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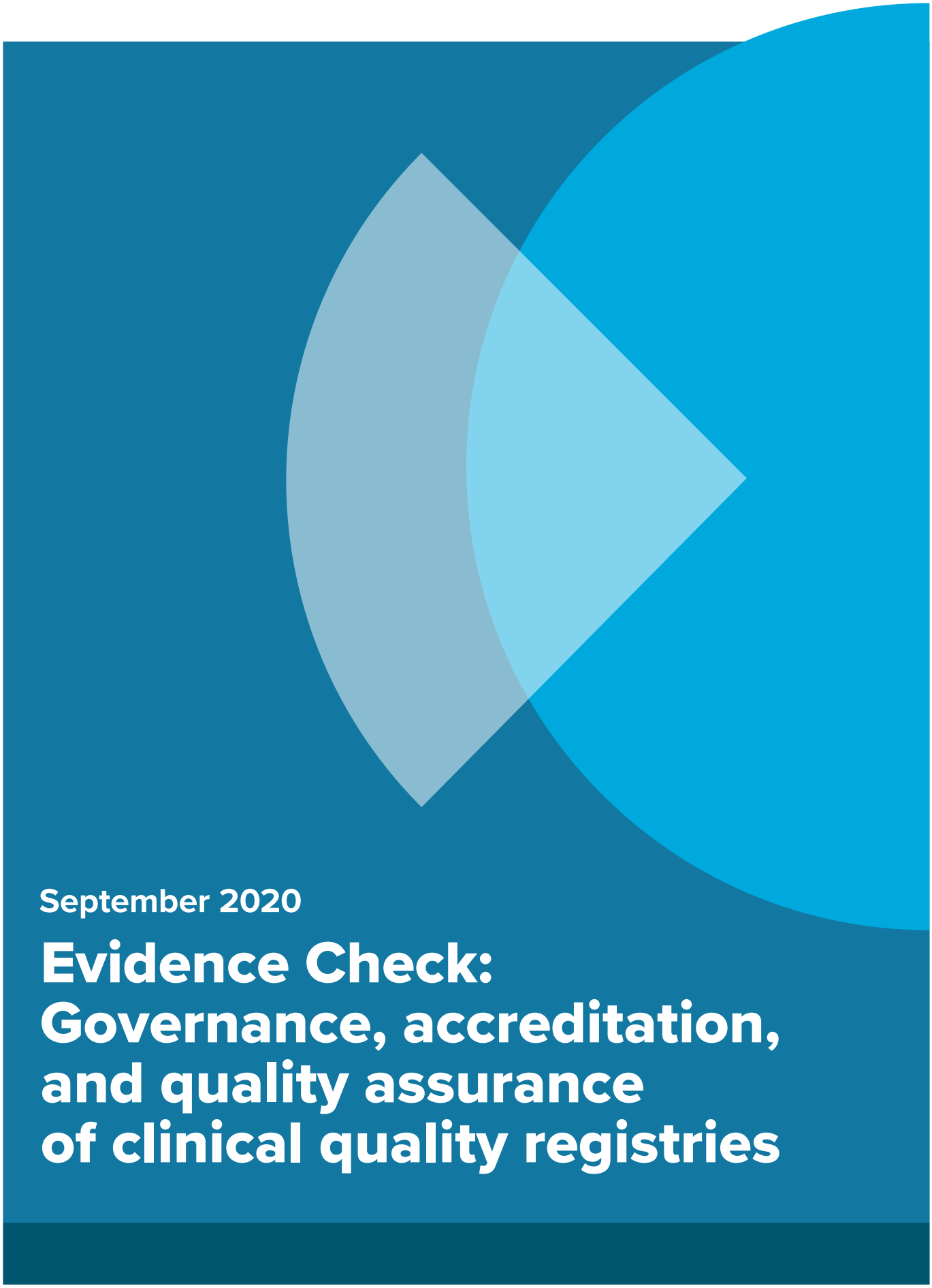

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Evidence Check: Governance, accreditation, and quality assurance of clinical quality registries

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

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Contents

Abbreviations and acronyms

ACC: American College of Cardiology

ACORN: Arthroplasty Clinical Outcomes Registry

ACPGBI: Association of Coloproctology of Great Britain and Ireland

ACRM: Association of Clinical Registries in Malaysia

ACS: acute coronary syndrome

AHMAC: Australian Health Ministers' Advisory Council

ANCR: Association of Nordic Cancer Registries

ANZACS-QI: All New Zealand Acute Coronary Syndrome Quality Improvement Programme

ANZICS: Australian and New Zealand Intensive Care Society

ANZLTR: Australian and New Zealand Liver Transplant Registry

AOA: Australian Orthopaedic Association

AOANJRR: Australian Orthopaedic Association National Joint Replacement Registry

AOTA: Australian Organ and Tissue Authority

APD: Adult Patient Database

APHA: Australian Private Hospitals Association

CABG: coronary artery bypass graft

CAP: Clinical Audit Platform

CCR: California Cancer Registry

CDC: Center for Disease Control and Prevention

CDPH: California Department of Public Health

CDSRB: Chronic Disease Surveillance and Research Branch

CEU: Clinical Effectiveness Unit

CHESS: Centre for Health and Social Economics

CHF: Consumer Health Forum

CICM: College of Intensive Care Medicine

CFHI: Canadian Foundation for Healthcare Improvement

CLABSI: Central Line Associated Blood Stream Infection Registry

CMS: Centre for Medicare and Medicaid Services

COMET: Core Outcome Measurement and Evaluation Tool

The Commission: Australian Commission on Safety and Quality in Health Care

CQC: Care Quality Commission

CQR: Clinical quality registries

CRC: Clinical Research Centre

CSANZ: Cardiac Society of Australia and New Zealand

CSRS: Cardiac Surgery Reporting System

DAA: designated auditing agency

DAHANCA: Danish Head and Neck Cancer Group

DANBIO: Danish Database for Biological Therapies in Rheumatology

DATO: Dutch Audit for Treatment of Obesity

DDKM: Danish Healthcare Quality Programme

DGAV: German Society for General and Visceral Surgery

DHB: District Health Boards

DHSSPS: Department of Health, Social Services and Public Safety

DICA: Dutch Institute for Clinical Auditing

DMCG: Danish Multidisciplinary Cancer Groups

DQR: Data Quality Report

ESRD: End Stage Renal Disease

GI: Gastro-Intestinal

HES: Hospital Episode Statistics

HQIP: Healthcare Quality Improvement Partnership

IACR: International Association of Cancer registries

IARC: International Agency for Research on Cancer

ICTA: Information and Communications Technology Agency

LMICs: low and middle-income countries

MOHLTC: Ministry of Health and Long-Term Care

MRRB: Malaysian Registry of Renal Biopsy

MSN: Malaysian Society of Nephrology

MSQH: Malaysian Society for Quality in Health

NAACR: North American Association of Central Cancer Registries

NBoCA: National Bowel Cancer Audit

NCDR: American College of Cardiology National Cardiovascular Data Registry

NCI: National Cancer Institute

New York State DOH: New York State Department of Health

NHMRC: National Health and Medical Research Council

NHS: National Health Service

NICST: Network for Improving Critical care Systems and Training

NIH: National Institute of Health

NMDS: National Minimum Dataset

NOGCA: National Oesophago-gastric Cancer Audit

NPCR: National Program of Cancer Registries

NQRN: National Quality Registry Network

NRR: Electronic National Renal Registry

NSQHS: National Safety and Quality Health Service Standards

NZCR: New Zealand Cancer Registry

PCI: percutaneous coronary intervention

PCPI: Physician Consortium for Performance Improvement

PERFECT Stroke: Performance, Effectiveness, and Costs of Treatment Episodes in Stroke

PHA: Private Healthcare Australia

PLAC: Prostheses List Advisory Committee

PROMs: Patient-reported outcome measures

QCDR: Qualified Clinical Data Registry

QoL: Quality of Life

RIKS-HIA: Swedish Register of Information and Knowledge about Swedish Heart Intensive Care Admissions

RKKP: Danish Clinical Quality Program – National Clinical Registries

RRT: Renal Replacement Therapy

SAHMRI: South Australian Health and Medical Research Institute

SALAR: Swedish Association of Local Authorities and Regions

SCAAR: Swedish Coronary Angiography and Angioplasty Registry

SEER: Surveillance, Epidemiology, and End Results

SEPHIA: Secondary Prevention after Heart Intensive Care Admission

SHAR: Swedish Hip Arthroplasty Register

SODA: Secure Online Data Access

StuDoQ: Study, Documentation and Quality Center

StuDoQ|Pancreas: Pancreatic Surgery Registry

SWEDEHEART: Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies

SWENTRY: Swedish Transcatheter Cardiac Intervention Registry

TAVR: Transcatheter aortic valve replacement

TGA: Therapeutic Goods Administration

TMF: Technology, Methods, and Infrastructure for Networked Medical Research

UCRC: Uppsala Clinical Research Centre

ZN: Zorgverzekeraars Nederland

Document structure

The Australian Commission on Safety and Quality in Health Care (the Commission) is undertaking a project to review and where required, revise the *Framework for Australian clinical quality registries* to provide guidance on governance arrangements for clinical quality registries (CQRs). This document includes the following sections:

- **Section 1** provides the key findings and the executive summary
- **Section 2** provides the project background and evidence check method
- **Section 3** provides the evidence check key findings
- **Section 4** provides countries in focus and CQR case studies
- **Section 5** provides the discussion, limitations and conclusion.

Section 1:

Executive summary

Key findings

- Complete, high quality clinical quality registry (CQR) data capture at a health system level is best achieved when data collection fits within existing reporting structures and is facilitated by national digital hosting capability[1]. This includes contemporary database technology and quality assurance processes (as evidenced in the United Kingdom National Health Service [UK NHS]) and national accreditation of CQRs (as evidenced in Sweden, Denmark and the Netherlands)
- Successful national CQRs have organisational governance arrangements; receive some government funding and are coordinated between national, state and territory governments and stakeholder groups[2,3]
- Internationally, there is evidence of central CQR organisation(s) that:
  - collect and analyse data for numerous databases
  - provide expertise and a skilled and reliable workforce
  - establish linkage with other national datasets and have established auditing and quality assurance systems (Sweden)
- In general, national CQRs, irrespective of the ownership model (government led and funded; stakeholder led and government funded and stakeholder led and funded) ensure peak bodies and/or expert clinicians:
  - advise on clinical indicators
  - include consumer participation in oversight committees
  - report benchmarks to health services and monitor outcomes
  - include public reporting of clinical outcomes and hospital performance
  - facilitate continual access to, or ownership of data by health services to facilitate continuous quality improvement
  - provide access to data for clinicians and patients
  - provide access to product information for implant manufacturers and allow data to be accessed with permission for research.

Implications for Australia

- In Australia, approaches to the evaluation of CQRs using maturity scales could inform the development of the criteria for a CQR quality Standard
- Contribution to CQRs could be facilitated by the requirement for hospitals to contribute data to accredited CQRs for quality improvement purposes[2]
- The establishment of prioritised national CQRs could be streamlined through the National Health Information Agreement arrangements and a national approach to CQR organisational governance.[2,4,5]

Background

CQRs systematically monitor the quality (appropriateness and effectiveness) of health care within specific clinical domains by routinely collecting and analysing longitudinal health-related data for an eligible population and generating risk-adjusted reports. They allow health services to measure and monitor the degree to which health care benefits the patient and how closely that care aligns with evidence-based practice.[6]

Internationally, CQRs are recognised as cost-effective and valuable sources of high-quality clinical data, which inform clinician behaviour and decision-making, and improve patient outcomes.[2] In 2014, the Commission developed the *Framework for Australian clinical quality registries* (the *Framework*).[6] The *Framework* provides national guidance on the development and implementation of CQRs in Australia. The application of the *Framework* to CQRs provides assurances that, registry data holdings and the systems that hold those data, have satisfied minimum security, technical and operating standards. The purpose of this report is to review the national and international evidence of approaches to CQR governance, accreditation and quality assurance processes. The definition of governance guiding this review is:

> Governance is the set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal, human resources) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance.
>
> Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of the different participants in the organisation to achieve the organisation's objectives. In the National Safety and Quality Health Service (NSQHS) Standards, governance includes both corporate and clinical governance.[7]

Evidence-check questions

The following overarching question guided the evidence check: What processes exist, or are recommended, for CQR governance, accreditation and quality assurance internationally and in Australia?

Five sub-questions expanded the scope of the review:

1. What governance, accreditation and quality assurance mechanisms exist or are recommended?
2. What are the barriers and enablers to implementing and sustaining the use of these mechanisms?
3. What evidence is there for the impact of these mechanisms?
4. How has CQR effectiveness, efficiency, appropriateness and sustainability been measured and reported?
5. What key governance, accreditation, quality assurance, and evaluation learnings may be relevant to the Australian context?

Summary of methods

A rapid review of the evidence-based and grey literature was undertaken utilising an abridged scoping review methodology to address each of the review questions. A systematic search across key databases including: Ovid MEDLINE(R); Embase Classic+Embase; Ovid Emcare; Scopus and the Cochrane Library (see Appendix I) was undertaken. The National Health and Medical Research Council (NHMRC) evidence hierarchy and body of evidence matrix was applied to determine the quality of the evidence (Appendix II). Evidence was restricted to English language articles, published from 1 January 2000 onwards to give the most current view of the topic. Sources of evidence, from countries most applicable to the Australian context that have established CQRs, were eligible for inclusion.

CQR case studies in nine countries, were considered for inclusion. Targeted peer-reviewed and grey literature searches were conducted to establish a shortlist. The selected CQRs focused on clinical quality improvement, had self-reported good rates of data completeness; wide-reaching clinician and/or hospital participation, documented leadership structures and quality assurance processes.

Further to this, the CQR Framework Review Advisory Group, a committee established by the Commission to advise on the project to update the *Framework*, suggested that CQRs in New Zealand and Sri Lanka also be examined. This report includes findings from 11 countries; 16 international CQRs; and three CQRs operating in Australia.

The selected Australian case studies include the:

1. Australian and New Zealand Intensive Care Society – Adult Patient Database, Australia
2. Australian and New Zealand Liver Transplant Registry, Australia
3. Australian Orthopaedic Association National Joint Replacement Registry, Australia.

The selected international case studies include the:

1. American College of Cardiology National Cardiovascular Data Registry, United States of America (USA)
2. California Cancer Registry, USA
3. Cardiac Surgery Reporting System – part of the Cardiac Quality Improvement Initiative, USA
4. CorHealth Ontario (formerly Cardiac Care Network of Ontario and Ontario Stroke Network), Canada
5. Danish Database for Biological Therapies in Rheumatology, Denmark
6. Danish Head and Neck Cancer database, Denmark
7. Dutch Audit for Treatment of Obesity, Netherlands
8. Electronic National Renal Registry (formerly The Malaysian Dialysis and Transplant Registry), Malaysia
9. National Bowel Cancer Audit, UK
10. Network for Improving Critical care Systems and Training, Sri Lanka
11. New Zealand Cancer Registry, New Zealand
12. All New Zealand Acute Coronary Syndrome Quality Improvement Programme
13. Pancreatic Surgery Registry (StuDoQ|Pancreas), Germany
14. Performance, Effectiveness, and Costs of Treatment episodes in Stroke, Finland
15. Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies, Sweden
16. Swedish Hip Arthroplasty Register, Sweden.

The evidence check considered each country of origin's approach to CQR governance and the regulatory frameworks within which each CQR operated. For individual case studies, information extracted included the CQR's purpose; scope; hosting organisation; funding source; approach to organisational governance; data hosting, collection and analysis; reporting and quality improvement mechanisms (see Appendix V).

Evidence grading

The quality of evidence was assessed in relation to the NHMRC Levels of Evidence hierarchy (Appendix II).

Summary of findings

CQR organisational effectiveness related to evidence* of the following:

- CQR data completeness and useability at both an individual hospital and wider healthcare system level
- Mandatory notification legislation or an opt-out model for CQR participant recruitment
- Interactive IT platforms that provide information to hospitals continuously and/or monthly, quarterly or annually
- Clinician and hospital access to and/or ownership of their collected data
- Clinical indicators determined by expert clinicians and reported with national benchmarks or benchmarks against international best practice
- Government organisations or research organisations with capacity to provide an expert workforce; infrastructure to validate, collect and analyse data; feedback calculated reports to health services and standard evaluation processes such as audits for quality assurance
- Compatible IT systems that facilitate data extraction from hospital records and other government databases to monitor prospective outcomes; verify data and ensure data completeness
- Engaged clinicians who realise the benefit of providing clinical information, and received immediate feedback to improve their clinical practice.

* Evidence of effectiveness was self-reported by the CQRs and referenced in the literature.

Gaps in the evidence

There was an identified gap in the literature regarding governance approaches to national CQRs. The peer-reviewed, and targeted grey literature searches revealed oversight structures and national legislation or regulatory frameworks for CQRs, but a lack of detail regarding the effectiveness of internal and external governance, quality assurance and quality improvement policies, procedures and mechanisms.

Discussion of key findings

The evidence check, which included 26 studies and a review of country approaches to CQRs, revealed diversity worldwide. CQRs ranged from state-led operations with dedicated CQR centres and legislated mandatory reporting requirements, to user-pays services purchased by individual hospitals to support internal quality improvement. The literature revealed measures of effectiveness largely related to CQRs achieving data completeness and providing information to participating clinicians and health services to inform quality improvement. For example, state-led CQRs in Sweden and Denmark have mandatory health service participation and reporting requirements, and report near-perfect data completeness. In these countries, there are also clearly defined processes for routine auditing of participating hospital data for quality assurance. CQRs not legislated at a national level that have voluntary reporting, such as the National Bowel Cancer Audit (UK), did not achieve as high healthcare system-wide coverage.

Stakeholder-led CQRs benefited from engaged and dedicated clinicians and/or health services that had developed a registry to address an identified need, but some lacked the interconnected infrastructure of population-wide, state-run mandatory CQRs. The contribution of expert clinical leaders was reported as beneficial to the development of clinical evidence-based indicators and benchmarking criteria.

Evidence on governance approaches for case study CQRs commonly included references to oversight by a board or committee and an audit structure. CQRs in Sweden, the UK and California included consumers in their oversight committees and auditing of participating health services was undertaken for quality assurance purposes and to validate source data. The literature revealed various approaches to data collection, data analysis and feedback mechanisms however there was limited information on the evaluation of CQRs that reflect the holistic definition of governance guiding this review.

Conclusion

This report provides insights into effective and sustainable CQRs through an evidence check of select Australian and international CQRs, including approaches to governance, accreditation and quality assurance processes. Barriers and enablers to implementing and sustaining the use of these mechanisms were identified, and evidence for the impact of these mechanisms were reviewed to inform the development of guidance on governance arrangements for CQRs in the Australian context.

Section 2:

Evidence check

Introduction

Clinical quality registries (CQRs) are registries that systematically monitor the quality (appropriateness and effectiveness) of health care within specific clinical domains by routinely collecting and analysing longitudinal health related data for an eligible population and generating risk-adjusted reports.[6] The collected data are used to identify variance in comparison to national and international evidence-based benchmarks.

CQRs typically focus on conditions and procedures where:

- There are serious consequences to the patient associated with poor quality of care
- Unwanted variation in outcomes can be identified and addressed
- An evidence-based sequence of care improves patient care (or there is a need to capture national data to develop an evidence base for care)
- There is a significant cost burden associated with the condition, the procedure or device (although low-volume registries also exist, for example, Cystic Fibrosis)
- The clinical condition/event can be systematically recognised
- Where the information requirements for a successful CQR can be met.[1]

The goal of CQRs are to improve health outcomes by stimulating improvements in the healthcare system.[6,8] The defining feature of a CQR is the feedback loop, that is, the provision of information to clinicians and health care administrators to improve patient care (Figure 1). Indeed, CQRs are increasingly recognised as a cost-effective and valuable source of high-quality clinical data, which informs clinician behaviour and decision-making.[2] CQR data reported at a national level facilitates international comparisons to guide health system improvements and health policy for the benefit of improved patient outcomes. This includes, but is not limited to: measures of treatment cost-effectiveness to inform health system investment decisions; regulatory decisions; policy development and public and private health service funding arrangements. Additionally, real world data captured through CQRs provide insights into issues of inequity, as they report on population groups not well represented in clinical trials, and indicate the extent to which the health system is meeting a population's needs and priorities.[9]

Figure 1: Conceptual diagram demonstrating the role of registries as part of a closed-loop cycle for improving the quality and safety of health care delivery*

* See: https://www.safetyandquality.gov.au/our-work/national-arrangements-clinical-quality-registries

Internationally, CQRs are well recognised as key components to system-wide safety and quality improvement. In Sweden, Denmark and the Netherlands, CQRs are organised and funded nationally, with a strong commitment from government. In these countries, CQRs have a high degree of integration with existing data systems, and both hospitals and clinicians are involved in data collection, reporting and quality improvement activities.[10]

In Australia, the landscape for CQRs is undergoing significant change as the value of CQRs is increasingly recognised and health information technology continues to develop. To date, CQRs have evolved via a 'bottom-up' approach, as clinician-led research initiatives to identify issues and improve outcomes in specific clinical areas.

Recent attempts to identify the number of CQRs in Australia suggest that there are 65 in operation.[11] The level of maturity of these registries, including their patient population and level of integration into existing health data systems, remains unclear. Of these registries, 46 fall within the prioritised clinical domains identified by the Commission for national CQR development.[12]

Successful international and Australian examples demonstrate the potential value of CQRs to the health system in terms of quality improvement, patient care and return on investment.[13] The Commission acknowledges this value and has undertaken significant work to assist CQR establishment and ongoing standards of practice, including publishing the *Framework* in 2014.[6]

Background

In September 2007, the Australian Health Ministers' Advisory Council (AHMAC) endorsed the recommendation that the Commission establish and validate national operating and technical standards for CQRs. In November 2010, AHMAC endorsed the *Strategic and operating principles for Australian clinical quality registries*[6,14], developed by the Commission. Additionally, AHMAC agreed that the Commission would draft national arrangements, including data and clinical governance, for CQRs, and prepare a costed infrastructure plan. Following this, the Commission drafted the *National health information arrangements for clinical quality registries* and the *Costed infrastructure model for clinical quality registries* in consultation with jurisdictions, the National Health Information and Performance Principal Committee, the National E-Health Transition Authority and CQR experts.

The Commission developed the *Framework* which incorporates the endorsed operating principles for CQRs and technical standards for CQRs, and the National Health Information Agreement arrangements and infrastructure model.[6] The *Framework* outlines guiding principles that CQRs should meet in order to achieve best practice operations and describes the background and rationale for developing nationally-representative CQRs.

The Commission has since published the *Prioritised list of clinical domains for clinical quality registry development*[12] and undertaken an *Economic evaluation of clinical quality registries in 2016*.[13] More recently, the Commission assessed how the *Framework* has been implemented in CQRs via preliminary consultation as detailed in the report, *Strengthening the 2014 Framework for Australian clinical quality registries* (2018).[15] The Commission is also working with the Australian Government Department of Health, as well as the state and territory health departments, to develop a national strategy for CQRs, *Maximising the potential of Australian clinical quality registries: a national strategy 2020–2030* and an associated implementation plan (in progress).[9]

The Commission also liaises and provides guidance to CQR staff, researchers and clinicians in their consideration of CQRs to support quality improvement. For example, the Commission provided advice on the Parliament of Australia Senate inquiry, *Number of women in Australia who have had transvaginal mesh implants and related matters*[16], and the Australian Government response to this inquiry, and also contributed the development of a business case for a pelvic surgery CQR in response to this inquiry.[17] In addition, the Commission recognises the need and the potential of nationally scaled CQRs to feed into the quality and safety of health care delivered in Australia. The Commission provided seed funding to support the development of a registry within the prioritised clinical domain of 'musculoskeletal disorders', the Arthroplasty Clinical Outcomes Registry (ACORN), which has since been incorporated into the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).[18]

This rapid review of national and international CQRs will inform review of the *Framework for Australian clinical quality registries* to provide guidance on governance arrangements for national prioritised CQRs.

