clinical Quality Registries as a web-based application for public access

Support the development of quality assurance processes and materials for national CQRs, including business case development.
Revision: Framework for Australian clinical quality registries

Guidance on governance *NEW*

Reporting principles *Updated*

*Updated* infrastructure and technical standards

FRAMEWORK FOR AUSTRALIAN CLINICAL QUALITY REGISTRIES
## Project overview

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Description</th>
<th>Status</th>
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<tbody>
<tr>
<td>Oct-Dec 2019</td>
<td>Review Evidence Check</td>
<td>Complete</td>
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<tr>
<td>Jan-Mar 2020</td>
<td>First draft guidance on governance arrangements for CQRs</td>
<td>Complete</td>
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<tr>
<td>Apr-Jun 2020</td>
<td>Report on legislation and regulation relating to health data clinical quality registries</td>
<td>Complete</td>
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<tr>
<td>Jul-Nov 2020</td>
<td>First draft of guidance on governance arrangements and updated legislative requirements for CQRs (NIHA)</td>
<td>Complete</td>
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<tr>
<td>Dec 2020 - Jan 2021</td>
<td>Develop initial draft reporting policy that takes into account the conditions of qualified privilege and open disclosure</td>
<td>In progress</td>
</tr>
<tr>
<td>Jan - May 2021</td>
<td>Update CQR operating and technical standards Second draft revised Framework incorporating updated and new components</td>
<td>In progress</td>
</tr>
<tr>
<td>Apr-Jun 2021</td>
<td>Final revised Framework ahead of national consultation</td>
<td></td>
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</tbody>
</table>
Australian Register of Clinical Registries

Purpose: To build a comprehensive list of national registries (CQRs and others) to;

• Increase awareness of registry activity among stakeholders
• Facilitate collaboration
• Inform coordination and strategic planning to establishment of CQRs in prioritised clinical domains.

[Online form to register an Australian clinical registry]
## Information collected

<table>
<thead>
<tr>
<th>Fields published on website</th>
<th>Additional information requested</th>
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<tbody>
<tr>
<td>Registration ID</td>
<td>Ascertainment rate</td>
</tr>
<tr>
<td>Prioritised clinical domain</td>
<td>Clinical care standards</td>
</tr>
<tr>
<td>Condition</td>
<td>Stand-alone registry</td>
</tr>
<tr>
<td>Registry name</td>
<td>Funding source</td>
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<tr>
<td>Abbreviation</td>
<td>Clinical quality registry</td>
</tr>
<tr>
<td>Description</td>
<td>Data management</td>
</tr>
<tr>
<td>Reporting process</td>
<td></td>
</tr>
<tr>
<td>Lead organisation</td>
<td></td>
</tr>
<tr>
<td>Year established</td>
<td></td>
</tr>
<tr>
<td>Participating sites</td>
<td></td>
</tr>
<tr>
<td>Ethics approval reference</td>
<td></td>
</tr>
<tr>
<td>Patient Reported Outcome Measures</td>
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<tr>
<td>Patient Reported Experience Measures</td>
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<tr>
<td>Registry Contact</td>
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<td>Web-link</td>
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## Overview

<table>
<thead>
<tr>
<th>Field</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Number of registrations</td>
<td>97 (62 curated)</td>
</tr>
<tr>
<td>Self-reported as a CQR</td>
<td>Yes = 88  No = 7  To be confirmed = 2</td>
</tr>
<tr>
<td>Number of registrations within prioritised clinical domains</td>
<td>65</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical domain</th>
<th>Total to date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic heart disease</td>
<td>10</td>
</tr>
<tr>
<td>Adult critical care</td>
<td>6</td>
</tr>
<tr>
<td>Neonatal critical care</td>
<td>4</td>
</tr>
<tr>
<td>High burden cancers</td>
<td>24</td>
</tr>
<tr>
<td>Burns</td>
<td>2</td>
</tr>
<tr>
<td>Maternity</td>
<td>1</td>
</tr>
<tr>
<td>Mental health</td>
<td>0</td>
</tr>
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<td>Stroke</td>
<td>1</td>
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<td>Musculoskeletal disorders</td>
<td>6</td>
</tr>
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<td>Renal disease</td>
<td>2</td>
</tr>
<tr>
<td>Major trauma</td>
<td>5</td>
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<td>Diabetes</td>
<td>3</td>
</tr>
<tr>
<td>Dementia</td>
<td>1</td>
</tr>
</tbody>
</table>
The search function allows users to search for information such as clinical condition, registry name and participating sites.

The ‘prioritised clinical domain’ field in the list is in line with the Prioritised list of clinical domains for clinical quality registry development.
Information on the weblink, registry contact, year established, description of the registry, lead organisation, ethics approval reference, reporting process, patient Reported Outcome Measures (PROMS), Patient Reported Experience Measures (PREMS) and participating sites is displayed under the ‘+’ button.

<table>
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<tr>
<th>Weblink</th>
<th><a href="http://biogrid.blob.core.windows.net/assets/uploads/files/data-forms/B5">http://biogrid.blob.core.windows.net/assets/uploads/files/data-forms/B5</a>...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry contact</td>
<td>Susie Bae, Peter MacCallum Cancer Centre, <a href="mailto:susie.bae@petermac.org">susie.bae@petermac.org</a></td>
</tr>
<tr>
<td>Year established</td>
<td>2009</td>
</tr>
<tr>
<td>Description</td>
<td>The Australia and New Zealand Sarcoma Association (ANZSA) supports sarcoma data collection at six major sarcoma referral centres around Australia through the ACCORD sarcoma database. Data collection was initiated as a pilot in 2009, firstly at Peter MacCallum Cancer Centre, and subsequently expanded to include additional sites. Each hospital has HREC approval in place for ongoing data collection for research purposes and only custodians of ethically approved studies can access de-identified data. Single-site and multi-site audits and patterns of care studies have been conducted and ANZSA produces six-monthly data reports and encourages the engagement of sarcoma researchers in utilising the sarcoma registry.</td>
</tr>
<tr>
<td>Lead organisation</td>
<td>The Australia and New Zealand Sarcoma Association</td>
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<td>Ethics approval reference</td>
<td>HREC 06/08 Petermac</td>
</tr>
<tr>
<td>Reporting process</td>
<td>Feedback to contributing clinicians via biannual ANZSA reporting to ANZSA members:</td>
</tr>
<tr>
<td></td>
<td>Shared with clinicians:</td>
</tr>
<tr>
<td></td>
<td>Shared with medical colleges:</td>
</tr>
<tr>
<td>Participating sites</td>
<td>Peter MacCallum Cancer Centre, Chris O'Brien Life House</td>
</tr>
</tbody>
</table>
Overview of progress

1. Evidence Check
   Governance arrangements for national CQRs

2. Update on the legislation as it relates to registries

3. Draft Governance arrangements for CQRs
   Australian Register of Registries

4. Update on the technical and operating Standards and reporting requirements

5. First draft of the revised Framework for Australian clinical quality registries

6. National consultation on the revised Framework