Methodology

Review aim and guiding questions

The aim of this evidence check is to provide insights from the national and international literature on governance approaches, quality assurance and mechanisms for accreditation of national CQRs. An internationally recognised methodology for the conduct of systematic scoping reviews was abbreviated for use, in this context.[19] A rapid review is a rigorous but efficient approach to identifying and synthesising the most relevant available evidence on a given topic. Rapid reviews abridge the stages of other evidence synthesis methodologies to provide a targeted, rapid assessment and synthesis of what is known about a topic. Rapid reviews have utility when results are required to inform policy and/or practice decisions regarding policy in a timely manner. This review was guided by the following question, and sub questions:

OVERARCHING QUESTION

What processes exist, or are recommended, for CQR governance, accreditation and quality assurance internationally and in Australia?

Sub-questions provided further guidance to the scope of the review:

1. What governance, accreditation and quality assurance mechanisms exist or are recommended?
2. What are the barriers and enablers to implementing and sustaining the use of these mechanisms?
3. How has CQR effectiveness, efficiency, appropriateness and sustainability been measured and reported?
4. What evidence is there for the impact of these mechanisms?
5. What key governance, accreditation, quality assurance, and evaluation learnings may be relevant to the Australian context?

Search strategy

To address the overarching review question and sub-questions posed, published sources of evidence were sought. Searches were conducted across Ovid MEDLINE(R), Embase Classic+Embase, Ovid Emcare, Scopus, and the Cochrane Library for relevant sources of evidence. The full search strategy for each database is included in Appendix I. A review of the grey literature (unpublished evidence) was undertaken using targeted searching of Google, Google Scholar, and examination of known CQR websites. Two research librarians assisted in the development of the search strategies and undertook the search across all databases.

Evidence was restricted to English language articles, published from 1 January 2000 to current. Sources of evidence from countries most applicable to the Australian context that have national CQRs were eligible for inclusion. All sources of evidence inclusive of duplicates were imported into EndNote™ (version 8.2). Sources of evidence excluding duplicates were uploaded to Covidence© for screening and selection.

Screening and selection of sources of evidence

Two reviewers screened the titles and abstracts of identified sources using Covidence© for relevance to the review questions. Other reviewers were consulted during the process, regarding the inclusion/exclusion of sources as required. Following screening, the full-texts of potentially relevant articles were reviewed for selection based upon a-priori criteria.

Inclusion criteria

Population

CQRs: Where CQRs are clinical registries that inform quality improvement and feedback to clinicians as a purpose and function of the registry. Includes virtual registries.

Concept

Governance: Where the associated processes for governance include (but are not limited to) quality improvement, mechanisms for data access by funders, researchers, governments and consumers, management of outlier hospitals and/or departments, ethics arrangements, national data agreements, data ownership and management, staff and process management, security, linkage and integration with existing data sources.

Accreditation/Standards: Where agreed attributes and processes are attributed to CQRs to ensure that they perform consistently at a designated level.

Quality Assurance: Where a system of procedures, checks, audits, and corrective actions are in place to ensure that all activities carried out by CQRs are of the highest achievable quality.

Efficiency: Where operational models utilised by CQRs and models of funding are described. This includes a focus on management (including financial management) and operational models.

Effectiveness: Where the reporting mechanisms utilised by CQRs for returning information to clinicians is described, as well accessibility of pertinent information by key stakeholders and CQR evaluation processes. Effectiveness may also relate to whether or not the information is used for quality improvement, has an outlier management plan or include levers of change. That is, how information is returned to clinicians, administrators, researchers, funders, government and consumers.

Appropriateness: Where the CQR operates within a quality improvement or research framework, how privacy issues are handled, and outlier management programs are identified. Also includes quality frameworks and prioritisation frameworks, how are new and emerging priorities are being addressed and how the CQR is managed and operated.

Sustainability: Where CQRs are sustainably funded and cost-effective over an extended period of time. Funding and support mechanisms include public/private, grants, government, industry and pharmaceutical.

Context

Countries where national or multinational CQRs operate to systematically monitor the quality (appropriateness and effectiveness) of health care within clinical domains to 'identify benchmarks and outcomes' for clinicians and informs improvements in health care quality.

Evidence grading

The quality of evidence was assessed in relation to the National Health and Medical Research Council (NHMRC) Levels of Evidence hierarchy (Appendix II). Three reviewers extracted data from the collected sources of evidence (Appendix I), and extraction tools were piloted on a subset of sources of evidence prior to use and modified as required during the conduct of the review. The extracted evidence was tabulated for each question and descriptions were prepared in response to the review questions, as narrative summaries.

Included studies

The literature search identified 5,170 sources of evidence. After the removal of duplicates, 3,394 unique sources remained for screening and selection. Following the identification of potentially relevant systematic reviews (n=19), the 1,776 sources (for Questions 1 and 2) published from 1 January 2016 to 26 September 2018 were screened, resulting in 239 potentially relevant sources for full-text examination. Following full text selection, eight sources relating to questions 1 and 2, and 18 sources relating to question three were included. As recommended by the PRISMA-ScR, Table 1 outlines the stages of the search and inclusion process.

Table 1: Stages of the search and inclusion process

Stages	Questions 1 and 2
Database search results	5,170
Duplicates removed	3,394
Sources screened (title/abstract)	1,776
Sources excluded	1,537
Sources screened (full text)	239
Citations excluded (full text)	213
Include	26
Seeking full-text	0

Grey literature

Targeted searches were undertaken to explore identified gaps in the peer-reviewed literature. There was an absence of peer-reviewed literature referencing CQR governance and the relationship between, and the responsibilities of the executive, workforce and stakeholders for CQRs internationally. Therefore, information regarding governance arrangements for specific CQRs identified in peer-reviewed articles were supplemented by the grey literature. Targeted grey literature searches were also utilised to select and examine the case studies prepared for this report (see below).

Quality of the included evidence

According to the NHMRC Levels of Evidence hierarchy (Appendix II), the sources of evidence that provided information for the evidence check were assessed as low level. Only one article that met the selection criteria was assessed as Level I evidence (a systematic review). Three were assessed as Level IV, with the remaining assessed at Level V. Level V evidence includes expert opinion and expert consensus, as defined by the Joanna Briggs Institute Levels of Evidence.[21] High-level analysis of governance mechanisms was an identified gap in the literature.

Case study selection process

Targeted online searches of the peer-reviewed and grey literature from the year 2000 onwards revealed numerous clinical registries operating both internationally and in Australia. The inclusion of CQRs in the evidence check was based on the following criteria:

- The CQR (including national quality registries or clinical audits) had a clinical quality improvement focus
- The primary CQR objective was health service quality improvement through monitoring quality and appropriateness of services and health outcomes, with research as a secondary function
- The CQR had a national reach with good clinicians and/or health services participation
- English-language annual reports were accessible online
- Governance and funding information were available in English language peer-reviewed literature and grey literature was accessible online. For Nordic countries, a collaborative website, 'NordForsk', was identified that provided English-language information on 'national quality registries' for Sweden, Denmark, Finland, Iceland and Norway in a 2017 report*
- Evidence of evaluation on CQR effectiveness, efficiency, appropriateness and/or sustainability of the CQR was accessible online
- The CQR featured in peer-reviewed articles.

* See: **https://www.nordforsk.org/en/programmes-and-projects/projects/project.2017-11-06.6533047689**

A shortlist of CQRs then informed the selection of case studies. Case studies included:

- CQRs in clinical conditions that represented a significant burden to the Australian health system, both in terms of costs for health service provision and rates of morbidity and mortality associated with the condition
- At least one surgical intervention CQR
- At least one registry that monitored organ transplant waiting list activity and outcomes
- Those CQRs that are now well established, having matured over time
- CQRs that are either relatively recent or adapted recently to utilise modern infrastructure
- CQRs that were included in international evaluations of CQRs.

A final list of 16 CQRs from 11 countries were selected for inclusion in this evidence check. Information extracted for case studies included: the CQRs purpose; scope; hosting organisation; funding source; governance; data hosting, collection and analysis; reporting; and quality improvement mechanisms. A summary table is provided at Appendix V.

Section 3:

Evidence check findings

Question 1: What governance, accreditation and quality assurance mechanisms exist or are recommended?

Governance, accreditation and quality assurance mechanisms were identified across 26 sources of evidence and included mechanisms of:

- Organisational governance
- External support
- Data governance
- Ethical, privacy and legal regulation
- Quality assurance
- Accreditation.

Of the sources of evidence identified, 26 sources of evidence met the inclusion criteria for question 1, as listed in Table 6, Appendix III. Descriptions of specific approaches to governance, accreditation and quality assurance were limited and there was broad commentary on varying approaches to clinical quality registry (CQR) operations including local state-based regulated and operated CQRs.[22]

Organisational governance

Nineteen sources of evidence (Table 6, Appendix III) were identified that provided commentary relating to aspects of 'organisational governance'. Of these, 11 sources of evidence noted that steering committees and other associated advisory groups were the primary leadership mechanism. Steering committee membership largely comprised clinicians and other professionals working within the clinical domain occupied by the registry. The literature also recommended that representatives from organisations/governments responsible for the ownership of data, members of funding bodies, registry experts, key stakeholders and consumers be included in steering committees and leadership groups.

External support

Mechanisms for financial and infrastructure support were described in the literature, for example, in Australia, the *Framework*[6] provides the national health information arrangements and the preferred infrastructure model for CQR operations.[6] The literature also recommended improved interoperability with existing clinical information systems with the potential for data linkage and scalability to future-proof CQR design.

Internationally, government and non-government organisations provide centralised support to multiple CQRs. For example, Swedish CQRs are funded through the Swedish Association of Local Authorities and Regions (SALAR), which supports regional 'competence' centres to foster the development of new CQRs and support collaboration between CQRs.[23] In the Netherlands, CQRs are supported through quality assurance processes provided by the Dutch Institute for Clinical Auditing (DICA)[24], a non-profit organisation regulated by government but funded through multiple health insurance companies. In the USA, the American Medical Association's Physician Consortium for Performance Improvement (PCPI) runs the National Quality Registry Network (NQRN®), a voluntary organisation that provides members resources to 'increase visibility and value' of their CQRs.[25,26]

Clinical quality registry quality

Descriptions of CQR quality were mostly concerned with data completeness, geographic and clinical coverage, data validity, timeliness and comparability (Appendix IV) to facilitate the collection, storage, analysis and release of data in an effective and efficient manner to drive quality improvement. Overall, sources primarily advocated a requirement for clear and standardised frameworks (such as the *Framework*[6] and the NQRN)[26], to guide CQR custodians on the collection, storage, analysis and release of data in an effective and efficient manner to key stakeholders to drive quality improvement.

Ethical, privacy and legal regulation

Ethical, privacy and legal regulatory requirements were associated with the transfer and linkage of identified data across healthcare data systems, data validation and quality assurance procedures and compliance with national and jurisdictional legislation. The literature outlined international and national calls for CQRs to be transparent in their operation[27], particularly in relation to data ownership, security and usage. Secure data hosting facilities, secure data access for the registry workforce and the presence of experts to sit on advisory bodies and provide expert knowledge of legal and ethical obligations, were also recommended.[28]

CQRs described in the evidence are largely conducted as quality initiatives within a research framework and are required to comply with ethical, privacy and legal regulatory requirements, with regards to the transfer and linkage of identified data across healthcare data systems.[27,29] Clearly defined roles and functions of data custodians and transparent processes regarding the use of data analysis, access and reporting were attributes identified as facilitating the uptake of key stakeholder engagement in the registry.[27]

Most voluntary registries adopted an opt-out process to ensure the maximum inclusion of an eligible population.[28] However, Hoque et al noted that in the case of rare disease CQRs an opt-in approach was more prevalent. Trauma and cancer registries adopted an opt-out or waiver of consent process.[30] In one study, opt-out registries were found to be three times more likely to have recruited more than 90% of the eligible population.[28] A requirement for patient consent was noted as being inappropriate in some circumstances, such as if a patient is a minor, seriously ill, mentally incapacitated or otherwise unable to communicate.[27]

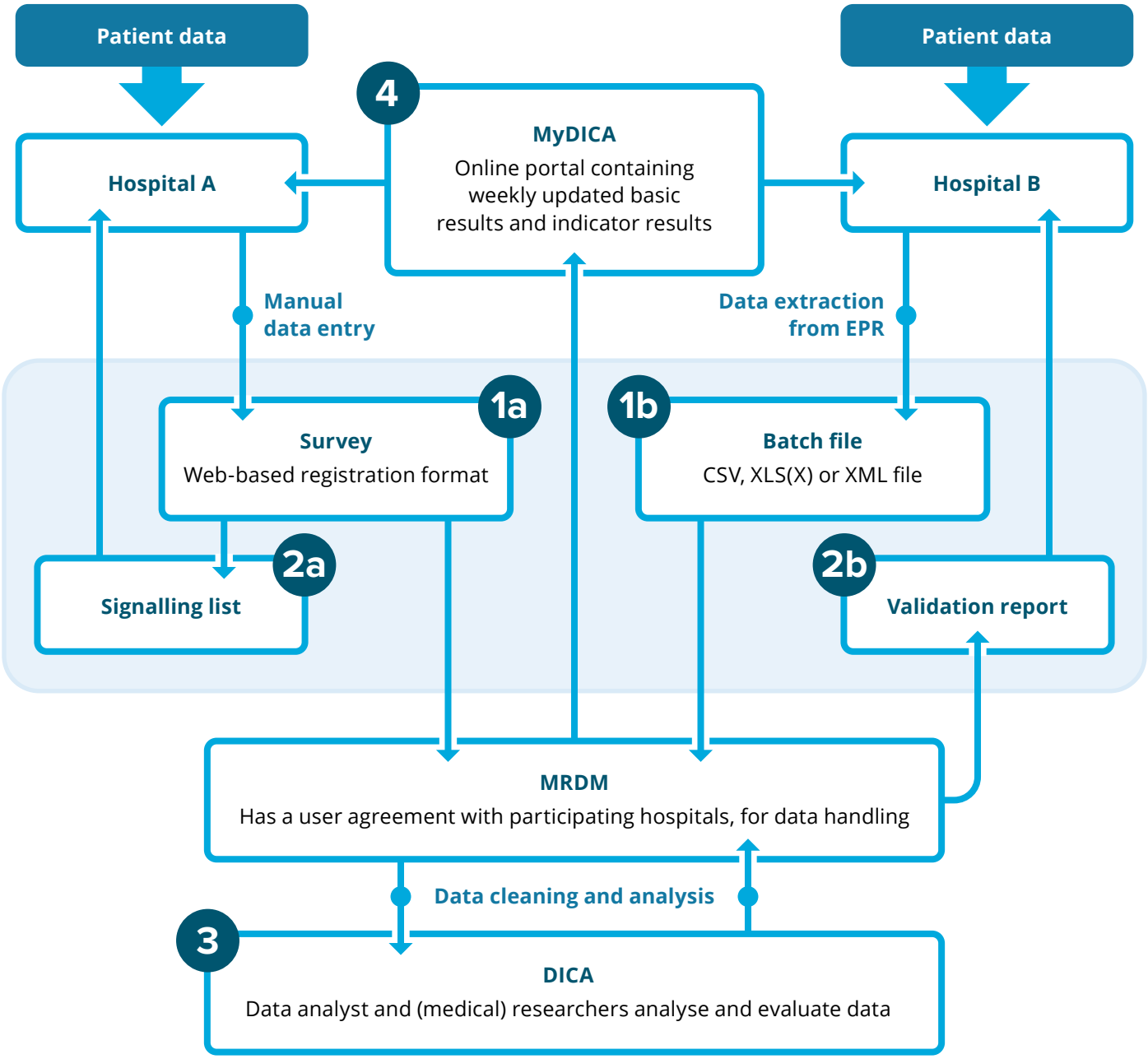
The literature overall supported streamlined ethical review processes[2] and recommended national mutual acceptance of ethics approval for CQRs within and between jurisdictions as an enabling approach to the development of new registries.[4]

Quality assurance

The greater the quality and reliability of the data, the greater potential for the data to inform improvements in healthcare delivery.[31] Internationally, effective CQR operations were underpinned by transparent high quality processes which are defined in the literature as data completeness, accuracy and useability of the information. These processes include automated and manual data auditing processes and source data verification.[23,28,30]

The literature identified DICA's nationwide healthcare data audits in the Netherlands[32] as having effective quality assurance processes. Additionally, participating CQRs can verify and compare the collected data against a national benchmark. The DICA auditing system provides a constant feedback loop, both in real time and at an aggregate level. Data verification processes locate and notify services of discrepancies in data entry across different hospital systems, identifying outliers and ensuring data completeness. The DICA feedback loop is illustrated opposite in Figure 2.

Figure 2: Two data collection and feedback mechanisms employed by the DICA*



1a Individual patient survey data quality is guided by required data items, conditions, validation and help texts upon entry into the system by a registrant.

1b The batch process allows hospitals to derive data from electronic patient records (EPR), this data can then be delivered in bulk.

2a A real time signalling list highlights where patient data is missing or incorrect.

2b A validation report provides feedback on the bulk data submitted by hospitals.

3 DICA cleans, analyses and provides feedback on results of submitted data to hospitals and scientific committee.

4 'MyDICA' provides clinicians and hospital boards with weekly updates on clinical quality, this information is disseminated visually via appropriate tables and graphs. Medical research data management (MRDM).

* Source: Hoeijmakers F, Beck N, Wouters MWJM, Prins HA, Steup WH. National quality registries: how to improve the quality of data? Journal of Thoracic Disease. 2018: S3490-S9.

Accreditation

There was limited peer-reviewed literature regarding accreditation mechanisms for CQRs internationally. However, targeted grey literature searches revealed a variety of voluntary government and non-government accredited CQR organisations. Voluntary accreditation organisations included the PCPI's National Quality Registry Network (NQRN®), a network of organisations with aligned registry interests in the USA, which required a minimum set of standards to be met prior to access being provided to the Centre for Medicare and Medicaid Services (CMS) quality payment program.[33] Some of these standards included:

- The CQR is operating for more than one year
- The CQR includes a minimum of 50 participant groups
- The CQR is not locally owned or managed by an individual or single specialty practice
- The CQR has transparent data collection methodology, specific data elements and risk models
- The CQR publicly reported quality metrics.

State-based accreditation programs found through the targeted grey literature searches included, Sweden, CQRs (called 'national quality registries') were accredited nationally, and rated against certification levels determined by the level of development attained by a registry.[34] However there was limited English-language information available on certification levels.

In Australia, grant funding drove adherence to the Commission's tested and validated *Operating Principles and Technical Standards for CQRs*. These are anticipated to underpin a quality Standard by which independent bodies could accredit CQRs in the near future.[29] Researchers also published a call to action for the 'independent credentialing of the registries and the development of national registry standards'.[3]

Question 2: What are the barriers and enablers to implementing and sustaining the use of these mechanisms?

Barriers and enablers identified included:

- Sustainable funding
- Collaboration, participation and engagement with stakeholders
- Administrative burden.

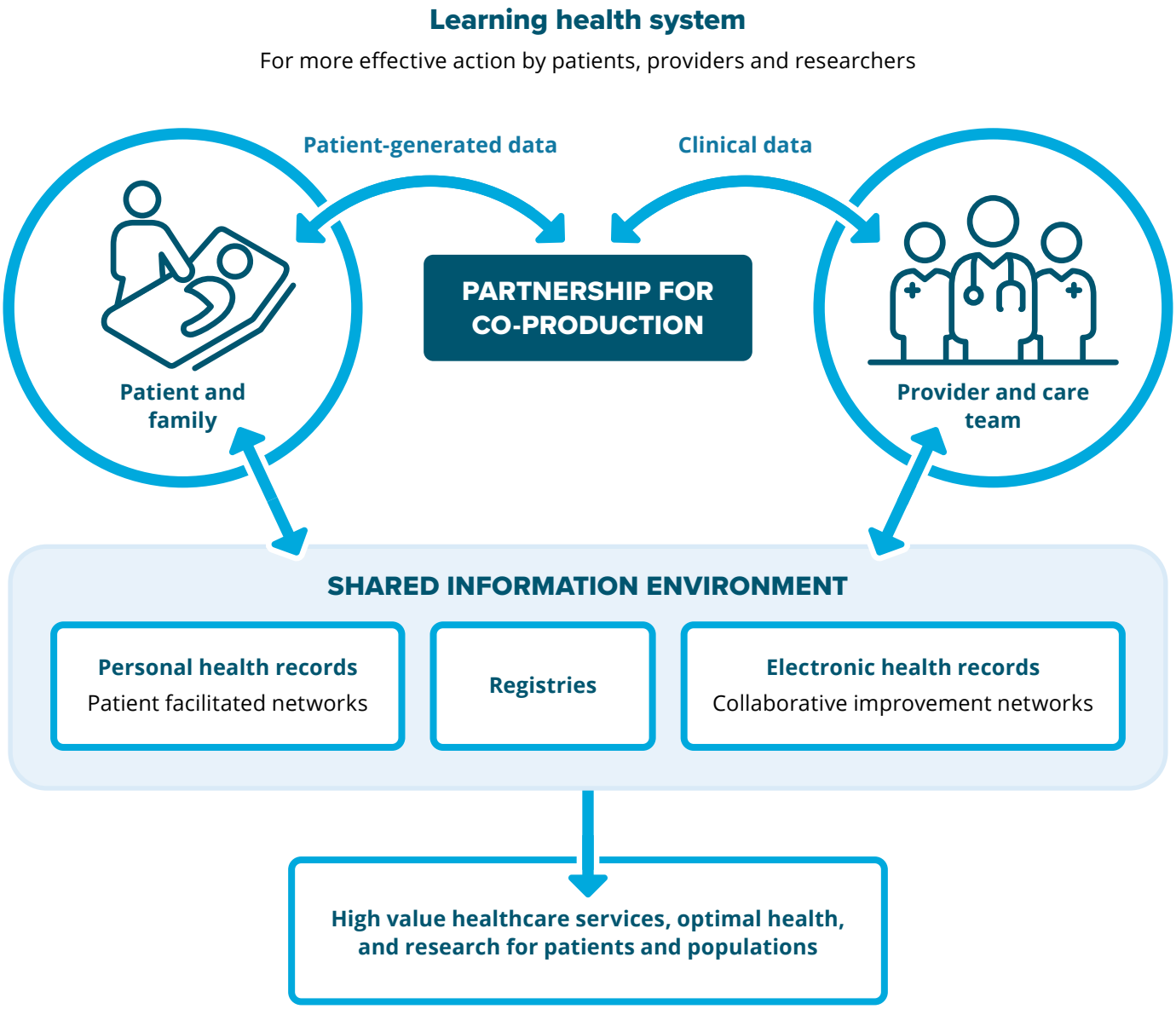
Funding

The review of 15 of the 26 sources of evidence (Appendix III) indicated that consistent and sustainable funding underpinned the success of CQRs. Assurance of medium to long term funding enabled the retention of appropriately qualified staff, facilitated resourcing of data quality processes and supported the maintenance of CQR infrastructure.[35] Where significant funding commitments, such as those in Sweden have been made, improvements in the delivery of health care have been realised through information feed-back.[31] Approaches to sustainable funding included leveraging data sets to inform health policy and, engaging the pharmaceutical industry and private health insurers in joint funding schemes.[36]

Collaboration, participation and engagement

Fourteen sources of evidence (Appendix III) related to the benefits of collaboration with key stakeholders. Participation by health care providers in CQR organisations bought clinical engagement and academic engagement whereas, enhanced collaboration with health service administrators and government ensured interoperability across systems and data linkage. Enhanced collaboration was also proposed as a mechanism to streamline ethical and other legal processes.[3] Where cohesion was unable to be achieved the operation of CQRs were found to be inhibited. Collaborative approaches within CQR organisations and between healthcare sites, at the jurisdictional level and bi-nationally, facilitated greater sharing of resources to drive quality operations.

Figure 3: Model for collaborative engagement and participation between patients and healthcare providers integrated with registry design to facilitate improved health outcomes and services*



* Source: Nelson EC, Dixon-Woods M, Batalden PB, Homa K, Van Citters AD, Morgan TS, et al. Patient focused registries can improve health, care, and science. BMJ. 2016;354:i3319.

The literature suggested an unmet potential of CQRs[37] is the inclusion of patients, carers and consumers in registry data governance and design. The benefits of consumer participation patient centred learning systems has been demonstrated to facilitate better health outcomes and improved services for patients and the community, through shared perception of health, function and wellbeing to drive the efficient use of resources. This integration is illustrated in Figure 3.

Administration

The burden of CQR administration was reported in 14 of the 26 sources of evidence reviewed (Appendix III). The description of administrative burden was multifaceted. Evidence of the greatest administrative burden related to CQRs attempting to capture too much data or inappropriate data collection methods. One study noted that, as the number of records, data fields and overall complexity of a registry increases the quality of data decreases due to a greater number of transcription errors; logical inconsistencies; missing information; duplicate records and measurement

errors.[36] Administrative burden was also associated with poor data governance procedures and database design.[5] Additionally, human factors influence data collection and auditing procedures and the assurance of administrative and operational support. The literature recommended that registry governance include a focus on the technical, operational and administrative requirements of CQRs in the development phase and continual processes for quality operational improvement.[38]

Question 3: How has clinical quality registry effectiveness, efficiency, appropriateness and sustainability been measured and reported?

The literature identified the following elements as measures of effectiveness, efficiency, appropriateness and sustainability:

- Completeness of data
- Validity of data and analysis
- Timeliness of reporting and feedback loops
- Comparability with other data or locations
- Reliability of data
- Independence of the observer
- Number of variables measured.

Of the 26 sources of evidence, 17 sources (Appendix III, and Appendix IV) considered elements of CQR quality assessment in terms of effectiveness, efficiency, appropriateness and sustainability. Two sources of evidence[23,35] applied a methodological approach to score the quality of CQRs against defined criteria, and a third described a maturational framework. A study by Emilsson et al in 2015, evaluated 103 Swedish registries by applying the following criteria:

- Completeness: the proportion of all eligible patients registered in a CQR
- Coverage: the number of healthcare units participating in the registry
- Validity: the extent to which the CQR reflected the true real-world experience of patients and healthcare in a region
- Timeliness: the time taken to record data into the registry
- Comparability: the extent to which data definitions and content was interoperable with other data sources.[23]

According to Emilsson et al, differing characteristics of Swedish CQRs led to difficulty in applying a generalised measure of quality. Completeness, coverage and validity differed and there was a lack of information regarding timeliness and data quality which limited the consensus agreement by CQR stakeholders.[23] Comparability across systems was reliant on data definitions and data systems, which also differed. A key quality indicator of CQRs internationally was data completeness. In Australia, Hoque et al assessed the quality of 34 Australian CQR's by applying a grading system (Table 2) that included similar factors:

- Completeness: the proportion of all eligible patients registered in a CQR
- Reliability: the inter and intra-rater reliability of coding conditions and interventions
- Data validation: assessed the level to which data validation procedures had been undertaken
- Independence of the observer assessing the primary outcomes of the procedure
- Completeness of the CQR's data set that had been filled
- The proportion of variables within the data set that had clear definitions.[35]

However, the robustness of Hoque et al's approach to sort CQRs by level of quality was limited as the data from the 34 CQRs were self-completed (Table 2). Furthermore, where governance committees were acknowledged, the quality of their constitution was not described.

Blumenthal described the NQRN Registry Maturational Framework[33], which was created to guide the development and evaluation of CQRs in the USA (Figure 4). The maturational framework provides a method for the evaluation of a CQR as it moves through phases of development whilst providing guidance throughout that process. In the NQRN® Framework, criteria to be achieved at each level of maturity including a requirement for clearly defined registry goals and a method to achieve them and, a process to facilitate shared levels of understanding between registries and stakeholders. Communication to consumers regarding the collection, processing and use of the collected information was emphasised. However, approaches to governance; funding; ownership and business models; technical and operational processes, including data agreements and privacy protection requirements are not included in the framework. Blumenthal noted that increased uptake of the NQRN® Framework was required to provide an opportunity to address these limitations.[33]

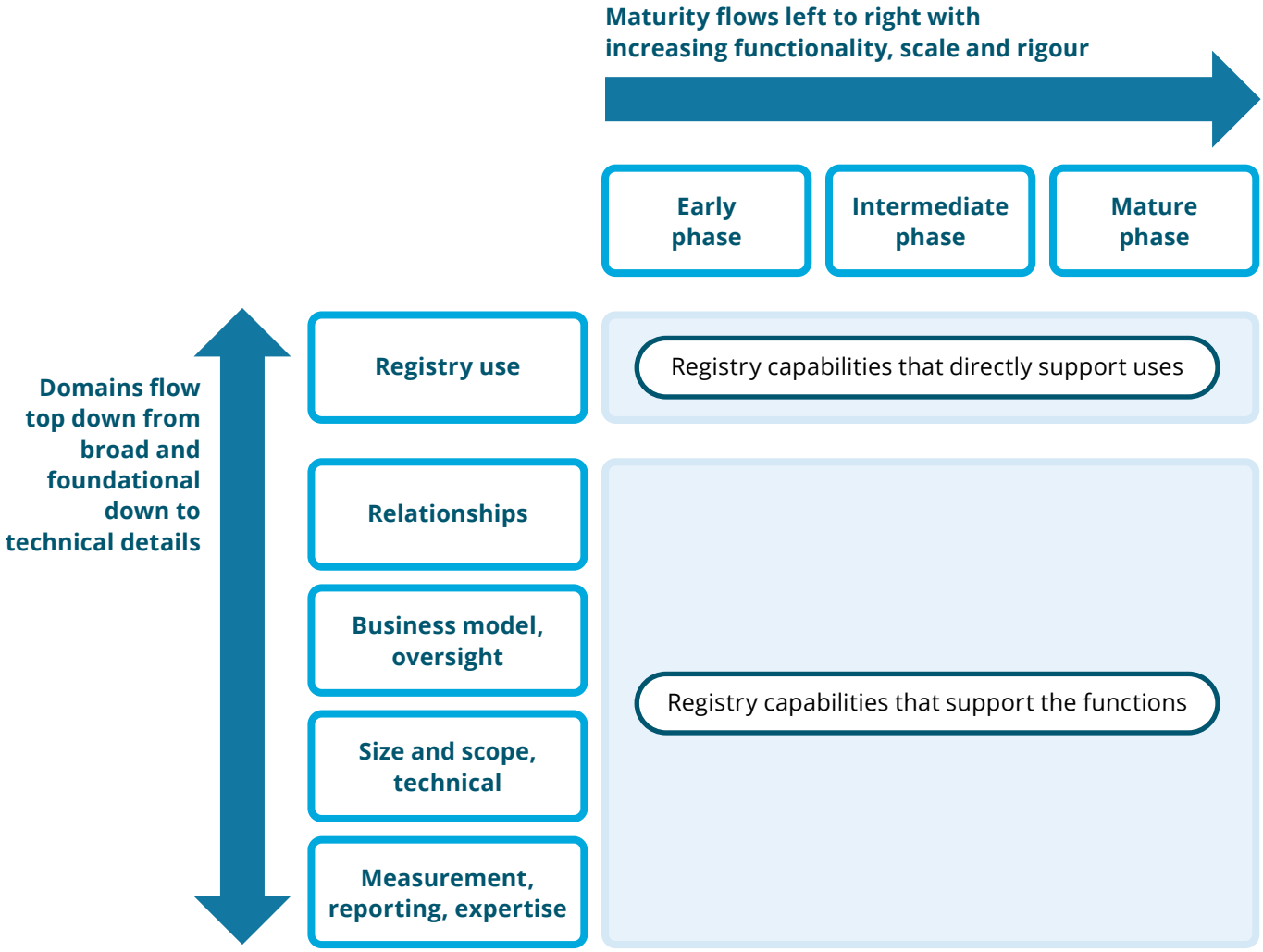
Table 2: Grading system used to assess the quality of CQRs within the Australian context†

Attributes of the CQR	Level 1 Score of 1 point	Level 2 Score of 2 points	Level 3 Score of 3 points	Level 4 Score of 4 points
Completeness of recruitment of eligible population	< 80%	80%–89%	90%–97%	>97%
Reliability of coding conditions and interventions (inter- and intra-rater reliability)	No	Poor Kappa < 0.5	Fair Kappa 0.5–0.8	Good Kappa > 0.8
Level to which data validation undertaken	No audit or validation	Either range or consistency check	Both range and consistency check	Range and consistency check with external validation
Independence of observations of primary outcome	Outcomes not included	Observer neither independent nor blinded	Independent observer not blinded	Independent observer blinded
Completeness of data (% of variable at least 95% complete)	< 50%	50%–79%	80%–97%	> 97%
Use of explicit definitions of variables	< 50%	50%–79%	80%–97%	> 97%

* Note: The system is limited through the self-reported information feedback mechanism employed by the study. See: Md. Emdadul Hoque D, Ruseckaite R, Lorgelly P, McNeil JJ, Evans SM. Cross-sectional study of characteristics of clinical registries in Australia: a resource for clinicians and policy makers. International Journal for Quality in Health Care. 2018;30(3):192–9.

† No active consent means either option to opt-out/via legislation/no consent.

Figure 4: A framework developed by the NQRN to provide guidance and evaluation criteria for the development of CQRs to ensure that they are capable of meeting required standards to drive value-based payments within the USA health system*



* Blumenthal S. The a. EGEMS. 2019;7(1):29.

CQRs in the early phase of development can be expected to provide quality improvement, performance and assessment insight at the local level. An intermediate phase registry will have increased participation and so be able to provide more robust quality performance indicators. Mature phase registries are developed to the point where they can provide data supporting national or international health care policy and research. Different phases of maturity can be expected across the varying domains at any one point in time.

Question 4: What evidence is there for the impact of these mechanisms?

Reviews of the literature revealed:

- A lack of direct evaluation of the impact of governance and accreditation mechanisms in robust peer-reviewed literature
- Indirect evidence of impact, through the evaluation of clinical outcomes and quality improvement related to effective CQRs.

Review of the literature did not provide direct evidence for the impact of governance and accreditation mechanisms. Indirect impact included, the association between quality improvement and cost savings to healthcare systems following implementation and investment in CQRs.[2,31,40] A Monash University report described cost savings to healthcare systems, following implementation of CQRs and[13], international studies confirm cost-savings to the healthcare system through improved quality of health service delivery as an outcome of large-scale investment in national CQRs. In Sweden, government investment supports over 100 CQRs nationwide.[2,31]

The literature also revealed that, the impact of a CQR on the healthcare system within which it operates is perceived (by its stakeholders) to be successful when there are:

- Clearly defined, organisational governance structures[22]
- Strong collaboration, engagement and participation processes[38,41]
- Clearly defined and applicable data governance and quality processes[41]
- Sufficient resourcing to ensure the sustained CQR operations[31]
- Supportive local regulations enabling CQR operation.[22]

Other examples from the literature contextually aligned to these factors are presented in Appendix IV. For example, Larsson et al detailed the impact of the Swedish CQR SWEDEHEART as contributing to decreasing the average 30-day mortality rate for patients suffering an acute heart attack by 65%, and the one-year mortality rate by 49%. This was determined through the collection and feedback of data from 74 of the nation's hospitals, comprising greater than 80% of all heart attack events in Sweden. The registry also monitors adherence to evidence-based best-practice clinical processes, further driving quality improvement.[31]

Question 5: What key governance, accreditation, quality assurance and evaluation learnings may be relevant to the Australian context?

Governance, accreditation, quality assurance and evaluation – insights for Australia:

- Clinician and stakeholder leadership for future CQR development
- Accreditation for CQRs
- Collaboration between health service providers and levels of government
- Combined CQRs for clinical specialities
- Streamlined administrative, ethics and legislative processes
- Sustainable funding arrangements.

Key learnings relevant to the Australian context, collated from seven sources of evidence[1–5,29,35], aligned with the components of the *Framework for Australian clinical quality registries*. Data quality was considered crucial to the overall reliability and validity of CQR outputs[32] and the literature recommended more guidance on organisational governance, collaboration, operational processes and funding.

Organisational governance

To improve organisational governance, the literature recommended:

- Support for clinician/ stakeholder participation in governance and leadership roles[2,5]
- Support for the application of the *Framework for Australian clinical quality registries* to facilitate the development of and linkage with existing registries[3]
- Development of an accreditation system to assess CQRs against specified criteria, and for these criteria to be incorporated into the *Framework for Australian clinical quality registries* and, for the assessment against those criteria to be undertaken through an independent third party.[29,35]

Collaboration

To improve collaboration between stakeholders, the literature recommended:

- A focus on improved coordination between national and state governments for CQR prioritisation and funding[2,3]
- A central national repository of registries to enable greater utilisation of registry holdings[1]
- Requirement for hospitals to contribute data to accredited CQRs.[2]

Streamlining ethical review and approval processes

To streamline CQR ethical review and approval processes, the literature suggested:

- The streamlining of ethical and site-specific assessment processes, through the consideration of CQR's as quality improvement activities[2,4,5]
- The reduction of ethical and legal barriers to promote recruitment rates whilst adhering to data security and privacy legislation[4,35]
- Automation of data collection and cross-referencing through data linkage processes[35]
- The timely provision of benchmarked patient outcome information to clinicians and key stakeholders to drive quality of care improvement.[3]

Funding

To improve funding of CQRs, the literature recommended:

- Funding targeted to support the development and ongoing operations of CQRs in clinical domains that have the potential to provide the greatest benefit to the healthcare system[29]
- A sustainable funding model with public and private contributions[2]
- Support to leverage clinician provider level participation in CQRs[2]
- Processes to evaluate existing CQR's performance as a funding requirement[2]
- State-level investment in hospital systems to facilitate CQR data collection as part of routine hospital data collections.[2]

Summary

The rapid review included 26 articles that related to the topics set by the Commission. There was an identified gap in the literature evaluating CQR governance although there were various approaches to CQR leadership. The evidence revealed approaches to the evaluation of CQRs using quality measures and maturity scales that could inform the development of criteria for a quality Standard. This review also highlighted different approaches to measuring and reporting CQR effectiveness, efficiency, appropriateness and sustainability.

Section 4:

Countries in focus and case studies

Countries in focus

Countries represented in the clinical quality registry (CQR) case study selection reflected:

- Various healthcare systems, with different combinations of public and private healthcare provision
- Various regulatory and legislative requirements for CQRs
- Various approaches to leadership and oversight of CQRs from no centralised oversight to well-established national leadership
- Countries (eight) with national organisations or departments that provided guidance to CQR organisations
- Accreditation programs that are associated with funding and/or access to larger CQR organisations
- Various funding mechanisms for CQRs from ad-hoc funding to universal funding of accredited CQRs.

Section 4 presents case studies of CQRs from Australia and overseas, identifying mechanisms for organisational oversight, governance, quality assurance, funding and quality improvement mechanisms. Nine countries were selected internationally and, an additional three case studies were included (12 countries in total) after consultation with the CQR Framework Review Advisory Committee. A summary of the selected countries healthcare systems and the context in which the CQR operates are provided in Table 3. The selected countries had various approaches to funding, monitoring and engagement of CQRs for clinical outcome quality improvement and quality assurance processes. The included CQRs differed in scope and level of maturity and operated within various regulatory and legislative frameworks however, all had access to some level of government funding. Sweden and Denmark provided mandatory national accreditation and governance for all CQRs, through CQR umbrella organisations, whereas similar organisations in the United Kingdom (UK), Germany, Malaysia and the Netherlands provided oversight voluntarily for affiliated CQRs. Canada, Finland and the United States of America (USA) had decentralised oversight mechanisms for CQRs.

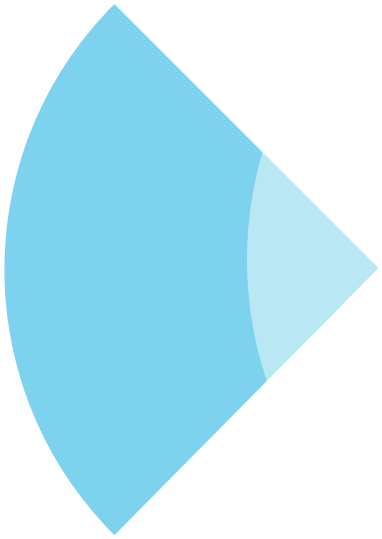
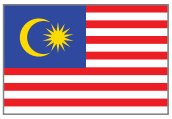
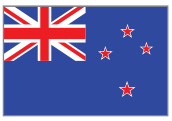


Table 3: Countries in focus

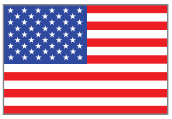
Country	Description	Details
 **Canada**	**Healthcare system**	Public, decentralised health system. Federal government co-finances provincial and territorial programs which deliver hospital, community, and long-term care, mental health and public health services. Some private insurance for excluded items such as vision and dental care.[42]
	Summary of CQRs	The federally funded not-for-profit Canadian Foundation for Healthcare Improvement (CFHI) works with provinces and territories to implement performance improvement initiatives. The CFHI runs two national registries: organ replacement and joint replacement.[43] Provincial cancer registries feed data to the Canadian Cancer Registry.[44] The CANadian Paediatric Weight management Registry and the Canadian Neuromuscular Disease Registry are also national. Many other clinical registries are run at province or territory levels.[45]
	Governance	Because of the high level of decentralisation, provinces have primary jurisdiction over administration and governance of their health systems, including the operation of clinical registries.[42]
	Accreditation / quality assurance	No information was found regarding accreditation and quality assurance for registries at a national or provincial level.
	Funding	Registries have varied funding sources. Some are funded by government and research grants, while others are funded partially or entirely by charities and industry sponsors.
	Reporting	The CFHI produce regular public reports on health system performance. Each registry may also publish annual reports, research articles or other reports.
 **Denmark**	**Healthcare system**	Publicly funded, decentralised healthcare system.
	Summary of CQRs	Denmark has 69 National Clinical Quality Databases[46] managed by the Danish Clinical Quality Program – National Clinical Registries (RKKP), which also provides the infrastructure. The registries are required to cover at least 90 per cent of eligible patients.[47] Clinical registries are led by a board of healthcare professions and owned and funded by the government.
	Governance	The Danish National Health Authority regulates national clinical quality databases.[46] Each registry has a professional board (steering group). Board members are appointed by professional societies.[48]
	Accreditation / quality assurance	Danish clinical quality databases must meet national criteria every three years to receive funding.[46] Once registration requirements are satisfied, hospitals and clinicians are required to report patient data to the database.
	Funding	Regions fund and operate the registries and are responsible for healthcare provision.[46]
	Reporting	After extensive evaluation and auditing, annual results are released publicly on the Danish e-health portal. Patients can access their own treatment data privately via the portal. Participating health care providers also receive monthly or quarterly data.[49]

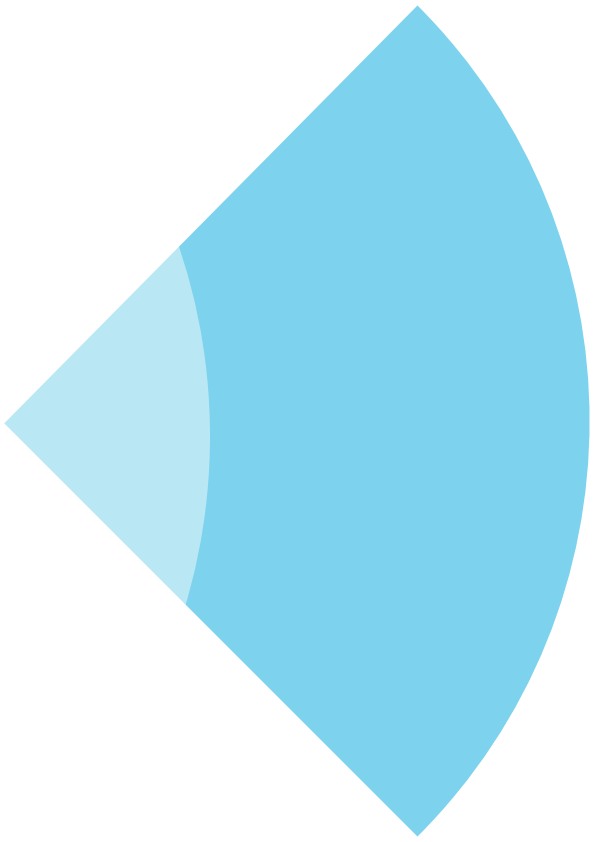
Country	Description	Details
 Finland	**Healthcare system**	Public system. Universal health care. Public Hospitals. Very small private sector.
	Summary of CQRs	Currently there are neither official guidelines nor funding for establishing national quality registers in Finland. However, more than 60 disease-specific patient registers have been established.[50]
	Governance	Currently in Finland there are neither national guidelines nor funding for establishing quality registers. There is no national information service portal of the existing patient registers.[48]
	Accreditation / quality assurance	At the moment there is neither national follow-up nor a benchmarking scheme for quality registers.[48]
	Funding	Each hospital district decides which registers it will maintain. These registers are funded by the hospital districts as there are no national funding schemes for quality registers. Registers maintained by or in association with the National Institute for Health and Welfare receive government funding.[48]
	Reporting	The National Institute for Health and Welfare has a service telephone line for research authorisation applications concerning healthcare registers. Additionally, free statistical databases produced by THL in Finnish and in Swedish enable compilation of statistical tables without a separate authorisation process.[48]
 Germany	**Healthcare system**	Universal health care for citizens if registered with state health insurance.
	Summary of CQRs	Technology, Methods, and Infrastructure for Networked Medical Research (TMF) is the umbrella organisation for networked medical research in Germany. Not all registries in Germany are members of the TMF. Some registries are national, and others are region-specific. The total number of registers operated by TMF member networks is unknown.[51]
	Governance	The TMF support the development and maintenance of infrastructures for clinical research, such as clinical registries on behalf of the Federal Ministry of Education and Research.[51] Each network, centre or consortium (connected with the TMF or not) has its own governance structure.
	Accreditation / quality assurance	The TMF assists registers operated by their member networks in quality assurance, management and improvement.[55] There is no comprehensive external monitoring for registries beyond audits conducted at the institutional level. However, some registers refer to a checklist of registry quality developed in a memorandum on methods for health research.[52]
	Funding	The German Federal Ministry of Education and Research is the main funding organisation for national registers.[51]
	Reporting	There is no centralised location for access to publications of registry reports.

Country	Description	Details
 Malaysia	**Healthcare system**	Two-tiered health system: universal public system and private sector. Private services mainly located in urban areas.
	Summary of CQRs	The Association of Clinical Registries in Malaysia (ACRM) was established in 2005. There are 31 registries affiliated with the association.
	Governance	The Institute for Clinical Research provides oversight to ensure that all registries produce the promised results and operationally comply with applicable ethical guidelines and best practices.[53]
	Accreditation / quality assurance	The Malaysian Society for Quality in Health (MSQH) stands as the accreditation organisation to the healthcare sector. The ACRM is a voluntary organisation established to coordinate national registries.[54] The Malaysian Society for Quality in Health (MSQH) provides voluntary accreditation for the healthcare sector.[55]
	Funding	The Ministry of Health Malaysia provides financial support to registries through special registry grants from the Clinical Research Centre (CRC).[53] Registries are often co-funded by relevant societies, associations and/or private industry funders.
	Reporting	Publications from the various registries are made available on the CRC government website.[53] Most registries also produce annual reports which are publicly available.[54–55]
 New Zealand	**Healthcare system**	Universal public health care and private sector.
	Summary of CQRs	The New Zealand Ministry of Health supports 10 Operating CQRs in New Zealand. The Australia and New Zealand Intensive Care Society runs two CQRs.[58]
	Governance	CQRs are developed by clinicians and have mixed funding structures, with most registries partially funded from central agencies, such as the Ministry of Health.[58] Generally, registries have a steering committee or governance group that are responsible for the strategic priorities of the registries.
	Accreditation / quality assurance	Health care services need to be certified under the Health and Disability Services (Safety) ACT 2001. This process requires a health service provider to be audited by a designated auditing agency (DAA). The DAA are required to be certified by HealthCERT, the New Zealand Government's certification agency.[59]
	Funding	The New Zealand Ministry of Health provides financial support to several registries. Registries are often co-funded by relevant societies/associations and/or private industry funders.
	Reporting	Each registry produces their own publications, available on their website. There is no centralised location for access to publications of registry reports.

Country	Description	Details
 **The Netherlands**	**Healthcare system**	Universal health care with mandatory private health insurance. Some excess paid by patients or insurance. Mostly privately-run hospitals.
	Summary of CQRs	The Dutch Institute for Clinical Auditing (DICA), a clinician-led, independent, non-profit organisation funded by Dutch private health insurers, manages 22 registries.[60] DICA was established to facilitate collaboration between insurers, hospitals and clinicians around clinical quality and outcomes data.
	Governance	The DICA's centralised directional and scientific boards oversee the operation of DICA and the registries (which have their own steering and clinical advisory groups).[24]
	Accreditation / quality assurance	The DICA registries are established and operated in accordance with the DICA's standardised model, with expert support.[24]
	Funding	The DICA registries are funded by an association of all Dutch insurers, known as the Association of Health Insurance Companies.[24]
	Reporting	The DICA providers receive reports on their own data, medical societies have access to de-identified aggregated data, and insurers receive data annually via an online portal. Results are also publicised through an annual conference and an annual report for each registry.[24]
 **Sri Lanka**	**Healthcare system**	Both universal health care and private sector. The Ministry of Health is primarily responsible for the delivery of comprehensive health services in the public sector, including preventative, curative and rehabilitative care.
	Summary of CQRs	The Network for Improving Critical care Systems and Training (NICST) is a non-for-profit organisation that has developed a digital platform, in collaboration with Ministry of Health, to provide real-time feedback, benchmark and improve patient care. This methodology and infrastructure has been adopted in establishing nation registries in Sri Lanka and other parts of South Asia.[61]
	Governance	The NICST is overseen by the Ministry of Health and the Information & Communication Technology agency
	Accreditation / quality assurance	No information was found on quality assurance or accreditation for CQRs in Sri Lanka.
	Funding	Funding is provided by private donations and international research grants
	Reporting	Digital dashboards provide real-time feedback to clinicians. Monthly reports provide individualised summary of each health centre.

Country	Description	Details
 **Sweden**	**Healthcare system**	Publicly funded, decentralised healthcare system. Responsibility lies with the county councils and, in some cases, local councils or municipal governments. This is regulated by the Health and Medical Service Act. Some councils engage private healthcare providers.
	Summary of CQRs	Sweden is a pioneer in quality registry development with 108 National Quality Registries, some of which have been in operation for more than 20 years.[62,63] Two thirds of the National Quality Registries cover over 80 per cent of all eligible patients.[60] The registries are initiated and led by healthcare professionals with government support and funding.
	Governance	The Swedish Office of National Quality Registries provides strategic direction and funding for registries and the National Board of Health and Welfare supports registries to improve data quality.[64]
	Accreditation / quality assurance	The Swedish National Quality Registries are certified according to criteria with higher funding attached to higher levels of certification.[65]
	Funding	Jointly by the Office of National Quality Registries and the Swedish Association of Local Authorities and Regions (representing local councils which are responsible for delivering health care), with a modest contribution by industry.[64]
	Reporting	The Swedish Association of Local Authorities and Regions publishes registry reports.[66] The results are openly available to healthcare providers and the public. Public disclosure is a key feature of Sweden's National Quality Registries and data transparency has accelerated improvements in health care.[62]
 **United Kingdom**	**Healthcare system**	The National Health Service (NHS) public health system. Some private providers.
	Summary of CQRs	The UK is home to over 50 clinical audit programmes.[37] Most of their clinical Audit and Registries are very recent. Registries used for implant lists. The Healthcare Quality Improvement Partnership (HQIP) is responsible for the largest program of clinical audit in the UK.[67] Other registries are run by charities, trusts and independent organisations.
	Governance	The HQIP provides guidance for clinical audit and registries governance through the Good Governance handbook.[56] 18 health organisations, charities, and research institutes, including HQIP, are members of the UK Health Data Research Alliance which was established in 2019 and is run by Health Data Research UK.[68]
	Accreditation / quality assurance	The Care Quality Commission (CQC) monitor, inspect and regulate health and social care services[57], including clinical audit programs and registries.
	Funding	The HQIP delivers their portfolio of national clinical audits and other programmes with funding from NHS England and the Welsh Government. Some projects are also funded by the Health Department of the Scottish Government and the Department of Health, Social Services and Public Safety (DHSSPS) Northern Ireland and the Channel Islands.[67]
	Reporting	The HQIP publishes annual reports for the clinical audits and registries they are responsible for. These are available to the public on their website.[67]

Country	Description	Details
 **United States of America**	**Healthcare system**	No universal healthcare. Private health insurance predominantly provided by employees. Safety net for vulnerable groups only (Medicaid and Medicare).
	Summary of CQRs	The National Institute of Health (NIH) lists registries. Very few have national reach due to state or county-based systems. Often operated by not-for-profit interest groups. The USA has over 110 federally qualified registries certified to report quality metrics.[37]
	Governance	No mandated governance for clinical registries was identified. Governance differed state-by-state. Registries have their own governance structures. In 2011, the AMA's Physician Consortium for Performance Improvement (PCIP) established the National Quality Registry Network (NQRN), which supports the development of CQRs.[26]
	Accreditation / quality assurance	A clinical data registry in the USA can be a qualified registry, a Qualified Clinical Data Registry (QCDR), or a registry that is not approved by the Centers for Medicare & Medicaid Services (CMS). QCDRs involve a higher level of rigor than other registries and need to demonstrate improvements in quality and efficiency. Registries benefit from becoming qualified as this means they can be used for use in value-based payment programs.[39]
	Funding	Registries in the USA have a variety of funding models. Many are self-funded, and some receive partial funding from private or federal grants. Others charge participation or data usage fees.[39]
	Reporting	No national reporting requirements were identified. Reporting varies for different states and for private and public registries.



Clinical quality registry case studies

This section of the report contains the findings from the case studies of selected Australian and international CQRs including three Australian registries and 16 international registries. To determine the regulatory frameworks for each CQR, each country of origin's approach to CQR governance was reviewed and is summarised in Section 4. The information provided includes: the CQRs purpose; scope; hosting organisation; funding source; organisational governance; data hosting, collection and analysis; reporting and quality improvement mechanisms. The completed table is at Table 8 (Appendix V).

The selected CQR case studies had various approaches to CQR organisation including the following:

- A focus on clinical outcomes
- Capacity to monitor a variety of conditions and procedures
- Documented quality assurance mechanisms
- Self-reported high rates of completeness and improvements in clinical outcomes over time
- State-led CQRs which favoured mandatory reporting
- Stakeholder-led CQRs
- Approaches to interconnectivity between CQRs and other databases
- Cluster approaches to collecting and analysing data for numerous CQRs
- Capacity for hospitals or clinicians to retain ownership of their data
- Mature CQRs that were contracted to maintain relevant government databases
- Approaches to organisational oversight by a board or committee, with outcomes and benchmark criteria set by experts or representatives from sponsor organisations working on advisory panels, working groups or committees
- Approaches to consumer engagement in CQRs oversight committees (for example, Sweden, the UK and California) included consumers in their oversight committees.

Of the 19 CQR case studies, three CQR case studies are from Australia. The selected Australian case studies include the:

1. Australian and New Zealand Intensive Care Society (ANZICS) – Adult Patient Database (APD), Australia
2. Australian and New Zealand Liver Transplant Registry (ANZLTR), Australia
3. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Australia.

The selected international case studies include the:

1. American College of Cardiology National Cardiovascular Data Registry (NCDR), USA
2. California Cancer Registry (CCR), USA
3. Cardiac Surgery Reporting System (CSRS) – part of the Cardiac Quality Improvement Initiative, USA
4. CorHealth Ontario (formerly Cardiac Care Network of Ontario and Ontario Stroke Network), Canada
5. Danish Database for Biological Therapies in Rheumatology (DANBIO)
6. Danish Head and Neck Cancer database (DAHANCA), Denmark
7. Dutch Audit for Treatment of Obesity (DATO), Netherlands
8. Electronic National Renal Registry (NRR) (formerly The Malaysian Dialysis and Transplant Registry), Malaysia
9. National Bowel Cancer Audit (NBoCA), UK
10. Network for Improving Critical care Systems and Training (NICST), Sri Lanka
11. New Zealand Cancer Registry (NZCR), New Zealand
12. All New Zealand Acute Coronary Syndrome Quality Improvement Programme (ANZACS-QI)
13. Pancreatic Surgery Registry (StuDoQ|Pancreas), Germany
14. Performance, Effectiveness, and Costs of Treatment episodes in Stroke (PERFECT Stroke), Finland
15. Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART), Sweden
16. Swedish Hip Arthroplasty Register (SHAR), Sweden.

The selected CQR case studies were analysed and summarised with a focus on their governance structures and quality improvement mechanisms. Of these, three ownership models were identified:

- State-led/owned and operated with legislated reporting requirements
- Stakeholder-led/operated and state-funded (stakeholder groups comprise: peak bodies; pharmaceutical companies; private insurers or as a user-pays service)
- Stakeholder-led, stakeholder funded.

A summary table of the case studies are provided at Appendix V. The case studies include: the CQRs purpose; scope; hosting organisation; funding source; ownership; data hosting, collection and analysis; reporting; and approaches to quality assurance. National requirements for CQRs and approaches to organisational oversight (including organisational governance) are summarised below, and provided in Table 8 (Appendix V). For several CQRs there was limited detail relating to regulatory frameworks or organisational structures, quality assurance and quality improvement mechanisms.

State-led and funded clinical quality registries

State-driven CQRs are owned and operated by the state, either through health departments, or government owned health organisations. Some state-driven CQRs have legislated reporting requirements, while others allowed health services or clinicians to voluntarily contribute to their registries.

State-driven CQRs include the:

- California Cancer Registry (CCR), USA
- Cardiac Surgery Reporting System (CSRS), USA
- National Bowel Cancer Audit (NBoCA), UK
- New Zealand Cancer Registry (NZCR)
- Performance, Effectiveness, and Costs of Treatment episodes in Stroke (PERFECT Stroke), Finland
- Swedish Hip Arthroplasty Register (SHAR), Sweden
- Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART), Sweden.

Cardiac Surgery Reporting System, United States of America

The Cardiac Surgery Reporting System (CSRS) was established in 1989, and is a part of the Cardiac Quality Improvement Initiative of the New York State Department of Health (New York State DOH). The initiative aims to improve treatments of heart disease by providing hospitals and physicians with information that can be used to improve processes and outcomes for patients. It also aims to identify and address barriers to access of appropriate cardiac care and provide information for patients to enable them to make better decisions about their own care.[69]

The CSRS is hosted at the University at Albany State University of New York, and funded by the New York State DOH. It is overseen by the CSRS Subcommittee who report to the New York State Cardiac Advisory Committee, an advisory group of independent practicing cardiac surgeons, cardiologists and other professionals in related fields.[70]

All hospitals in New York State where cardiac surgery is performed, excluding federal hospitals, submit data to the CSRS. This includes 38 hospitals.[70] The CSRS collects patient characteristics and risk factors; mortality rates after coronary artery bypass graft (CABG) surgery and valve repair or replacement surgery; readmissions after CABG; and preliminary information on transcatheter aortic valve replacement (TAVR); readmission rates following surgery and the number of cases of cardiac surgery for hospitals and surgeons. Data are used to help hospitals, surgeons and cardiologists to improve their care, and well as for research purposes including evaluation of the impact of patient characteristics, treatment strategy and provider characteristics on short and long-term outcomes. The CSRS data are also used by the New York State DOH for monitoring, planning and regulatory functions.[69]

The CSRS data are submitted electronically to the New York State DOH Cardiac Services Program/University at Albany School of Public Health for cleaning, auditing, and analysis.[20] Accuracy of the data is ensured by reviewing unusual reporting frequencies, cross-matching cardiac surgery data with other Department of Health databases, and reviewing medical records for a sample of cases.[70] Hospitals' medical records, risk factors and procedures are audited periodically. When minor data accuracy problems are detected, hospitals must re-abstract the data and document this. If there are major issues with data accuracy the New York State DOH may require the hospital to pay for an independent abstractor. Hospitals are provided with immediate feedback on their approximate risk-adjusted mortality rates when they submit data so that they can internally work towards improving quality where it is needed. The New York State DOH also alerts hospitals by letter if there are high mortality rates during the course of the year in between reports.[20]

Reports from the CSRS provide data on performance (risk-adjusted mortality rate) and volume (number of cases) by hospital (in each year) and by surgeon (in three-year periods). The reports are usually published one to three years after the collection period and are made publicly available on the New York State DOH website.[71]

California Cancer Registry, United States of America

The California Cancer Registry (CCR), established in 1988, is managed by the California Department of Public Health (CDPH). It is a program of the CDPH's Chronic Disease Surveillance and Research Branch (CDSRB). The CCR is a state-wide population-based cancer registry which collects information about most cancers diagnosed in California. California state law requires all cancers diagnosed in California (excluding non-melanoma skin cancers and carcinoma in situ of the cervix) to be reported. The CCR aggregates this data and performs quality control and data analysis.[72]

The CCR is a collaborative effort between the California Department of Public Health, the Institute of Population Health Improvement, UC Davis Health Systems, and the regional cancer registries.[73] California also participates in the Centers for Disease Control and Prevention's (CDC) National Program of Cancer Registries (NPCR) and in the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute (NCI), so the CCR meets all NPCR and SEER standards for quality, timeliness, and completeness of collected data. The CCR is also Gold Certified by the North American Association of Central Cancer Registries (NAACR).[72]

The CCR's stated purpose is to collect state-wide cancer data, conduct surveillance and research into the causes, controls, and cures of cancer, and communicate the results to the public to improve understanding of cancer and develop strategies and policies for its prevention, treatment, and control.[72] The CCR is funded by the California Department of Public Health, Center for Disease Control and Prevention's (CDC) National Program of Cancer Registries, and the NCI SEER program.[74]

All hospitals, facilities, and physicians diagnosing or providing treatment to cancer patients are required by law to report cases of cancer to CCR, including demographic, diagnostic, and treatment data. Data are submitted electronically, either via the Direct Data Entry Web Portal or automatically from electronic health records where applicable.[72]

The CCR provides statistics, reports, and tools for researchers, patients, and the general public, including cancer statistics for California as a whole, statistics for specific regions of California, and statistics for individual counties. Data from the CCR are publicly available on the website via a data library which provides access to the CCR annual reports, cancer fact sheets, the CCR publications, data retrieval mapping reports, and behavioural risk factor surveillance system snapshots. An Interactive Query Tool and a Geographical Information System provide the ability to search for cancer data in a specific region. Cancer patients can obtain their individual case file data from the CCR, and researchers can also request access to specific data sets.[72] Therefore, while the CCR's primary purpose is to collect data for surveillance, research, and transparency; mandatory reporting requirements allow data from the CCR, and the SEER program nationally in the USA, to identify outliers and provide information for health services to direct resources, facilitate quality improvement and improve care for cancer patients state-wide.

National Bowel Cancer Audit, United Kingdom

The National Bowel Cancer Audit (NBoCA), a UK registry, began in 2005.[75] It was commissioned by the Healthcare Quality Improvement Partnership (HQIP) and was developed by the Association of Coloproctology of Great Britain and Ireland (ACPGBI). The purpose of the NBoCA is to improve the quality of care and survival of patients with bowel cancer, and to ensure that care meets requirements outlined in the NHS cancer plan.[76]

The NBoCA is managed by the Clinical Audit Support Unit within the Health and Social Care Information Centre on behalf of the Clinical Effectiveness Unit (CEU) of the Royal College of Surgeons of England. While the CEU holds the contract for the Audit, the NHS Digital provides project management and technical infrastructure, while the ACPGBI provides clinical leadership and direction. Since 2014, the NBoCA has been hosted by the NHS Digital's web interface, the Clinical Audit Platform (CAP).[75]

The NBoCA is overseen by a Clinical Advisory Group, with an Audit Project Team. The NBoCA is part of the Gastro-Intestinal (GI) Audit, along with the National Oesophago-gastric Cancer Audit (NOGCA). The GI Board oversees both Audit Workstream Project Teams and Workstream Advisory/Reference groups.[77]

The NBoCA is a national register, covering all of England and Wales. Participation in the audit is voluntary, although all eligible public health sites participated in 2018.[75] Patients can object to participation. When a patient is first diagnosed with bowel cancer, clinicians submit patient data via CAP on the NHS Digital webpage. Data are also collected at a Trust (regional) level and is linked to the Hospital Episode Statistics (HES) database for further information on patient care and follow-up. Five outcomes are analysed using funnel plots, and potential outliers are reported back to the relevant health service for verification prior to publication of the NBoCA reports. While the NBoCA only includes patients newly diagnosed each year, performance indicators span from diagnosis to two year follow up, which are determined through data linkage.[78]

Since 2011, there has been a requirement to make clinical audit data publicly available, through the Clinical Outcomes Publication programme. Through this programme, data from the NBoCA data are made available through the data.gov website, identifiable to the health service, Trust or Cancer Alliance, via their name and their national code.[79] Outcome data are published both on this website, and in the NBoCA annual report. The NBoCA also produce supplementary Short Reports throughout the year.[76]

New Zealand Cancer Registry

The New Zealand Cancer Registry (NZCR) is a population-based tumour registry, established in 1948. The NZCR is hosted by the New Zealand Ministry of Health, with oversight provided by the New Zealand Cancer Control Agency. According to the *Cancer Registry Act 1993* the purpose of the NZCR is to provide information on the incidence of, and mortality from, cancer and provide a basis for cancer survival studies and research programs.[80]

The NZCR collects data on almost all malignant tumours (invasive and in-situ) that are first diagnosed in New Zealand. Data on squamous and basal cell skin cancers are not collected.[81] The NZCR collects detailed pathological information about each tumour, including data of diagnosis, site of primary cancer, type of cancer test, morphology, grade, stage and site-specific information. The NZCR use the SEER summary staging develop by the National Cancer Institute, USA to record the stage of disease at diagnosis. Key demographic information is also collected to ensure that each new cancer is recorded only once.[82] Incidence is based on primary tumours rather than the number of individuals. As such, multiple primary cancers in the same person can be recorded, according to the rules of the International Agency for Research on Cancer (IARC) and the International Association of Cancer registries (IACR). The data are collated and coded by a specialised team at the NZCR.[83] The NZCR electronic system carries out data validation as the data are being entered, and provides immediate feedback.[81]

The NZCR's primary source of cancer data are pathology laboratories, who by law are required to report all new diagnosis of cancer to the registry.[83] Additional data sources include the National Minimum Dataset (NMDS), Mortality Collection, screening programme and clinicial-maintained databases.[84] Pathology reports are sent via the secure electronic link, Healthlink. Hardcopy reports are scanned into the NZCR.

The NZCR have implemented routine data assurance measures to ensure the completeness of data collection and the accuracy, completeness and consistency of coding. Some of the assurance measures include monitoring reporting from laboratories, reconciling information from multiple sources, validation checks and having a team of specialist coders. Data are reported in cancer publications, such as the *New Zealand Cancer Action Plan 2019–2029*, annual reports and other national data collections, such as the Mortality collection (MORT) and the NMDS. Provisional datasets are published on the New Zealand Ministry of Health's website.[84]

Performance, Effectiveness, and Costs of Treatment episodes in Stroke, Finland

Performance, Effectiveness, and Costs of Treatment (PERFECT) episodes in Stroke (PERFECT Stroke) database is a sub-project of the PERFECT project, which began in 2004 with the aim to provide data on selected disease groups, and to develop methods to measure the cost-effectiveness of treatment for key disease groups[85] and to create comparative databases that allow comparisons between hospitals, hospital districts, regions and population groups.[50]

The PERFECT project is run by health districts, Social Insurance Institute (KELA) and the National Institute for Health and Welfare (THL). It is co-ordinated by the Centre for Health and Social Economics (CHESS) within the THL.[40] The PERFECT project was also sponsored in its development by the Academy of Finland (Terttu program) and the European Union (Euphoric).[85]

The PERFECT project is hosted by the CHESS in the THL.[86] A methodological group within the CHESS developed cost approximation and benchmarking methodologies. In addition to this, each of the disease groups, including Stroke, has a steering group consisting of clinical experts and the CHESS personnel.[87] There is no national governance of National Quality Registers or patient registers in Finland.[50]

Using data from the Finnish national Hospital Discharge Register (HILMO), the project produces information on patients, their treatment and the effectiveness of treatment using a variety of indicators, comparable between hospital districts and hospitals. This allows for continuous monitoring of the cost and effectiveness of stroke care.[87] Benchmark data are updated in an annual report, available online in Finnish only, to be used by health services to inform care.[40] Furthermore, the PERFECT databases inform performance indicators for Finnish hospitals on selected diseases, including stroke.[50]

The PERFECT Stroke can operate efficiently and effectively because of existing nation-wide registers, including the Hospital Discharge Register and National Causes of Death Register, and all data can be linked with each patient's unique personal identification code.[50] The PERFECT project model of registry follows diseases at an individual level, 'with specific interest in the role of health services as a determinant of the progress'[50], which differs greatly from National Quality Registers in other Nordic countries or in Australia. Nevertheless, the stated aim of the PERFECT to examine cost-effectiveness of treatment has allowed the PERFECT projects, such as the PERFECT Stroke, to provide benchmarks for care and facilitate quality improvement nationally for health facilities in Finland.

Swedish Hip Arthroplasty Register, Sweden

The Swedish Hip Arthroplasty Register (Svenska Höftprotesregistret) (SHAR) was established in 1979.[88] The SHAR stated purpose is to improve care provision for patients who undergo hip arthroplasty in Sweden.[89] Every unit, private or public, which implants artificial hips in Sweden reports to the SHAR, with 98.3% compliance in 2015.[89] Hemiarthroplasties have also been recorded since 2005. The SHAR's role is to provide continuous quality assurance through activity analysis with the aim of giving patients the best possible care.[89]

The Centre of Registers Västra Götaland hosts and supports the SHAR infrastructure, though the use of Secure Online Data Access (SODA) to host data.[90] Health professionals input data, including demographic information, diagnosis, surgical technique and type of implant used. Since 2002, patient-reported outcome measures (PROMs) have also been measured and recorded, using the EuroQol's level 3 EQ-5D questionnaire.[91] Patients complete questionnaires before an operation and one, six, and 10 years post operation. Repeat surgeries are recorded. Clinicians can compare their results with other hospital units across the country and can act if their unit is performing below standard through the use of shared decision-making tools provided by the SHAR.[92]

Since 1999, the SHAR has been publicly reporting results for all hospitals in an annual report, which is available in English and Swedish on their website.[93] Data are also reported online via their website throughout the year via an interactive 'statistics' interface, and implant manufacturers can obtain select information regarding implants through a special web tool and separate website.[94] The SHAR is unique in the way that it allows continuous, real-time access to information for surgeons, patients and the implant industry.[95]

Every Swedish quality registry works with the Office for National Quality Registries, and are required to have a national steering board, operational design or decision group, reference groups and an expert group.[50] Patient representation is required on the steering committee.[50] Since 1989, the SHAR has been supported by the Swedish Association of Local Authorities and Regions and the Region Västra Götaland. The Center for Registies Västra Götaland hosts the SHAR.[90] The SHAR Registry Board and Steering Group are appointed in consultation with the Swedish Orthopaedic Association.[96]

Data analysis is continuous and extensive. 'Completeness' analysis is carried out annually and is reported by hospital unit in the annual report.[89] Key information on implants, including reoperation rates and five- and 10-year implant survival rates, is reported to inform clinicians and implant manufacturers on the success of devices over time.[89] The SHAR data are also used extensively in national and international research, with 29 peer-reviewed articles published so far in 2019 and 20 in 2018.[97] Research indicates that the SHAR has been effective in reducing repeat surgeries. For example, a recent international comparison, which included Australia, revealed that Sweden had fewer comorbidities, higher five- and 10-year survival rates, and had the lowest percentage of repeat surgery in which it is necessary to replace all or parts of an implanted device.[98]

Swedish Web-system for Enhancement and Development of Evidence-based care in heart disease Evaluated According to Recommended Therapies, Sweden

The Swedish Web-system for Enhancement and Development of Evidence-based care in heart disease Evaluated According to Recommended Therapies (SWEDEHEART) was created in 2009. It merged existing Swedish cardiac registries via a single online web-based interface.[99] Included registries are the:

- Swedish Coronary Angiography and Angioplasty Registry (SCAAR) (established 1998)
- Swedish Register of Information and Knowledge about Swedish Heart Intensive Care Admissions (RIKS-HIA) (established 1992)
- Secondary Prevention after Heart Intensive Care Admission (SEPHIA) (established 2005)
- Swedish Transcatheter Cardiac Intervention Registry (SWENTRY) (established 2010, formerly TAVI)
- Swedish Cardiac Surgery Registry (established 1992)
- Swedish National Cardiogenetic Registry (currently under development).[100]

The stated purpose of the SWEDEHEART is to support the development of evidence-based therapy for cardiac disease by providing continuous information on patient care needs, treatments, and treatment outcomes.[101] The SWEDEHEART is hosted at the Uppsala Clinical Research Center (UCRC), which is part of Uppsala University and Uppsala University Hospital, Uppsala. A not-for-profit research centre established in 2001, UCRC is Sweden's largest clinical research centre and first Centre of Expertise for National Quality Registries. It hosts more than 20 quality registers on behalf of the Swedish Association of Local Authorities and Regions (SALAR).[100]

The SWEDEHEART is financed by the SALAR, the Swedish State and the Swedish Heart-Lung Foundation. It is also supported by the Swedish Society of Cardiology, the Swedish Society of Thoracic Radiology, the Swedish Society of Thoracic Surgery, and the Swedish Heart Association.[101]

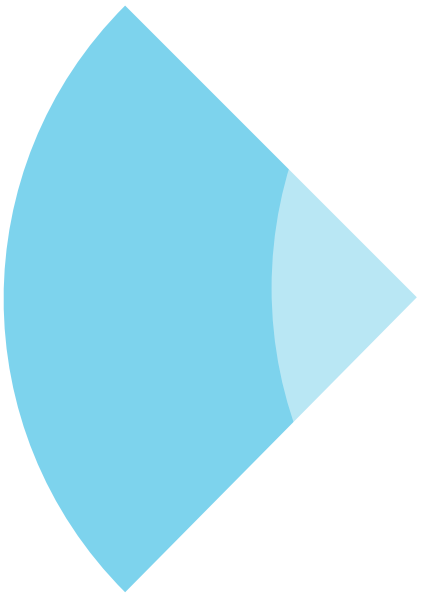
Every hospital in Sweden that provides care for cardiac patients participates in the SWEDEHEART, 72 hospitals in total in 2018.[101] The SWEDEHEART records patient characteristics, treatments, and outcomes.[102] Reporting is done by clinicians during treatment. As an interactive interface, the SWEDEHEART both collects and provides key information to clinicians in real time. This example demonstrates how a patient undergoing angiography would be reported into the SCAAR registry via the SWEDEHEART database:

> The treating physician reports each procedure on-line via a web-interface directly from the catheterization laboratory … During the registration of a coronary angiography or PCI a mandatory question regarding the existence of any type of restenosis has to be answered. A detailed interactive presentation of all previously (in Sweden) treated coronary segments of the patient is displayed. Information about date, hospital and coronary segment together with name and dimension of stents used are shown. The treating physician must record any restenosis and, from April 2005, also information about acute occlusions in the specified stents. From 2007 also non-occlusive angiographical stent thrombosis is reported in the SCAAR.[103]

The SWEDEHEART allows immediate access to relevant information for a treating physician[104] and, as demonstrated above, through asking pertinent compulsory questions can also improve care immediately for a patient during treatment. This also allows for the rapid identification of adverse events and outliers. The registry also allows data to be collated and analysed at a patient, clinician, condition, hospital, or national level.[50] Changes are identified within and between hospitals, which, using risk prediction tools and decision support, contributes to continuous improvement efforts for participating cardiac units.[101] Patient information is regarded the same as a patient's medical record and so is deidentified if utilised externally.[50] Annual reports are available publicly (in Swedish and English) in the SWEDEHEART annual report for all registries within the SWEDEHEART.[105] In 2018, 69 peer-reviewed publications were produced from the SWEDEHEART data.[101]

Quality improvement mechanisms are included in the SWEDEHEART. In 2011, the SWEDEHEART Quality Index was introduced, with 11 indicators that 'reflect the quality of the whole chain of patient care'[101], and the scores for each hospital are included in their annual report. Since 2011, all indicators have shown continuous improvement and improved compliance with national guidelines, which has been attributed to the SWEDEHEART.[101,106] Further, a monitor visits approximately 20 hospitals each year to audit the program.[104] A 2013 user survey found strong support for the SWEDEHEART.[101]

Every Swedish Quality Registry works with the Office for National Quality Registries. They are required to have a national steering board, operational design or decision group, reference groups and expert group.[50] Patient representation is required on the steering committee.[50] The SWEDEHEART's governance structure consists of Working Groups of experts for each registry[101], overseen by the SWEDEHEART steering committee.[101] Committee members include operational managers, healthcare professionals, patients and researchers.[50] Each Swedish registry also has a central data controller (CPUA) who has responsibility for the overall quality of the register.[50]



Key points

The characteristics of state-led CQRs include:

- The capture of population-wide data to facilitate clinical outcome quality improvement on a national scale
- Funding by government organisations or directly through state or national health departments. The SWEDEHEART has shared ownership and funding with several stakeholder groups.

Data collection, hosting and analysis mechanisms:

- All utilised secure online database technology, either purchased, maintained or developed by state organisations
- The CCR, the NBoCA, the PERFECT Stroke, and the SHAR were operated by government-funded organisations that were established to carry out data collection and statistical analysis for multiple CQRs
- The CSRS and the SWEDEHEART engaged external research institutions to carry out data collection and statistical analyses
- The SWEDEHEART, the SHAR and the PERFECT Stroke had databases that interconnected with other state registries. These were utilised for data collection, validation, or to monitor prospective outcomes
- The PERFECT Stroke extracted all data from existing patient databases and so required no clinician or health service involvement
- The NBoCA utilised electronic patient records to monitor patients prospectively
- The SWEDEHEART, the SHAR, the PERFECT, the CSRS and the CCN included mandatory reporting requirements that were legislated at a local (CSRS, CCN) or national (SWEDEHEART, SHAR, PERFECT) level. Reporting to the NBoCA was voluntary, with patients given the option to opt out of participation.

Governance, benchmarking and quality improvement mechanisms:

- All included multi-layered oversight from government organisations and input from peak bodies or expert clinicians
- All utilised registries for benchmarking health services to inform quality improvement
- All outcomes or benchmark criteria were determined by clinical advisory working groups, expert panels/committees
- The SWEDEHEART, the SHAR, the CCR and the CSRS provided continual access or ownership of data by health services to facilitate continuous quality improvement
- The SWEDEHEART and the SHAR provided continuous access to data for clinicians and patients
- The SHAR provided continuous access to product information for implant manufacturers through a separate online portal
- All included public reporting of outcomes to provide transparency regarding hospital performance
- All allowed data to be accessed with permission for research
- The CCR and the NBoCA prioritised consumer access to information
- The SWEDEHEART, the SHAR and the CCR included consumer participation in oversight committees.

Stakeholder-led, state-funded clinical quality registries

Stakeholder-led, state-funded CQRs are registries that were initiated by clinicians or peak body interest groups and are now funded by government departments or affiliated organisations with or without funding contribution from other non-government sponsors. Their governance structures included oversight or regulation by government departments or agencies. Stakeholder-driven, state-funded CQRs include the:

- Australian and New Zealand Intensive Care Society (ANZICS) – Adult Patient Database (APD), Australia
- Australian and New Zealand Liver Transplant Registry (ANZLTR), Australia
- CorHealth Ontario (formerly Cardiac Care Network of Ontario (CCN) and Ontario Stroke Network), Canada
- Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Australia
- Danish Head and Neck Cancer database (DAHANCA), Denmark.

Australian and New Zealand Intensive Care Society Adult Patient Database, Australia

Australian and New Zealand Intensive Care Society (ANZICS) is an advocacy group established in 1975 by physicians, surgeons and anaesthetists working in intensive care. It has been a Specialist Society of the Royal Australasian College of Physicians since 1980.[107] The ANZICS Centre for Outcome and Resource Evaluation (ANZICS CORE) was established in 1992 to provide benchmarking and auditing services for intensive care units (ICUs) in Australia and New Zealand. The Adult Patient Database (APD) was one of the registries established by the society in 1992.[107,108] Other CORE registries include the Paediatric Intensive Care Registry (ANZPIC), Critical Care Resources (CCR), and the Central Line Associated Blood Stream Infection Registry (CLABSI).[109] The ANZICS CORE also provides user pays ICU Registry Services internationally, to Oman, Iran and Hong Kong.[109]

The ANZICS office is in Camberwell, Victoria.[107] The CORE is funded by the Australian state and territory Departments of Health and the Health Quality and Safety Commission New Zealand.[108] It also receives funding from national and international agencies such as College of Intensive Care Medicine, the Australian Organ and Tissue Authority (AOTA), the Agency for Clinical Innovation – New South Wales, and the Health Round Table. Research Agencies that provided funding in 2017 include the Australian and New Zealand Intensive Care Research Centre, Monash University, The George Institute, the University of Adelaide, and the SAX Institute. The ANZICS CORE also collaborates with several international organisations.[109]

All Australian and New Zealand Intensive Care Units are invited by the ANZICS to contribute to the ANZICS CORE Registries. According to the ANZICS CORE APD Activity Report, 90.4% of ICU units in Australia and 58.6% in New Zealand participated in 2018, covering over 95.2% of all ICU admissions bi-nationally.[108] The APD has registered more than 2.4 million individual ICU episodes of care since 1992, making it one of the largest ICU registries worldwide.[108]

The purpose of the APD and the other CORE registries is to produce comparative benchmarking reports for Australian and New Zealand ICUs, to identify and analyse outlier ICUs, to provide data quality training to ICU staff, and to assist research into ICU improvement and patient outcomes.[107,108] The APD collects de-identified data from intensive care episodes every quarter from intensive care units in Australia and New Zealand.[107]

Data collection is carried out through an online secure portal, the CORE portal, via the Core Outcome Measurement and Evaluation Tool (COMET). The COMET Software is provided to participating ICUs to assist in data collection. Data collection forms are also available on the ANZICS website. Templates are provided for different datasets.[110,111]

Quarterly dates are set by the ANZICS for participating ICUs to upload data directly into the COMET.[110] Submissions produce a validation report which is sent back to the unit. After this information is validated, it is uploaded into the CORE central database. Additional validation reports are sent to sites where correction may be required, and data are also subject to internal APD audit processes.[110]

Data are then grouped by hospital classification and analysed by many variables, including age, length of stay, the ANZROD Standard Mortality Risk, and the Standardised Mortality Ratio (SMR).[108] These data are then used to benchmark the performance of the contributing units.[108,109] Funnel plot graphs are provided to participating ICUs so performance can be compared to other units, and outliers with higher SMRs are identified[108] and investigated. Quarterly risk adjusted reports are then provided to individual units and jurisdictional data review committees.[111] Reports are also produced by the ANZICS CORE include standard outcome reports for ICUs, regional reports for jurisdictional or regional liaison committees to review outcomes, as well as user requested data analyses. All participating hospitals have unrestricted access to their own data.[111] Routine reports can be generated by ICUs using these data via the COMET software.[111] The ANZICS also publish a publicly available ANZICS CORE annual report (2017 latest).[109] An APD Activity Report is also published annually.[108] The APD and other CORE registry data are also available for research purposes, with the ANZICS producing 13 peer-reviewed articles from the APD data in 2018.

Oversight for the APD is provided through the ANZICS Board of Directors, with oversight provided by two groups: the Jurisdictional Advisory Group (formerly the National Intensive Care Registry Steering Committee), with representatives from all jurisdictional funding agencies; and the CORE Advisory Committee, which in 2017 included representatives from the ANZICS Executive, the ANZICS Clinical Trials Group, the ANZICS Safety and Quality Committee, the ANZICS Paediatric Group, the CORE Working Groups including the Research Publication and Outlier Working Groups, and the College of Intensive Care Medicine (CICM) trainees.[109]

Australian and New Zealand Liver Transplant Registry, Australia

The Australian and New Zealand Liver Transplant Registry (ANZLTR) is a collaboration between the liver transplantation units of Australia and New Zealand.[112] The first liver transplants in Australia and New Zealand were performed in 1985. In 1988, liver transplant units in Australia agreed to combine their data, and so the registry was established, and the first annual report produced. Funding from 1988 to 2000 was provided by the transplant units themselves. In 1999, when liver transplantation was established in New Zealand, the participating hospitals joined the register, establishing the ANZLTR register. Commonwealth funding was secured the following year in 2001.[113] The ANZLTR is currently funded by the Commonwealth Government, through the Australian Organ and Tissue Authority (AOTA). Additional funding from Astellas Pharma Australia was noted in the 2017 Annual Report.[114]

The ANZLTR purpose is to collect, collate and analyse data on the outcomes of treatment of patients with acute or end stage liver failure.[112] Currently, liver transplant units in Auckland, Brisbane, Sydney,

Melbourne, Adelaide and Perth participate in the register.[112]

The ANZLTR management committee oversees the operation of the register.[114] It was established in 2001 and currently includes the Head or Senior Consultant from seven participating liver transplant units. The ANZLTR continues to be owned and operated by liver transplantation units across the country.[112] It is hosted and maintained at Transplantation Services, Royal Prince Alfred Hospital, Sydney, New South Wales.[114] The ANZLTR coordinating centre is located at Princess Alexandra Hospital, Woolloongabba, Queensland.[114] Contact details for the registry refer to a manager at Austin Hospital, Heidelberg, Victoria.[112] Commonwealth funding allows for a data manager and report production costs, and since 2007, the costs of web-based program hosting, data entry and relevant software.

In 2003, the ANZLTR developed a web-based database to include historical and prospective data on liver transplant patients, expanding to include the collection of hepatocellular cancer data in 2005. It was funded by the liver transplant units until 2007.[113] Participating hospital staff within the liver transplant units input data directly into the register via the web-based interface.[114] Data are then fed back to transplant units to inform clinicians and facilitate quality improvement. The details of data input are not publicly available, however, the ANZLTR annual report includes de-identified demographic data, primary diagnosis, patient survival, graft outcome, cause of patient death, deceased donor information, living donor transplantation information, transplant waiting list outcomes, and cancer after liver transplantation, from 1985 to present.[114] Data are shared selectively for research purposes with management committee approval.[112]

The Australian Orthopaedic Association National Joint Replacement Registry, Australia

The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) was established by the Australian Orthopaedic Association (AOA) in 1999. It was implemented state by state until it became a national register in 2002.[115] Overall, the purpose of the AOANJRR is to improve and maintain the quality of care for individuals receiving joint replacement surgery. To achieve this, the AOANJRR has 10 aims, including provide demographic data and the use of different types of prostheses, determine variation in practice, identify patient characteristics that effect outcomes, analyse the effectiveness of different prostheses and treatment for specific diagnoses and analyse their survival rates, educate orthopaedic surgeons on the most effective prostheses and techniques to improve patient outcomes, provide surgeons with an auditing facility, provide information that can instigate tracking of patients if necessary, and provide information for comparison with other countries.[18]

All hospitals, private and public, undertaking joint replacement surgery in Australia participate, with 312 hospitals currently participating nationwide.[18] A patient information sheet is provided, and patients are given the option to opt out of the register.[116] The AOANJRR is funded by the Commonwealth Government through the Australian Government Department of Health.[18]

The Federal Board of the AOA nominate an AOANJRR Committee to develop policies for the operation of the AOANJRR. This committee reports directly to the AOA Board of Directors. The Board appoints a Director, who manages the registry and liaisons with hospitals, surgeons, and the government, and is also responsible for preparing the Annual Report.[117] External to the AOA is the AOANJRR Consultative Committee, which is an external committee of experts that is appointed and administered by the Commonwealth. It includes industry, government and consumer representatives, who meet quarterly and advise the AOA on the strategic direction of the AOANJRR. Committee members include representatives from: the Australian Government Department of Health (chair), the Therapeutic Goods Administration (TGA), the Prostheses List Advisory Committee (PLAC), Private Healthcare Australia (PHA), the Consumer Health Forum (CHF), the Australian Private Hospitals Association (APHA), the AOA, and orthopaedic sponsors or suppliers. The AOANJRR also collaborates with orthopaedic registers internationally.[18]

The AOANJRR collects information on hip, knee, shoulder, elbow, wrist, ankle and spinal disc replacement. More than 100,000 joint replacement operations are recorded nationally each year.[18] Data collection forms are available on the AOANJRR website for hip, knee, knee osteotomy, multi-joint, shoulder and spinal disc replacement surgeries. They are brief two-page forms that ask for basic patient and surgeon information, diagnosis (tick boxes), and then the make, model and identification number of all components inserted during the joint replacement surgery.[118] A pilot Patient Reported Outcome Measures (PROMs) project is currently underway, where patients are asked to report 'on their general health status, pain, function, pre- and post-operative comorbidities as well as pre-operative expectations and post-operative satisfaction' via an automated web-based system commenced in 2018.

Hospitals are responsible for the dissemination of these paper-based forms and their collection, filled out in theatre at time of the surgery.[18] These forms are currently collected as a paper-based system, although the AOANJRR website indicates that this was due to

hospital preference for a paper-based system and electronic collection is feasible when supported by hospital infrastructure in the future.[119]

The paper data collection forms are then sent by the hospitals to the AOANJRR, which is currently hosted by the South Australian Health and Medical Research Institute (SAHMRI). The SAHMRI has been contracted to carry out data collection and analysis for this register.[18] Data are validated through comparison with state and territory health department data, which is provided on an individual patient level, using hospital and patient identity number with subsequent matching undertaken on relevant procedure codes and appropriate admission time period. 94% validation rates are noted on the AOANJRR website.[119]

However, the AOANJRR notes that they collect information on more procedures than information provided by the departments.[119] Outcomes are determined by the research team at the SAHMRI using the 'Kaplan-Meier estimates of survivorship'.[18] Additional data are obtained through state and territory departments, and mortality information is obtained utilising the National Death Index (maintained by the Australian Institute of Health and Welfare AIHW) biannually.[18]

Data from the AOANJRR are disseminated and provided to facilitate clinical outcome quality improvement in several ways. Since 2017, the AOANJRR has provided surgeons with access to their individual data and downloadable reports through a secure online portal.[18] Another secure online portal has been provided for orthopaedic companies to monitor their own prostheses, and for Australian and regulatory bodies in other countries to monitor the effectiveness of prostheses used in Australia.[18] Both online portals provide 'real time' automated reports for users.[18] Hospitals can access this information to facilitate internal quality improvement measures. For example, data from the AOANJRR can be used to identify protheses shown to have 'less satisfactory outcomes' and hospitals can replace their use with ones that are shown to have better outcomes.[18] The registry also releases a publicly available Annual Report, which includes 10- and 15-year outcome data, and ad-hoc supplementary reports that are published on an ad-hoc basis, 11 published in 2018.[18] Data have also been utilised for approved research, with 303 peer-reviewed publications in 2017.[18]

CorHealth Ontario (formerly Cardiac Care Network of Ontario and Ontario Stroke Network), Canada

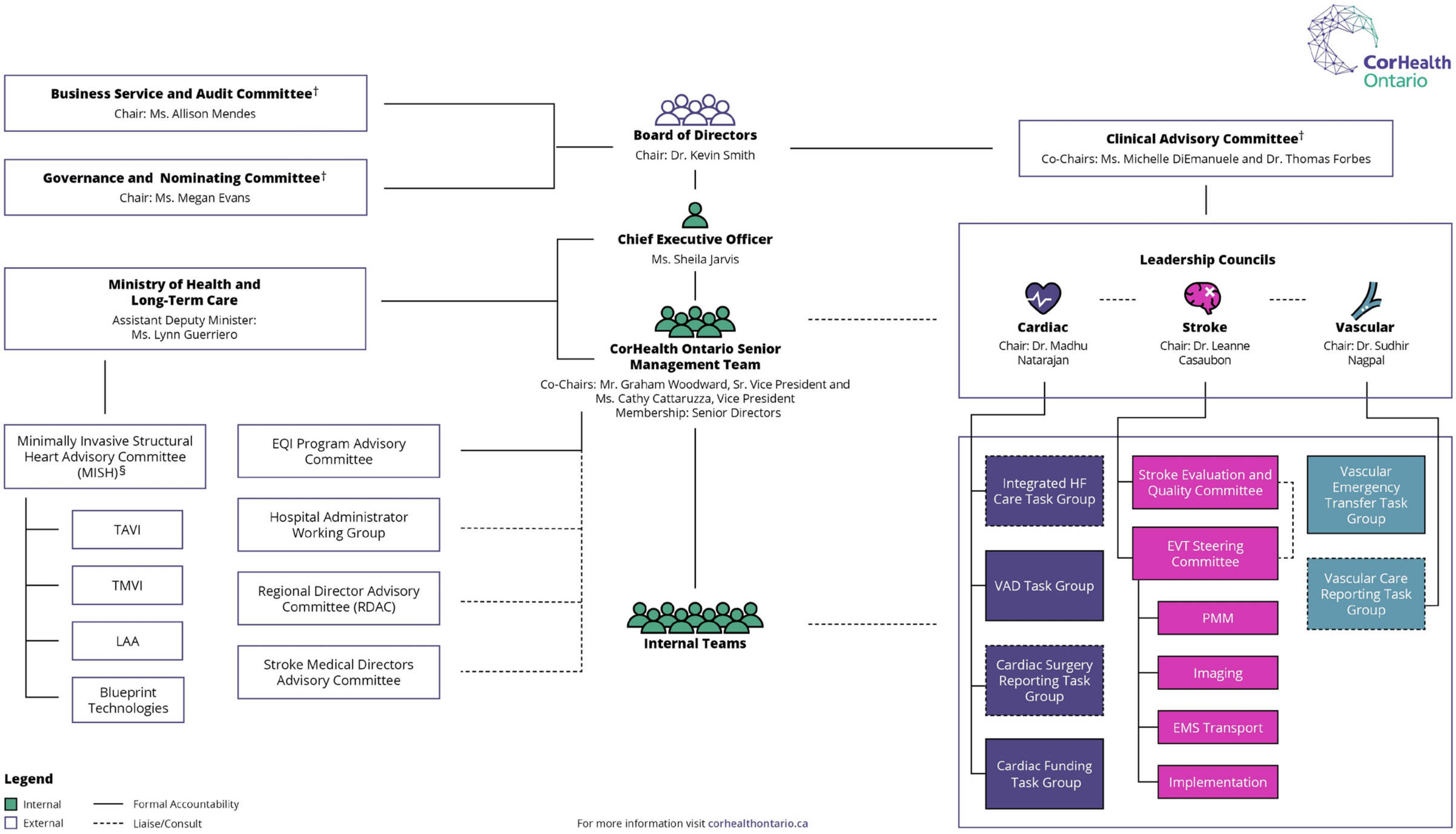
The CorHealth Ontario was established in 2016 through the merger of the Cardiac Care Network of Ontario (CCN), established 1994, and the Ontario Stroke Network. It aims to advance cardiac, stroke and vascular care for patients. Forty health services throughout Ontario, Canada, contribute to the registries. The CorHealth Ontario receives financial support from the Heart and Stroke Foundation of Canada[120] and government funding through the Ministry of Health and Long-Term Care (MOHLTC).[121]

The CorHealth Ontario governance structure includes a Board of Directors that oversee Clinical Advisory Committees for all three disease groups – cardiac, stroke and vascular. Each Advisory Committee has Task Groups of experts on topics of concern. The CorHealth Ontario Senior Management also work with the MOHLTC as well as other Advisory Committees and working groups. A visual outline of the Advisory and Task Group Structure can be found on the CorHealth Ontario website[122], as provided in Figure 5.

Data entry is carried out by cardiac and vascular coordinators at member health services via standardised forms. They record information such as cardiac wait times, comorbidities, procedural details, and complications for recipients of cardiac or vascular procedures. Data are then available to hospitals and health services that are members of CorHealth and contribute to the registry, for care coordinators clinicians, hospital administrators, decision support and finance staff. It is not made available publicly, but access can be granted for research purposes only.[123]

Data are fed back to clinicians through Standard Reports that are sent via email back to hospitals for their own internal analysis. Data are available for extraction 15 minutes after entry into the registry. The CorHealth utilises the information to report procedure volumes and identify opportunities for quality improvement to hospitals, government departments and other stakeholders. The MOHLTC and Local Health Networks also receive regular reports and can request information as needed.[123]

Figure 5: CorHealth Ontario's Advisory and Task Group Structure 2018–19 – Expanded*[122]



*Source: https://www.corhealthontario.ca/img/CorHealth-Ontario-Advisory-and-Task-Group-Structure2018-19-Expanded.jpg

† Board of Directors Subcommittee.

§ CorHealth Ontario acts as the secretariat for MISH. CorHealth Ontario also participates in the Ontario Telestroke Committee which has a shared governance model.

The Danish Head and Neck Cancer database, Denmark

The Danish Head and Neck Cancer database is a nationwide clinical quality database managed by the Danish Head and Neck Cancer Group (DAHANCA), established in 1976. It is one of more than 60 CQRs that form the Danish Multidisciplinary Cancer Groups (DMCG). It aims to improve clinical outcomes for patients with head and neck cancer through multidisciplinary care.[124] The DAHANCA is recognised worldwide as leaders in their field.[124]

The DAHANCA was started by a medical physicist, Mogens Hjelm Hansen, in the Department of Oncology, Aarhus University, in the 1960s.[124] It eventually became a full national register in the 1970s, beginning with larynx cancer but expanding to include all cancers of the larynx, pharynx and oral cavity to form the national DAHANCA clinical database.[125] From 1995 the database included sub-databases for thyroid cancer, unknown primary neck tumors, salivary gland tumor, and sinonasal cancer. In 2000, the DAHANCA was upgraded to a secure central web-based database (OCX), allowing for immediate quality and validity checks of all data input into the system.[124] In 2011, the DAHANCA transferred from a private research database to a public clinical quality database, government funded and hosted by the Danish Clinical Quality Program – National Clinical Registries (RKKP).[124,125]

The DAHANCA records all patients with head and neck cancers and tracks their progress over time. Approximately 1,400 new patients are registered each year, with approximately 16,000 patients registered.[125] Clinicians provide patient data via paper registration forms, available online. Forms are available for Inclusion (new patient), On study (patient already in the register), Recurrence, Primary treatment, Control during treatment and comorbidities via the Charlson Comorbidity Index.[126] There are approximately 100–150 different parameters.[125] Data input is carried out by 'a few knowledgeable people, mainly senior specialist doctors'[124] at oncology centres across the country. The online secure database has error indicators built in to the interface so users are alerted when inputting data.[124] This allows for local, very high-quality data to be recorded. Irregularities or outliers are identified immediately, allowing for completeness, continuous notification and quality improvement.[124] Participating oncology centres have access to and ownership of their own data.[125]

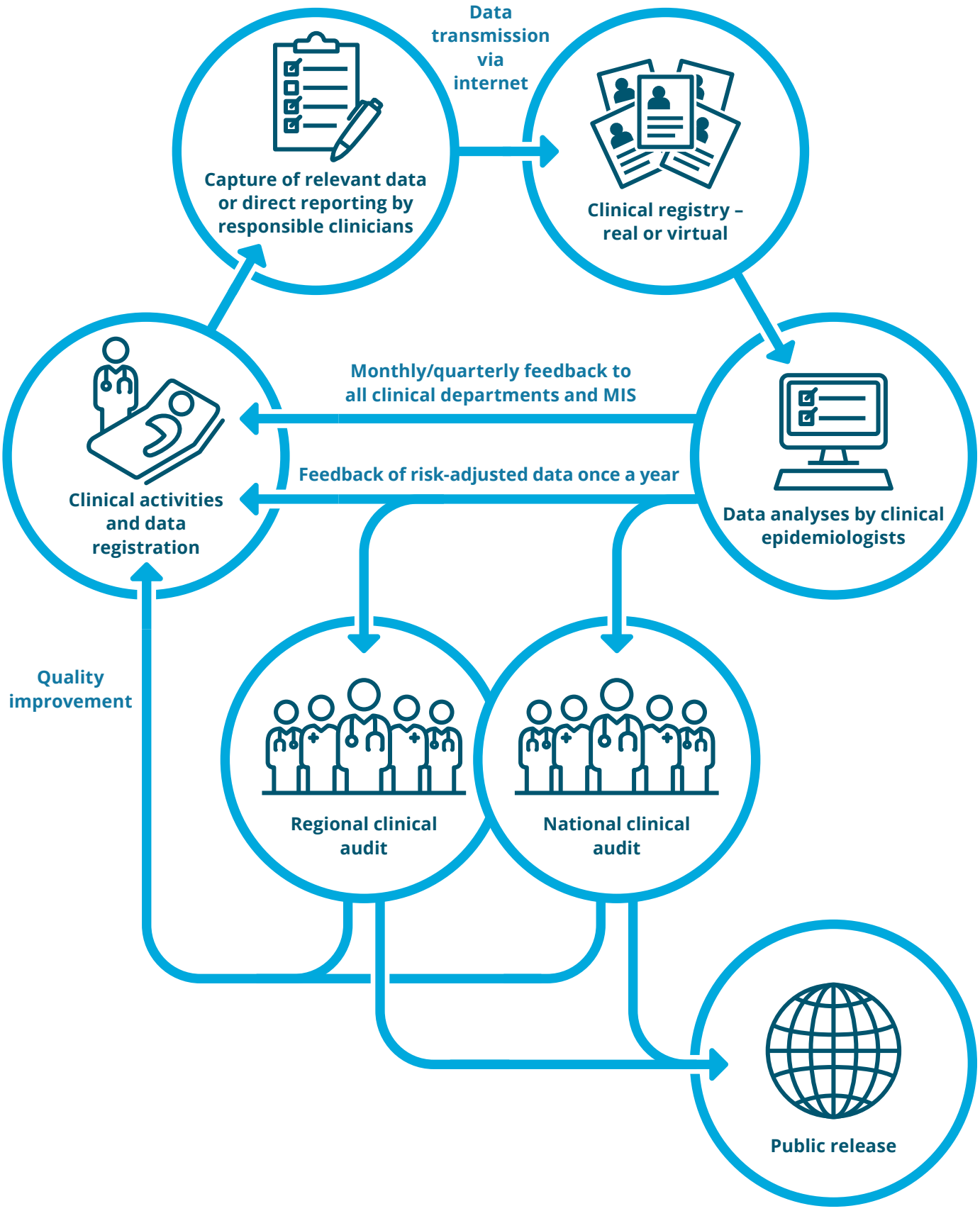
Denmark has a long history of registering cancer treatment and outcomes. The Danish Cancer Registry was established in 1942 by the Danish Cancer Society as a clinical population-based cancer registry.[127] The Danish Cancer Registry, along with the National Patient Registry, Medical Birth Registry, and Cause of Death Registry[50], which are all hosted by the Danish Health Data Authority (Sundhedsdatastyrelsen), records vital health information digitally for every Danish citizen, traceable to an individual level through Personal Identification Code. They are used to monitor improvements in effectiveness, patient safety and access in the Danish healthcare system, as specified by the Danish Healthcare Quality Programme (DDKM).[50] The Danish Cancer Registry is also part of the Association of Nordic Cancer Registries (ANCR), which, along with neighbouring country cancer registries that produce comparable data, contributes to NORDCAN, the database of cancer statistics for Nordic countries.[128] The data in the DAHANCA are verified through comparison with the Danish Cancer Registry on an ongoing basis.[124,125]

While these population-based registries inform research and healthcare improvements at a population level, National Quality Registers form an essential second tier which focus on improving clinical outcomes. Notification is compulsory. National Quality Registries are mandated by law, without the need for patient consent.[50] Each National Quality Registry has a steering group, or professional board, appointed by professional societies.[50] The DAHANCA operates the registry and selects members for its steering committee.[125] The DAHANCA is overseen by the RKKP. The RKKP provides a visual diagram of Denmark's National Quality Registries clinical outcome quality improvement processes[46], as provided in Figure 6.

Registries feed monthly indicator results into the regional business intelligence system where they are distributed to all levels of management and individual clinical teams in order to facilitate clinical quality management.[46,50] As the National Quality Registries focus on clinical outcomes rather than research, the RKKP reports are only available in Danish, although their clinician handbook and other resources are publicly available on their website.[46] Note that some grey literature information gathered for this report has been translated through Google Translate.[125]

The DAHANCA is financed by the Danish government through the RKKP and the Danish Multidisciplinary Cancer Groups.[46,125] Sponsorship for research projects has occurred through the Danish Cancer Society and the Medical Research Council.[124] The responsibility and operation of the DAHANCA database lies with individual oncology centres[125], with central DAHANCA staff located at the Department of Experimental Clinical Oncology at Aarhus University Hospital, Aarhus.[124]

Figure 6: Diagram illustrating important phases in the Danish Clinical Registries[46]



* Source: https://www.rkkp.dk/in-english/

All New Zealand Acute Coronary Syndrome Quality Improvement Programme

The primary aim of the All New Zealand Acute Coronary Syndrome Quality Improvement Programme (ANZACS-QI) is to support secondary care clinicians to implement appropriate, evidence-based guidelines to manage acute coronary syndrome (ACS), and meet national performance standards. The ANZACS-QI uses two registry cohorts as complementary data sources, the ACS Routine Information cohort and the ACS-CathPCI. The ACS-CathPCI registry cohort is a web-based software that enables secondary care clinicians to collect data on ACS patients, coronary angiography and percutaneous coronary intervention (PCI) procedures in all New Zealand hospitals. The ACS routine Information cohort is derived directly from national health datasets.[129]

The ANZACS-QI was established in 2012, when the New Zealand National Cardiac Network proposed a combined national ACS-CathPCI Registry to be governed under the auspices of the New Zealand branch of the Cardiac Society of Australia and New Zealand (CSANZ). The registry is Funded by the New Zealand Ministry of Health.[129] Data management is provided by the National Institute of Health Innovation and the software is licensed by Enigma Solutions.[130] By November 2013, the ANZACS-QI was implemented in all 20 publically funded District Health Boards (DHB) and their 41 hospitals. In New Zealand, ACS patients are predominately admitted and managed in public hospitals.[129]

Governance of the ANZACS-QI registry data are by the ANZACS-QI governance group on behalf of the CSANZ. The governance group includes clinical leaders of the Cardiac Clinical Networks of the four New Zealand regions, the Chairs of the New Zealand interventional working group, and the CSANZ, Heart Rhythm New Zealand, nursing, consumer, Ministry of Health and the national Health Information Technology Board representatives.[129]

Clinical staff from participating hospitals are responsible for entering data. Patients admitted to hospital are registered using an ANZACS-QI web form. The form collects demographic, risk factor, investigation, management, and in-hospital outcome data for all patients admitted with a suspected ACS. Patient demographic data can be located within the ANZACS-QI registry, via the Ministry of Health's Health Identity Programme. These data are then automatically populated into the web form. There are minimum requirement for form completion, which is assessed monthly by DHB completion reports and provider initiated ANZASC-QI system reports.[129]

Data quality is assured through a mandatory dataset, in-from definition statements, in-form validation rules, automatic data capture from source datasets on demographics and laboratory results, as well as standardised user training and regular auditing. Audits of participating hospitals is conducted annually.[129]

Data are reported in real-time to support DHB and hospital-level quality improvement. Users can access evidence-based indicators, allowing for the examination of individual-level data on patients not meeting certain criteria. Summary reports containing nationally agreed indicators data are generated monthly, quarterly and annually. These reports allow for comparison of DHBs and national averages.[129]

Registry of biologics use in Danish rheumatoid arthritis patients, Denmark

The Danish Database for Biological Therapies in Rheumatology (DANBIO) was established in 2000 by the Danish Society of Rheumatology and the Danish Institute for Rational Pharmacotherapy.[131] The DANBIO aims to monitor clinical quality of treatment using selected quality indicators for patients with rheumatoid arthritis in Denmark.[132]

Since 2006 it has been registered as a National Quality Register by the Danish National Board of Health and is now government funded at a regional level. Pharmaceutical companies that provide biological treatments in rheumatology contribute through unrestricted grants but have no influence on the operation of the register.[131]

Reporting has been mandatory since 2006 for all patients with rheumatologic diseases treated with biological drugs at a hospital or a private rheumatologic clinic. Other patients with other diagnoses that are treated with biological disease-modifying antirheumatic drugs are also included in the register.[132] Clinicians report diagnosis, year of diagnosis, age, and sex at a patient's initial appointment to the DANBIO. At follow up visits, patient-reported outcomes for disease activity, pain, fatigue, functional status, and physician-reported objective measures of disease activity, treatment, C-reactive protein and imaging, as well as variables such as quality of life, sociodemographic factors, lifestyle, and comorbidity are registered. PROMS are recorded via touchscreen at follow-up appointments. As a lifelong condition, reporting is updated at least annually.[132]

As clinicians update patient details on the register at least annually, quality indicators are part of the register design. Goals indicate whether patients are treated to 'target', with a standard indicator set by the DANBIO steering committee. Indicator results are published at a national, regional, and hospital department level in the Annual Clinical Quality Report.[132]

The DANBIO has a steering committee with experts from around the country and representatives from the Danish Society of Rheumatology, Junior Rheumatologists and hospital owners.[131] The daily administration is handled by two staff members in the DANBIO general office at Rigshospitalet, Glostrup.[132] The DANBIO infrastructure is hosted by the RKKP.[46] Their quality improvement structure can be seen in Figure 6.

Registries feed monthly indicator results into the system where they are distributed to all levels of management and individual clinical teams in order to facilitate clinical quality management.[46] Registry data are also used to monitor the quality of the national speciality plan with the objective of safeguarding high quality in tertiary care.[50,132]

Key points

Summary of stakeholder-led, state-funded CQRs characteristics:

- Benefit from engaged participants who developed their registry based on need
- Were primarily funded government organisations but were managed or owned by a not-for-profit stakeholder organisation. APD was also a user-pays service.

Data collection, hosting and analysis mechanisms:

- The ANZLTR, the DANBIO and the APD utilised secure online database technology for health services or clinicians to input data
- The CorHealth, the DAHANCA and the AOANJRR used paper-based data collection. The AOANJRR cited incompatibility between different hospital systems as a reason for paper-based data collection. All then input data into their own databases for analysis
- The ANZICS (APD) developed their own interactive interface that is now marketed as a commercial CQR tool internationally
- The DANBIO and the DAHANCA were operated by a government-funded organisation that was established to carry out data collection and statistical analysis for multiple CQRs
- The AOANJRR contracted an external research institution, the SAHMRI, to carry out data collection and statistical analyses
- The CorHealth sent data back to hospitals to carry out their own analysis
- The AOANJRR and the ANZLTR maintained critical databases for government organisations
- The DANBIO and the DAHANCA had databases that interconnected with other state registries. These were utilised for data collection, validation, or to monitor prospective outcomes
- The AOANJRR also utilised existing government databases to complete patient information
- The DANBIO and the DAHANCA required mandatory reporting legislated in Denmark
- While reporting to the Australian CQRs was not mandatory, all reported high participation rates. The APD claimed to be the largest intensive care CQR in the world.

Governance, benchmarking and quality improvement mechanisms:

- All had their own internal boards and committees, with experts selected from stakeholder organisation members or expert clinicians
- All had oversight and regulation provided by government organisations or government organisations were represented in their governance structures
- All outcomes or benchmark criteria were determined by clinical advisory working groups, expert panels or committees of experts
- The AOANJRR, the CorHealth and the APD included external funding organisations, such as industry sponsors, in their governance structures
- The AOANJRR included consumer participation in oversight committees
- The APD, the AOANJRR, the CorHealth and the DAHANCA provided health service ownership of and continuous access to their data, to facilitate continuous quality improvement
- The AOANJRR and the DAHANCA allow direct access by clinicians to their own data
- The AOANJRR provides a secure online portal for orthopaedic companies and government regulatory bodies to monitor their own prostheses
- All CQRs utilised registries for clinical outcome quality improvement
- The APD, the ANZLTR, the AOANJRR, the DAHANCA and the DANBIO included public reporting of outcomes
- The CorHealth does not provide public annual reports. Reports are provided to the Ministry of Health and Long-Term Care and directly to participating hospitals
- All allowed data to be accessed with permission for research.

Stakeholder-led and funded clinical quality registries

While the majority of stakeholder-led CQRs examined were supported by state funding or state-funded organisations, stakeholder-driven CQRs were also identified that were primarily funded by end users, or by pharmaceutical, private health or stakeholder organisations. While they may have included some state funding through government organisations or were contracted by government departments to provide select services, the state was not their primary source of funding.

Stakeholder-led CQRs that were stakeholder or user funded included the:

- Dutch Audit for Treatment of Obesity (DATO), Netherlands
- Electronic National Renal Registry (NRR) (formerly The Malaysian Dialysis and Transplant Registry), Malaysia
- Pancreatic Surgery Registry (StuDoQ|Pancreas), Germany.

Dutch Audit for Treatment of Obesity, Netherlands

The Dutch Audit for Treatment of Obesity (DATO) was established in 2014, following an increase in bariatric surgery in the 1990s, to improve the quality of bariatric surgery in the Netherlands.[133] The registry is hosted and operated by the Dutch Institute for Clinical Auditing (DICA), a not-for-profit organisation.

Participation in the DATO is national and mandatory. All 18 Dutch bariatric centres from hospitals throughout the Netherlands participate in the DATO. A scientific committee and clinical audit board was established to oversee the Registry, which included representatives from all 18 centres. These sit under the DICA scientific bureau, which provides data analysis support, and is informed by the DICA methodological board, directional board and privacy committee, which oversee all Dutch clinical registries under the DICA (Figure 2).[133]

In the Netherlands universal health system, private insurance providers are required to fund quality registers through their umbrella organisation, Zorgverzekeraars Nederland (ZN). The ZN provided the funds to establish and maintain the DATO.[133] The DICA provides a secure online interface for clinician or hospital input of data.[134] Hospitals either use a 'batch file' method, where data are extracted from their medical record software and uploaded into the DATO, or clinicians input patient data directly into the DATO via the DICA interface.

The DATO collects information on patient characteristics; pre-surgery screening requirements including co-morbidities (using the Charlson Comorbidity Index) and patient reported outcome measures (PROMs) (using the RAND-36 questionnaire); previous procedures, details of the surgery undertaken including data, surgeon, procedure, and complications; and follow up, including evaluation of co-morbidities and complications, and PROMs.[133]

Clinical quality improvement is possible through the DATO as hospitals are granted access and permission to analyse their own data, while keeping other hospital data anonymous.[133] The DICA interface provides standardised reports and detailed quality indicators, through a secure web-based interfaced called 'myDATO'. Furthermore, every two years, the DICA employs an external organisation to monitor data quality, where the DATO data are compared to patients electronic health record data to verify for accuracy in reporting.[133] The DICA also publishes an annual report (in Dutch). The DATO is also able to be used for research, with permission, and several peer-reviewed articles are available based on the DATO data.

Electronic National Renal Registry, Malaysia

The Malaysian Dialysis and Transplant Registry was established in Malaysia in 1992 by the Department of Nephrology, then moved to the Malaysian Society of Nephrology (MSN) in 1995. In 2017 it upgraded to an online format and became the Electronic National Renal Registry (NRR). NRR is an independent not-for-profit organisation operated by the MSN in partnership with the National Kidney Foundation with financial support from the Ministry of Health Malaysia through the Clinical Research Centre. Some funding is also received through corporate and not-for-profit sponsors.[135]

The NRR aims to determine the disease burden, outcomes and factors influencing End Stage Renal Disease (ESRD) and Renal Replacement Therapy (RRT) in Malaysia, to facilitate research on RRT and ESRD, and to maintain the national renal transplant waiting list.[136] The NRR compares outcomes achieved with 'gold standards' or comparative benchmarks for specific health outcomes, to determine disparities and identify 'opportunities for improvement'.[135]

The NRR collects information on patients with ESRD on renal replacement therapy. It also provides a national database for deceased donor kidney allocation (MOSS) and collects data for the Malaysian Registry of Renal Biopsy (MRRB). The NRR has plans to expand to include the Living Kidney Donor Registry and the Interventional Nephrology Registry.[137]

Hospitals that treat patients with end stage renal disease throughout Malaysia report voluntarily to the register via their online platform, covering all 16 regions. Patients can opt out. When clinicians log in to the online platform, they can access summary statistics for their health centre for the current year. Announcements from the NRR can be viewed and they are alerted to pending tasks that are required. Multiple patient records can be uploaded in the same session. Clinicians are required to register new patients and complete Notification and Outcome Notification forms.[138] Clinicians also submit updates on each eligible patient at least annually during their routine appointments[135] through a condition specific Annual Return form and Quality of Life (QOL) form, as well as a Peritonitis Form and Acute Rejection Form when relevant. Patient and condition specific measures are reported and categorised, as well as vascular access, prescriptions, funding for procedures, medication treatment, therapy and event information including surgical details and complications, vital signs, dialysis performance, lab data, blood transfusions, serology, and quality of life indicators. These are recorded via online stepped interactive forms, which allow clinicians to view patient history as records are updated. Once all sections are completed, the clinician can submit the completed record to the NRR.[139] Detailed instructions are available in Malaysian and English on the NRR website. Data are verified through cross-referencing with the National Vital Registration System.[136]

The NRR publishes detailed annual reports, available publicly, the last published in 2018 under the previous name of The Malaysian Dialysis and Transplant Registry, to provide transparency.[135] The Clinical Research Centre, part of the Ministry of Health Malaysia, utilises registry data to evaluate ESRD outcomes nationwide. Data are available to researchers on request. However, data are primarily gathered to monitor ESRD, improve clinical outcomes, and maintain the national renal transplant waiting list.[135]

The NRR is owned by the MSN. It is overseen by the National Renal Registry Advisory Board, which includes representatives from the Ministry of Health, Clinical Research Centre, Ministry of Education, private sector, and representatives from the MOSS, MBBB and MDTR steering committees.[135] Expert panels are appointed by the steering committees from around the country and contribute to the annual report. The NRR operational staff and the NRR database are situated at the MSN.[140]

Network for Improving Critical care Systems and Training, Sri Lanka

The Network for Improving Critical care Systems and Training (NICST) is a UK based non-profit organisation, operating in South Asia. The NICST was established in 2013, after researchers set-up the first national electronic critical care registry to enable continuous evaluation of critical care services in low and middle-income countries (LMICs).[141] The NICST operates as an acute-care, agile mobile data surveillance platform, enabling direct feedback to frontline clinical staff. Coupled with collaborative research and clinical training, the NICST's methodology helps to evaluate current processes and identify barriers and enablers to improve the quality of patient care, in LMICs.[142]

As part of the platform, the NICST operates several registries, including, cardiology; vascular surgery; critical care, neonatal and major laparotomy. The direct feedback to clinicians in real-time helps directly enhance frontline clinical care, while simultaneously enabling high quality research and benchmarking.[142] For example, data reported from the intensive care registry includes demographic and occupancy information, infectious episodes and adverse events. Checklists are provided, aimed at improving adherence to best practice guidelines. Additionally, the registry informs a national 24 hour bed availability system and has located ICU beds for over 4,800 patients. Data reported from the registry resulted in collaborative service evaluations, validation of prognostic models and research projects.[143]

A key feature of the registries design is a digital dashboard. The dashboard displays real-time de-identified information, supporting clinicians in routine clinical care by displaying trends in unit activity, severity of illness, bed occupancy and outcomes within their respective institution.[143]

Data input is voluntary. Data are entered via a secure cloud-based portal (mobile or desktop). Drop-down menus and check-box options are used, rather than free-text boxes. This is to reduce burden of data entry. Information on completeness of reporting is displayed monthly through dashboards, to assist ICU's achieve greater data completeness.[143]

The NICST is overseen by The Sri Lankan Ministry of Health and the Information and Communications Technology Agency (ICTA).[142] The NICST encompasses almost the entire network of state ICUs, including paediatric, neonatal and specialised units. It is funded by private donations and international research grants.[141]

The Pancreatic Surgery Registry (StuDoQ|Pancreas), Germany

Study, Documentation and Quality Center (StuDoQ) was set up in 2012 to improve quality outcomes through registers for several surgical procedures.[144] It is operated by the German society for general and visceral surgery, Deutsche Gesellschaft fYesr Allgemein- und Viszeralchirurgie (DGAV). The Pancreatic Surgery Registry (StuDoQ|Pancreas) was set up by the DGAV in 2013 as a national registry for quality control, risk assessment and outcomes research in pancreatic surgery in Germany.[52]

All surgical clinics in Germany and Austria can participate in the StuDoQ registries. Participation in voluntary and does not require DGAV membership.[144] The DGAV collects participation fees to fund the register. The DGAV is supported financially by its members.

The DGAV Executive Board of the StuDoQ Registry project oversees the StuDoQ|Pancreas Steering Committee. The DGAV employs professional personnel to maintain the registry. The Executive Board ensures that the registries operate according to the DGAV consititution.[52] The registry was evaluated using the German Network Health Services Research checklist for clinical registries.[52] No government oversight of clinical registries was identified.

Data are entered online by clinicians from participating clinics prospectively through a web-based tool, which is then deidentified for analysis. Validation is carried out by cross-checking with institutional medical data as part of annual pancreatic cancer centre certification processes.[52] Quality indicators are analysed, and benchmarking data are produced.[145] The StuDoQ registry data are then available to participating clinicians at any time through their secure webpage. Annual reports, with benchmarking data, are then sent to participating clinics only after the hospital department has confirmed that all eligible patients were included in the register.[144] Through access to registry data, the StuDoQ|Pancreas claims that surgeons are able to 'assess risk factors for impaired perioperative outcomes as well as guideline adherence on the institutional level, in comparison with the national average'.[52]

National Cardiovascular Data Registry, United States of America

The National Cardiovascular Data Registry (NCDR) began in 1997.[146] This suite of 10 registries hosted by the American College of Cardiology (ACC) includes both hospital and outpatient registries which aim to measure, benchmark and improve cardiovascular care.[147] The hospital registries include the:

- Chest Pain – MI Registry (acute myocardial infarction treatment)
- AFib Ablation Registry (catheter-based atrial fibrillation ablation procedures)
- CathPCI Registry (diagnostic cardiac catheterisation and percutaneous coronary intervention)
- ICD Registry (implantable cardioverter defibrillator and leads procedures)
- IMPACT Registry (paediatric and adult congenital treatment procedures)
- LAAO Registry (left atrial appendage occlusion procedures)
- PVI Registry (lower extremity peripheral vascular interventions, carotid artery revascularisation, and endarterectomy procedures)
- STS/ACC TVT Registry (transcatheter valve therapy procedures).[147]

Outpatient registries are the:

- Diabetes Collaborative Registry (outpatient diabetes and cardiometabolic care)
- PINNACLE Registry (outpatient cardiovascular care for coronary artery disease, heart failure, hypertension, and atrial fibrillation).[147]

Each registry within the suite has its own specific objectives, however the overall stated purpose of the NCDR is to help hospitals and private practices measure and improve the quality of their cardiovascular care, including improving patient outcomes and lowering healthcare costs through evidence-based practice.[147]

The NCDR partners with a variety of other organisations which support the work of one or more of the registries. Key partners include the American Academy of Paediatrics, American Association of Clinical Endocrinologists, American College of Emergency Physicians, American College of Physicians, American Diabetes Association, FIGMD (technology partner), Joslin Diabetes Center, The Society for Cardiovascular Angiography and Interventions, The Society of Thoracic Surgeons, and the ACC's Accreditation Services.[147]

Most participants are within the USA; however, some international hospitals and outpatient providers also participate in one or more of the NCDR registries. More than 2,400 hospitals and over 8,500 outpatient providers worldwide participate in the registries.[147]

The NCDR registries are online, and participants of can submit data using the free web-based data collection tool provided by the NCDR or choose to use a certified software vendor, a NCDR compatible data abstraction provider, to enter their data quarterly. For some registries, relevant data fields may be extracted and submitted directly from participants' Electronic Health Record. Each registry collects a different set of data, however, most registries include the collection of data around patient demographics, provider and facility characteristics, rates of adverse events, and selected performance and quality measures and outcomes in addition to their more specific criteria.[147]

The quality of data reporting is checked at the time of data submission through a confidential Data Quality Report (DQR) which ensures the data submitted are complete and consistent.[146] Annually, a national on-site audit program also randomly selects some participating providers for on-site audits. After being audited, sites receive a detailed report of the audit findings to assist them to improve the quality of their future data collection.[146]

Facilities which submit clinical data to the NCDR receive quarterly reports of their own data. Quarterly reports are risk-adjusted benchmark reports with performance measures and quality metrics to compare their sites' performance with that of others and aggregated national data. This feedback allows providers to track their progress, identify areas for improvement, and apply feedback to improve the quality of their daily practice. Some data are also available, through the ACC Public Reporting program, on the ACC's CardioSmart website, which searching by hospital name, address, zip code, or cardiac services provided. Hospital-specific and practice-specific registry data are not made publicly available unless the specific site has volunteered to share this publicly.[147]

Oversight of all the NCDR programs is provided by a management board and the Science and Quality Oversight Committee, reporting to the ACC Board of Trustees. Each registry has a steering committee which provides strategic direction and monitors the research and clinical activities of the registry. Reporting to the steering committee are three subcommittees: research and publications, clinical support team, and quality improvement. These subcommittees are responsible for managing a variety of registry and quality improvement projects.[148]

Key points

Summary of stakeholder-led, stakeholder-funded CQRs characteristics:

- Benefited from engaged participants who developed their registry based on need
- Funding was provided by stakeholder organisations through membership fees (StuDoQ|Pancreas, NRR), external sponsors including government and private organisations (DATO, NRR), or as user-pays services (StuDoQ|Pancreas, NCDR).

Data collection, hosting and analysis mechanisms:

- All utilised secure online database technology
- The NDCR marketed their registries as commercial CQR services for hospitals to carry out internal clinical outcome quality improvement
- The DATO was operated by a government-funded organisation, the DICA, that was established to carry out data collection and statistical analysis for multiple CQRs. Government departments received reports and had access to the DATO data
- The NRR was funded and contracted to maintain transplant waiting lists
- The DATO, the NDCR and the NRR allowed health services to extract data from hospital records for bulk submission. Records were also utilised for validation, or to monitor prospective outcomes
- The DATO included mandatory reporting requirements, legislated in the Netherlands
- The StuDoQ|Pancreas, the NDCR and the NRR noted that participation was voluntary, however all reported high participation rates from clinicians or hospitals in their field
- The NRR allowed patients to opt out, but participation was required to be listed on national transplant waiting lists
- The StuDoQ|Pancreas required all eligible patients details to be submitted to the register before allowing hospitals to access their data
- All provided regular benchmarked outcome reports to health services for internal quality improvement.

Governance, benchmarking and quality improvement mechanisms:

- All had their own internal boards and committees, with experts selected from stakeholder organisation members or expert clinicians
- The DATO and the NRR had oversight and regulation provided by government organisations. Government organisations were also represented in their governance structures
- Each CQR provided by the NDCR had their own internal boards and committees, with experts selected from stakeholder organisation members or external sponsors
- All had outcomes or benchmark criteria that were determined by clinical advisory working groups, expert panels or committees of experts
- The NCDR provided hospitals with quarterly access to their own data, for internal analysis and to facilitate quality improvement
- The StuDoQ|Pancreas allowed direct access by clinicians to their own data
- All utilised registries for clinical outcome quality improvement
- The DATO and the NRR included public reporting of outcomes via an annual report
- The NDCR included limited public reporting of select outcomes through the ACC Public Reporting program, but only with hospital approval
- No evidence of public reporting was found from the StuDoQ|Pancreas. However, reports were made available to participating clinicians and hospitals
- All allowed data to be accessed with permission for research.

Summary

Case studies presented included three Australian CQRs, the two Swedish, two Danish, one Finnish, one Canadian, one German, one Dutch, one Malaysian, two from New Zealand, one from Sri Lanka, one from the UK and three from the USA. Selected CQRs represent various clinical domains, and included self-reported high rates of population coverage, mechanisms for organisational oversight and mechanisms to feedback information to health services and/or clinicians.

National regulatory frameworks and governance mechanisms are summarised in Table 3. Summaries of each CQRs purpose; scope; hosting organisation; funding source; organisational governance; data hosting, collection and analysis; reporting; and quality improvement mechanisms are detailed above and listed in Table 8 (Appendix V).

National approaches to operating CQRs varied. Sweden, Finland, Denmark, and the Netherlands favoured mandatory reporting and provided oversight of all registries. The Californian Cancer Registry was similarly structured at a state level. Interconnectivity between CQRs and other population-wide mandatory databases in Sweden, Finland, and Demark facilitated near-complete prospective data collection. Denmark and the Netherlands had dedicated organisations to collect and analyse data for numerous databases, providing expertise and a workforce to maintain CQRs and establish data linkages, as well as systematic auditing and quality assurance mechanisms. The Healthcare Quality Improvement Partnership performed a similar function in the UK, with NHS Digital hosting required CQR database technology.

Alternatively, the USA CQRs as well as the StuDoQ|Pancreas, Germany, and the CorHealth, Canada, focussed primarily on individual clinician or hospital performance, granting ownership of data to participating health services or clinicians, allowing them to use the data to identify outliers and contribute to their own internal quality improvement processes.

The Australian and Malaysian CQRs included a mixture of individual health service or clinician feedback mechanisms that returned data to participants, and monitoring of national outcomes, identifying outliers and benchmarking based on analysis of all data collected. The NRR in Malaysia and the AOANJRR in Australia were also contracted to maintain relevant government databases.

Stakeholder-led CQRs benefited from engaged clinicians addressing an identified need, and the case studies selected have self-reported good population coverage for both mandatory and voluntary reporting CQRs. Some were maintained for years without government assistance, although reported that population coverage was achieved after government funding was established. However, some reported limitations in terms of adequately funded staff and infrastructure incompatibility.

Some CQRs operated within rigid national regulatory frameworks, while others were self-governed by clinicians with additional input from stakeholder organisations. However, internal governance structures were similar for all case studies. Oversight was provided by a board or committee, with outcomes and benchmark criteria set by experts or representatives from sponsor organisations working on advisory panels, working groups or committees. Auditing was carried out of participating health services to validate data and for quality assurance. CQRs from Sweden, the UK and California included consumers in their oversight committees. Limited detailed information was available on relationships between the executive, workforce and stakeholders for case study CQRs. Only two CQRs detailed consumer involvement in oversight organisations.

Overall, there was a gap in detailed information or evaluation of governance procedures for several case studies. While oversight structures, often with lists of members, were mentioned or illustrated, little to no detail was found that examined internal CQR governance procedures or their effectiveness. The relationships and responsibilities between CQRs and their executive, workforce and stakeholders, including patients and consumers, were implicit for several examples, rather than explicit. Processes, customs, policy directives, laws and conventions affecting the way organisations were directed were absent from the literature.

In conclusion, effective CQRs internationally were found to have similar approaches to organisational oversight structures, but differed in their approach to data collection and data analysis, and in their feedback mechanisms.

Section 5:

Discussion and limitations

This report provided an evidence check of literature regarding governance and quality improvement processes of clinical quality registries (CQRs), as well as selected case studies of international and Australian CQRs. It sought to determine:

- Governance, accreditation and quality assurance mechanisms
- Barriers and enablers to implementing and sustaining the use of these mechanisms
- Measuring and reporting CQR effectiveness, efficiency, appropriateness and sustainability
- Evidence of impact of these mechanisms
- Key governance, accreditation, quality assurance and evaluation learnings that may be relevant to the Australian context.

Completeness and quality assurance

Our rapid review of the literature revealed that CQRs were considered effective if they achieved data completeness and useability at both an individual hospital and wider healthcare system level.[2] Streamlined ethical and legal processes were recommended. Some CQR case studies achieved data completeness at a healthcare system level when reporting was mandatory and fit within existing reporting structures and requirements, and CQRs were accredited at a national level. For example, Swedish and Danish CQRs that are accredited and legislated on a national level, reported near-perfect data completeness, with routine auditing of participating hospitals for quality assurance, and they consistently demonstrated ongoing success in quality improvement indicators in their annual reports.[89,101] Alternatively, CQRs with voluntary reporting that were accredited but not legislated at a national level, such as the NBoCA (UK), did not achieve as high healthcare system-wide coverage, but could still capture relevant patients through an opt-out approach to CQR participation.[76] Literature reviewed revealed that a patient requirement to opt-out, either verbally or formally, was the most often employed mechanism to ensure the maximum collection of data from the eligible population.

Stakeholder-led CQRs benefited from the engagement of health services or clinicians themselves that established the CQR to address an identified need to achieve data completeness and conduct quality assurance processes at an individual hospital level. The Australian CQRs examined here, while not achieving complete national or bi-national coverage, self-reported consistent data completeness from participating health services or clinicians.[2,109,112,114] Alternatively, some CQRs required participation to complete patient care, for example, in Malaysia, the NRR required patient records to be entered into the CQR to also be listed on the renal transplant waiting list.[135] These examples demonstrate different approaches to data completeness and quality assurance at both individual hospital and healthcare system-wide levels, both of which are informative for the Australian context.

Interconnectivity and digital infrastructure

Articles identified in our rapid review emphasised the effectiveness of interconnected population-wide data catchment mechanisms[28], and advocated for clear and standardised frameworks to facilitate the collection, storage, analysis and release of data in an effective and efficient manner to drive quality improvement.[27] This emphasised the need for CQRs to not only collect timely, high-quality and appropriate core data, but also to pursue broader collection of non-core data through data linkage. For case study CQRs, those with interconnected databases that allowed CQRs to share and collect information with other population registries reported high population coverage and demonstrated ongoing success in quality improvement indicators in their annual reports.[89,101,124,132] In particular, the Nordic countries examined here cross-referenced data with patient registries that record vital health information for citizens from birth to death, allowing information to be verified and analysed to an individual patient level through unique citizen identification numbers.[50] This allowed CQR data to be part of broader coordinated data initiatives for population-wide health improvement. Emilsson noted that such linkage with government administered registries is one of the main

strengths of Swedish quality registries.[23] Furthermore, these interconnected databases allowed for review of clinical outcomes and benchmarking internationally. For example, while specific cancer registries operate in each country to facilitate clinical quality improvement, data collected via population-wide cancer registries were combined through NORDCAN, a regional registry, which allowed regional rates of cancer to be monitored over time.[149] These international comparisons were only possible with the use of internationally recognised data dictionary definitions, and the CQRs being directly involved in benchmarking studies[149], recommended for international interoperability.

According to Hickey et al, effective local data management protocols are a vital aspect of any large clinical registry.[36] For CQR case studies without access to comprehensive population-wide national databases, prospective data collection and data analysis was assisted through access to hospital discharge databases or patient electronic medical record data. CQRs such as the PERFECT (Finland) and the DATO (Netherlands) relied on data extracted from existing medical records or hospital databases, easing data submission processes for hospitals and providing population-wide data.

Effective CQR digital infrastructure was also found in case studies from the private sector. Commercial user-pays CQRs are part of the international CQR landscape. They provide a service to clinicians or hospitals to facilitate continuous clinical outcome improvement. In our case studies, two stakeholder-led CQRs, the APD and the NCDR, had created efficient and effective CQR software and data analysis that was marketed as a commercial CQR product to hospitals' internationally, providing efficient clinical outcome feedback loops on an individual hospital level.[108,146] Both case study CQRs benefited from stakeholder engagement in their development.

Regardless of whether a country has well established population-wide digital registries, interconnected digital systems that are compatible and interconnected are an advantageous way of retrieving and verifying necessary data for effective CQRs. Connecting with other health system data systems to verify registry data was an identified strength of state-driven CQRs, which could be applicable to the Australian context.

Data analysis, clinical outcome and quality improvement

The Commission's *Framework* recommended the establishment of a single national data hosting facility to support the handling of and facilitate linkage of data across centres of excellence and other healthcare systems.[6] This would allow CQR data to be part of broader coordinated data initiatives for quality assessment and quality improvement. Our rapid review found that a central repository of registries enabled further utilisation by stakeholders. The CQR case studies reviewed benefited from dedicated government organisations or research institutions that perform data collection and analysis. Centres provided consistent quality assurance mechanisms across multiple CQRs, and effective standardised clinical outcome quality improvement feedback loops for participating health services or clinicians.[24,49]

Ownership of data and transparency around the use of data was noted as being important for facilitating the uptake of registry use.[2,5,8,23,28,65] Ownership was further facilitated through the involvement of health service or clinician stakeholders in governance structures. CQR data could be utilised to provide feedback loops to clinicians or benchmarking for hospitals or can be incorporated into annual audits. The DATO, the DANBIO, the DAHANCA, the SHAR and the CSRS provided continuous feedback to either clinicians or health services through continuous access to data, and all self-reported improvements in key clinical outcomes over time in their annual reports.[89,132,150,151] Benchmarking, feedback loops, ownership of data, timeliness and transparency of analysis processes are all relevant to the Australian context.

Governance mechanisms

Literature found recommended steering committees and other associated advisory groups as leadership mechanisms for CQRs, with membership of steering committees to predominantly include clinicians and other professionals intrinsically linked to the clinical domain occupied by the registry.[2,23] Recommendations were also made that representatives from organisations responsible for the ownership of the data, members of funding bodies, registry experts, key stakeholders and patient representatives be represented in organisational governance structures.[2,8,23,38,39,65,152] For CQR case studies, governance processes included oversight by boards or committees, with expert panels selected either by government organisations or by peak bodies or other stakeholder groups relevant to the CQR. Some also included consumer representatives. Governance processes were less transparent for privately run CQRs. Significantly, all CQRs examined included clinicians with expertise in the CQR's field, through committees, expert panels, advisory or working groups.

Literature revealed that where significant funding commitments have been made by state agencies, improvements in the delivery of health care through CQR processes including information feedback have been evidenced[2,8,23,28,36,39,64,65,153,154], which was supported by the funding structures analysed in our CQR case studies. Coordination also allowed CQR data to be utilised to facilitate quality improvement at both a health service and health system level. However, a review of the governance structures and funding arrangements of Australian case studies showed inconsistencies. All selected Australian case studies were stakeholder-driven CQRs, that is, CQRs developed by peak bodies that later received funding from state and commonwealth government departments, resulting in three different funding and governance structures. These CQRs, while they benefit from stakeholder engagement, could potentially benefit from coordinated national infrastructure and governance, as identified by the AOANJRR[118] and as seen in successful CQR case studies presented in this report.

Nevertheless, governance mechanisms from all case studies emphasised the importance of stakeholder engagement, particularly through expert panels or working groups that establish benchmarking criteria, set outcomes to be measured, and provide guidance. Secure funding was also critical for their continued success.

Limitations

This review focused on effective and efficient CQRs, both internationally and in Australia. An investigation into CQRs that have failed or were unable to achieve data completeness could also provide valuable insights. There was a lack of peer-reviewed literature that addressed governance structures and quality assurance mechanisms of CQRs internationally. Articles that matched the selection criteria were descriptive rather than analytical. Similarly, self-reported grey literature was the only source of this information for several CQR case studies.

There were few reports on internal governance processes beyond oversight boards and committees, audit procedures and the regulatory frameworks in which CQRs operated. Therefore, there was a lack of detailed evaluation and examination of internal governance structures that could be analysed in this report. Finally, several CQR case studies came from non-English speaking countries, and so information translated by the service or through external translation software could not be verified.

Conclusion

In conclusion, effective CQRs identified in both the case studies and in the rapid review of the literature have the following characteristics:

- Achieve data completeness and useability at both an individual hospital and wider healthcare system level
- Include mandatory notification legislation or are based on an opt-out process for patient participation
- Have interactive IT platforms that feedback information to hospitals, either continuously, monthly, quarterly or annually
- Allow clinicians and/or hospitals access to, or ownership of their own data
- Provide benchmarking for key outcomes based on national data collection, as set by panels of expert clinicians
- Have established government organisations or research centres that are able to provide the expert workforce and infrastructure to validate, collect and analyse data, feedback to health services, and provide standard evaluation processes such as audits for quality assurance
- Have compatible systems that allow for data extraction from hospital records and other government databases, to monitor prospective outcomes, verify data and ensure data completeness. Coordination of data also allowed for quality improvement at both an individual health service and population-wide health system level
- Stakeholder-led CQRs benefited from engaged clinicians addressing an identified need
- CQRs benefit greatly when clinicians themselves participate, see the benefit of providing the information, and receive immediate feedback that can improve their own work.

Through the examination of select Australian and international CQRs, and a rapid review of peer-reviewed literature concerning governance, accreditation and quality assurance of CQRs, this report has highlighted mechanisms utilised in effective and sustainable CQRs internationally. Barriers and enablers to implementing and sustaining the use of these mechanisms were identified, and evidence for the impact of these mechanisms were reviewed. These findings can inform the development of national governance and quality assurance for CQRs in an Australian context.

Appendices

Appendix I

Figure 8: Ovid MEDLINE(R) database search strategy

Database(s): **Ovid MEDLINE(R) ALL** 1946 to August 02, 2019
Search Strategy:

#	Searches	Results
1	(clinical quality register? or clinical quality registries or CQR? or clinical registry or clinical registries or clinical register? or quality registry or quality registries or quality register? or clinical?quality registry or clinical?quality registries or clinical?quality register? or quality database? or clinical outcomes register? or clinical outcomes registries or national quality registr* or disease registry or disease register? or disease registries or data registry or data registries or data register or data registers or national outcome? registry or national outcome? register? or national outcome? registries or quality improvement register? or quality improvement registry or quality improvement registries or "clinical audit and registr*" or "clinical audit and register?" or quality database? or clinical database? or clinical?quality database? or outcome? database? or disease database? or quality improvement database? or national outcome? database?).ti.	1634
2	Clinical Governance/	494
3	Quality Improvement/	20884
4	exp "Quality of Health Care"/	6577340
5	"quality indicators, health care"/	14758
6	Accreditation/	13535
7	quality assurance, health care/	55075
8	Quality Control/	47417
9	benchmarking/	12690
10	total quality management/	12434
11	(benchmark* or quality management or quality control? or quality indicator? or TQM or QM or governance or accredit* or standard? or framework? or regulat* or quality improv* or improv* quality or assessment? or quality assur* or efficien* or effective* or appropriate* or sustain* or audit* or evaluat* or barrier? or enabler? or implement* or impact? or measur* or access* or manage* or ethic? or data or secur* or linkage? or integrat* or procedure? or process* or perform* or model? or report* or location* or storage or store or cost effect* or cost?effect* or "quality of care" or "quality of health?care" or care quality or health?care quality or excellence or mechanism?).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	19511701
12	2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	20558673
13	1 and 12	1562
14	limit 13 to yr="2000 -Current"	1347

Figure 9: Embase Classic+Embase database search strategy

Database(s): **Embase Classic+Embase** 1947 to 2019 August 02
Search Strategy:

#	Searches	Results
1	(clinical quality register? or clinical quality registries or CQR? or clinical registry or clinical registries or clinical register? or quality registry or quality registries or quality register? or clinical?quality registry or clinical?quality registries or clinical?quality register? or quality database? or clinical outcomes register? or clinical outcomes registries or national quality registr* or disease registry or disease register? or disease registries or data registry or data registries or data register or data registers or national outcome? registry or national outcome? register? or national outcome? registries or quality improvement register? or quality improvement registry or quality improvement registries or "clinical audit and registr*" or "clinical audit and register?" or quality database? or clinical database? or clinical?quality database? or outcome? database? or disease database? or quality improvement database? or national outcome? database?).ti.	2511
2	exp health care quality/	3012736
3	clinical competence/	58227
4	protocol compliance/	11317
5	outcome assessment/	491522
6	Accreditation/	35023
7	Quality Control/	174782
8	total quality management/	58043
9	(benchmark* or quality management or quality control? or quality indicator? or TQM or QM or governance or accredit* or standard? or framework? or regulat* or quality improv* or improv* quality or assessment? or quality assur* or efficien* or effective* or appropriate* or sustain* or audit* or evaluat* or barrier? or enabler? or implement* or impact? or measur* or access* or manage* or ethic? or data or secur* or linkage? or integrat* or procedure? or process* or perform* or model? or report* or location* or storage or store or cost effect* or cost?effect* or "quality of care" or "quality of health?care" or care quality or health?care quality or excellence or mechanism?).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]	25217056
10	2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	25570998
11	1 and 10	2379
12	limit 11 to yr="2000 -Current"	2156

Figure 10: Ovid Emcare database search strategy

Database(s): **Ovid Emcare** 1995 to 2019 week 30

Search Strategy:

#	Searches	Results
1	(clinical quality register? or clinical quality registries or CQR? or clinical registry or clinical registries or clinical register? or quality registry or quality registries or quality register? or clinical?quality registry or clinical?quality registries or clinical?quality register? or quality database? or clinical outcomes register? or clinical outcomes registries or national quality registr* or disease registry or disease register? or disease registries or data registry or data registries or data register or data registers or national outcome? registry or national outcome? register? or national outcome? registries or quality improvement register? or quality improvement registry or quality improvement registries or "clinical audit and registr*" or "clinical audit and register?" or quality database? or clinical database? or clinical?quality database? or outcome? database? or disease database? or quality improvement database? or national outcome? database?).ti.	647
2	exp health care quality/	957524
3	clinical competence/	9052
4	protocol compliance/	4464
5	outcome assessment/	186357
6	Accreditation/	14130
7	Quality Control/	49046
8	total quality management/	25214
9	(benchmark* or quality management or quality control? or quality indicator? or TQM or QM or governance or accredit* or standard? or framework? or regulat* or quality improv* or improv* quality or assessment? or quality assur* or efficien* or effective* or appropriate* or sustain* or audit* or evaluat* or barrier? or enabler? or implement* or impact? or measur* or access* or manage* or ethic? or data or secur* or linkage? or integrat* or procedure? or process* or perform* or model? or report* or location* or storage or store or cost effect* or cost?effect* or "quality of care" or "quality of health?care" or care quality or health?care quality or excellence or mechanism?) mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]	4850558
10	2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	4762653
11	1 and 10	614
12	limit 11 to yr="2000 -Current"	575

Figure 11: Scopus database search strategy

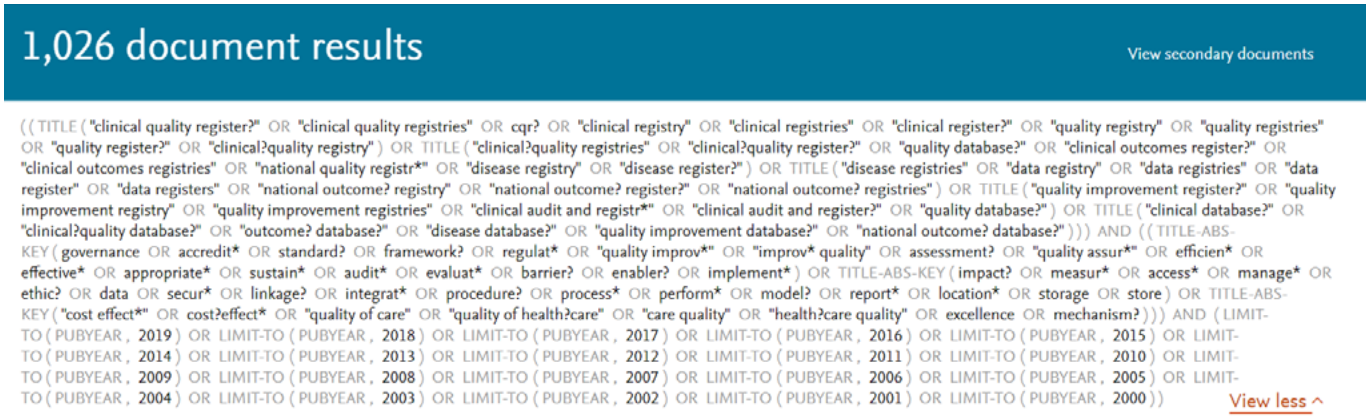


Figure 12: Cochrane Library database search strategy

#	Searches	Results
1	("clinical quality register" or "clinical quality registers" or "clinical quality registry" or "clinical quality registries" or CQR or CQRs or "clinical registry" or "clinical registries" or "clinical register" or "clinical registers" or "quality registry" or "quality registries" or "quality register" or "quality registers" or "clinical-quality registry" or "clinicalquality registry" or "clinical-quality registries" or "clinicalquality registries" or "clinical-quality register" or "clinical-quality registers" or "quality database" or "quality databases" or "clinical outcomes register" or "clinical outcomes registers" or "clinical outcomes registry" or "clinical outcomes registries" or "national quality registries" or "national quality registry" or "disease registry" or "disease register" or "disease registers" or "disease registries" or "data registry" or "data registries" or "data register" or "data registers" or "national outcome registry" or "national outcomes registry" or "national outcome register" or "national outcomes register" or "national outcomes register" or "national outcomes registers" or "national outcomes registry" or "national outcome registries" or "national outcomes registries" or "quality improvement register" or "quality improvement registers" or "quality improvement registry" or "quality improvement registries" or "clinical audit and registry" or "clinical audit and registries" or "clinical audit and register" or "clinical audit and registers" or "quality database" or "quality databases" or "clinical database" or "clinical databases" or "clinical-quality database" or "clinical-quality databases" or "outcome database" or "outcomes database" or "outcomes databases" or "outcome databases" or "disease database" or "disease databases" or "quality improvement database" or "quality improvement databases" or "national outcome database" or "national outcomes database" or "national outcome databases" or "national outcomes databases"):ti	67
2	MeSH descriptor: [Clinical Governance] this term only	3
3	MeSH descriptor: [Quality Improvement] this term only	593
4	MeSH descriptor: [Quality of Health Care] explode all trees	433856
5	MeSH descriptor: [Quality Indicators, Health Care] this term only	209
6	MeSH descriptor: [Accreditation] this term only	20
7	MeSH descriptor: [Quality Assurance, Health Care] this term only	615
8	MeSH descriptor: [Quality Control] this term only	476
9	MeSH descriptor: [Benchmarking] this term only	98
10	MeSH descriptor: [Total Quality Management] this term only	139
11	benchmark* or "quality management" or quality NEXT control? or quality NEXT indicator? or TQM or QM or governance or accredit* or standard? or framework? or regulat* or quality NEXT improv* or improv* NEXT quality or assessment? or quality NEXT assur* or efficien* or effective* or appropriate* or sustain* or audit* or evaluat* or barrier? or enabler? or implement* or impact? or measur* or access* or manage* or ethic? or data or secur* or linkage? or integrat* or procedure? or process* or perform* or model? or report* or location* or storage or store or cost NEXT effect* or cost?effect* or "quality of care" or "quality of healthcare" or "quality of health-care" or "care quality" or health?care NEXT quality or excellence or mechanism?	1572990
12	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11	1572990
13	#1 AND #12 with Cochrane Library publication date Between Jan 2000 and Dec 2019	66
Total duplicates removed		**3394**
Total citations identified		**5170**

Appendix II

Table 4: National Health and Medical Research Council (NHMRC) levels of evidence hierarchy and body of evidence matrix

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening intervention
I	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	A pseudorandomised controlled trial (alternate allocation or some other method)
III-2	A comparative study with concurrent controls: Non-randomised, experimental trial; Cohort study; Case-control study; Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls: Historical control study; Two or more single arm study; Interrupted time series without a parallel control group	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/ post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Table 5: NHMRC body of evidence matrix

Component	A Excellent	B Good	C Satisfactory	D Poor
Evidence base*	Several level I or II studies with low risk of bias	One or two level II studies with low risk of bias or a SR/multiple level III studies with low risk of bias	Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	Level IV studies, or level I to III studies with high risk of bias
Consistency†	All studies consistent	Most studies consistent and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability	Population(s) studied in body of evidence are the same as the target population for the guideline	Population(s) studied in the body of evidence are similar to the target population for the guideline	Population(s) studied in body of evidence differ to target population for guideline but it is clinically sensible to apply this evidence to target population§	Population(s) studied in body of evidence differ to target population and hard to judge whether it is sensible to generalise to target population
Applicability	Directly applicable to Australian healthcare context	Applicable to Australian healthcare context with few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to Australian healthcare context

* Levels of evidence determined from the NHMRC evidence hierarchy.

† If there is only one study, rank this component as 'not applicable'.

§ For example, results in adults that are clinically sensible to apply to children or psychosocial outcomes for one cancer that may be applicable to patients with another cancer.

Appendix III

Table 6: Data extraction table: Processes that exist, or are recommended, for clinical quality registry (CQR) governance, accreditation, and quality assurance internationally and in Australia

Study			Describes governance mechanism(s)				Describes quality assurance mechanism(s)	Describes accreditation mechanism(s)		Describes barrier/enabler to implementing mechanisms						Provides evidence for the impact of mechanisms
Author, date	Country	No. of registries observed	Organisational governance	External support (centres)	Data governance (elements, custodianship, security)	Ethics, privacy and legal	Quality of data (validation/ verification processes, linkage, etc.)	Accreditation mechanism	Requirement for accreditation	Funding	Guidelines and system limits	Staff	Collaboration, participation and engagement	Administration	Other	Evidence of impact
The Commission (2014)	Australia		Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes			Yes	
Ahern (2019)	Australia, Europe		Yes	Yes		Yes	Yes		Yes	Yes				Yes		
Bejerot (2011)	Sweden		Yes			Yes	Yes		Yes							
Blumenthal (2017)	USA	38					Yes	Yes		Yes		Yes		Yes		
Blumenthal (2019)	USA		Yes				Yes	Yes	Yes				Yes	Yes		Yes
Brown (2016)	Australia	1				Yes	Yes									
Earle (2019)	New Zealand	1	Yes			Yes				Yes	Yes					
Eldh (2014)	Sweden	1	Yes				Yes				Yes	Yes	Yes	Yes		Yes
Eldh (2015)	Sweden	1	Yes								Yes		Yes	Yes		Yes
Emilsson (2015)	Sweden	103	Yes	Yes	Yes	Yes	Yes			Yes			Yes			
Evans (2011)	Australia	28	Yes	Yes	Yes	Yes	Yes			Yes			Yes			
Fredriksson (2014)	Sweden		Yes		Yes					Yes			Yes	Yes	Yes	
Hickey (2013)	UK	1			Yes	Yes	Yes			Yes				Yes		Yes
Hoeijmakers (2018)	Netherlands	1		Yes	Yes	Yes	Yes					Yes		Yes		
Hogan (2013)	Canada		Yes		Yes	Yes	Yes									
Hoque (2018)	Australia/ New Zealand	34	Yes		Yes	Yes	Yes			Yes			Yes			

Study			Describes governance mechanism(s)				Describes quality assurance mechanism(s)	Describes accreditation mechanism(s)		Describes barrier/enabler to implementing mechanisms						Provides evidence for the impact of mechanisms
Author, date	Country	No. of registries observed	Organisational governance	External support (centres)	Data governance (elements, custodianship, security)	Ethics, privacy and legal	Quality of data (validation/ verification processes, linkage, etc.)	Accreditation mechanism	Requirement for accreditation	Funding	Guidelines and system limits	Staff	Collaboration, participation and engagement	Administration	Other	Evidence of impact
Jain (2012)	USA		Yes	Yes	Yes		Yes			Yes			Yes			
Larsson (2012)	Various	13	Yes		Yes					Yes	Yes		Yes			
Levay (2016)	Sweden, USA		Yes			Yes		Yes		Yes	Yes		Yes	Yes	Yes	Yes
Nelson (2016)	Various		Yes			Yes							Yes	Yes	Yes	
Soderholm (2016)	Sweden	1					Yes							Yes		
Watterson (2012)	Australia and New Zealand	1	Yes		Yes	Yes	Yes			Yes			Yes	Yes		
Wellner (2017)	Germany	1	Yes			Yes	Yes									
Wilkins (2015)	Australia					Yes	Yes	Yes	Yes	Yes			Yes	Yes		
van der Veer	Various	53 (studies, no. of registries not detailed)					Yes									
Willcox (2015)	Australia						Yes	Yes		Yes	Yes	Yes	Yes	Yes		
26			**18**	**6**	**11**	**16**	**20**	**5**	**5**	**15**	**7**	**5**	**14**	**14**	**4**	**5**

Appendix IV

Table 7: Articles that describe specific mechanisms for the assessment of CQR 'quality'

Author, date	Completeness	Coverage	Validity	Timeliness	Comparability	Other
The Commission (2014)	Yes	Yes	Yes			
Blumenthal (2017)			Yes			
Blumenthal (2019)	Yes					
Eldh (2014)		Yes	Yes			
Eldh (2015)				Yes		
Emilsson (2015)	Yes	Yes	Yes	Yes	Yes	
Evans (2011)			Yes	Yes		Comprehensible; accessible
Fredriksson (2014)				Yes		
Hickey (2013)	Yes					Accessibility of information; proven usefulness
Hoeijmakers (2018)	Yes		Yes		Yes	External data verification
Hogan (2013)						
Hoque (2018)	Yes		Yes			Reliability of coding conditions; independence of primary outcome observations; % of variables with clear definitions
Levay (2016)	Yes		Yes	Yes		
Nelson (2016)						
Soderholm (2016)	Yes	Yes	Yes		Yes	
Watterson (2012)	Yes			Yes		Accuracy of data
Wellner (2017)			Yes			
Wilkins (2015)	Yes	Yes	Yes			
Willcox (2015)	Yes		Yes			Allowance for risk adjustment as quality measure
19	**11**	**5**	**12**	**6**	**3**	**7**

Appendix V

Table 8: CQR case studies

Registry name	Description	Detail
Australian and New Zealand Liver Transplant Registry (ANZLTR)	**Purpose**	To collect, collate and analyse data on the outcomes of treatment of patients with acute or end stage liver failure.
	Year	Established 1988.
	Hosting organisation	The ANZLTR. Maintained at Transplantation Services, Royal Prince Alfred Hospital, Sydney.
	Funding source	The Australian Organ and Tissue Authority (AOTA) – Australian Government (Federal). Additional funding from Astellas Pharma Australia.
	Scope	Bi-National. Includes liver transplant units in Australia and New Zealand.
	Governance	The ANZLTR management committee (established 2001), includes the Head or Senior Consultant from participating liver transplant units.
	Data hosting	Online via a web-based database since 2003.
	Data collection	Transplant Units contribute via direct data entry into the ANZLTR database.
	Data analysis	De-identified data includes demographics, condition, survival rates and donor information, waiting list activity and cancer after transplantation.
	Reporting	Annual report publicly available.
	Quality improvement	Feedback direct to transplant units to inform clinicians.

Registry name	Description	Detail
Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)	**Purpose**	To improve and maintain the quality of care for individuals receiving joint replacement surgery.
	Year	Established 1999.
	Hosting organisation	The Australian Orthopaedic Association (AOA).
	Funding source	The Australian Government Department of Health.
	Scope	National. Implemented state-by-state 1999–2001. National data collection since 2003. All 312 hospitals, public and private, undertaking joint replacement submit their data to the Registry.
	Governance	Federal Board of the AOA nominate the AOANJRR Committee to develop policies for the operation of the AOANJRR. The AOANJRR Consultative Committee is appointed and administered by the Commonwealth.
	Data hosting	Data collection and analysis is contracted to the South Australian Health and Medical Research Institute (SAHMRI).
	Data collection	Paper based data collection forms are filled out by clinicians in theatre during procedure. Hospitals responsible for collecting and submitting data to the SAHMRI. A pilot PROMs project is underway.
	Data analysis	Provides surgeons with access to their individual data and downloadable reports through a secure online portal. Separate online facilities are available for orthopaedic companies, Australian and regulatory bodies in other countries to monitor prostheses used in Australia.
	Reporting	Publicly available annual and supplementary reports, journal publications and ad hoc reports (303 in 2017).
	Quality improvement	Individual surgeon reports and hospital reports. Industry provided with access to real time automated reports on the performance of individual prostheses.

Registry name	Description	Detail
Australia and New Zealand Intensive Care Society (ANZICS) – Adult Patient Database (APD)	**Purpose**	To produce comparative benchmarking reports for Australian and New Zealand ICUs, to identify and analyse outlier ICUs, to provide data quality training to ICU staff, and to assist research into ICU improvement and patient outcomes.
	Year	Established 1992.
	Hosting organisation	The Australian and New Zealand Intensive Care Society (ANZICS) Centre for Outcome and Resource Evaluation (CORE).
	Funding source	Commonwealth and state departments of health. Funding also provided by government and non-government agencies and research institutions.
	Scope	Bi-National. Contributing ICUs across Australia and New Zealand.
	Governance	The ANZICS Board, overseen by the Jurisdictional Advisory Group and the CORE Advisory Steering Committee.
	Data hosting	All APD data submissions and reporting occurs online via the CORE Portal, utilising Core Outcome Measurement and Evaluation Tool (COMET).
	Data collection	ICUs provide data to CORE on a quarterly basis. COMET software is provided to participating ICUs to assist data collection.
	Data analysis	Data are grouped by hospital classification and analysed by many variables, including age, length of stay, ANZROD Standard Mortality Risk, and Standardised Mortality Ratio.
	Reporting	The ANZICS CORE annual reports available publicly. The APD Activity report available publicly. Quarterly risk-adjusted reports are then provided to individual units and jurisdictional data review committees. ICUs have access to their own data and comparative graphs.
	Quality improvement	The APD data are used to benchmark the performance of the contributing units. Funnel plot graphs are provided to participating ICUs so performance can be compared to other units, and outliers are identified.

Registry name	Description	Detail
California Cancer Registry (CCR)	**Purpose**	To collect state-wide cancer data, conduct surveillance and research into the causes, controls, and cures of cancer, and communicate the results to the public to develop strategies and policies for its prevention, treatment and control.
	Year	Established 1988.
	Hosting organisation	A collaborative effort between the California Department of Public Health, the Institute of Population Health Improvement, UC Davis Health Systems, and the regional cancer registries.
	Funding source	The California Department of Public Health (CDPH), Center for Disease Control and Prevention's (CDC) National Program of Cancer Registries, and the National Cancer Institute's Surveillance, Epidemiology and End Results Program (SEER).
	Scope	State-wide. All hospitals, facilities, and physicians diagnosing or providing treatment to cancer patients are required by law to report cases of cancer to the CCR.
	Governance	Managed by the CDPH. The CCR is a program of the CDPH's Chronic Disease Surveillance and Research Branch.
	Data hosting	Online. Data are submitted electronically, either via the Direct Data Entry Web Portal or automatic entry from electronic health records where applicable.
	Data collection	All health services required to submit cancer patient data to the CCR. Collected data include: demographic, diagnostic, and treatment data.
	Data analysis	Provides statistics, reports, and tools for researchers, patients, and the general public, including cancer statistics for California as a whole, statistics for specific regions of California, and statistics for individual counties.
	Reporting	Data are publicly available via a data library. Searchable via Interactive Query Tool and a Geographical Information System. Cancer patients can obtain their individual case file data from the CCR.
	Quality improvement	Meets all the National Program of Cancer Registries and the SEER standards for quality, timeliness, and completeness of collected data. Also Gold Certified by the North American Association of Central Cancer Registries.

Registry name	Description	Detail
Cardiac Surgery Reporting System (CSRS) Part of the Cardiac Quality Improvement Initiative	**Purpose**	To improve treatment of heart disease; to identify and address barriers to equitable access to appropriate cardiac care; to provide information for patients to enable them to make better decisions about their own care.
	Year	Established 1989.
	Hosting organisation	University at Albany, State University of New York.
	Funding source	The New York State Department of Health (New York State DOH).
	Scope	All state hospitals where cardiac surgery is performed in New York State, 38 (non-federal) hospitals.
	Governance	Cardiac Surgery Reporting System (CSRS) Subcommittee, reporting to and advised by the New York State Cardiac Advisory Committee.
	Data hosting	Data are submitted electronically to the New York State DOH Cardiac Services Program/University at Albany School of Public Health, University at Albany.
	Data collection	Hospitals submit data to the CSRS. Data are collected about: patient characteristics, risk factors, mortality rates, readmissions, the number of cases for hospitals/surgeons.
	Data analysis	Data are analysed to determine observed, expected, and risk-adjusted mortality rates; and observed and expected readmission rates for different cardiac surgeries, hospitals and surgeons. 95% confidence intervals are calculated.
	Reporting	Reports from the CSRS provide data on performance (risk-adjusted mortality rate) and volume (number of cases) by hospital (in each year) and by surgeon (in three-year periods). Reports are usually published one to three years after the collection period and are made publicly available on the New York State DOH website.
	Quality improvement	Accuracy determined through review of unusual reporting frequencies, cross-matching of cardiac surgery data with other New York State DOH databases and review of some medical records. Hospitals are provided with immediate feedback so that they can internally work towards improving quality.

Registry name	Description	Detail
CorHealth Ontario Formerly Cardiac Care Network of Ontario (CCN) and Ontario Stroke Network	**Purpose**	To advance cardiac, stroke and vascular care for patients in Ontario.
	Year	Established 2016 (CCN established 1994).
	Hosting organisation	The CorHealth.
	Funding source	Government funding through the Ministry of Health and Long-Term Care (MOHLTC). Some support from Heart & Stroke Canada.
	Scope	Hospitals in the state of Ontario.
	Governance	Board of Directors oversee Clinical Advisory Committees for cardiac, stroke and vascular, which oversee Expert Task Groups.
	Data hosting	Data are sent to the CorHealth Ontario by hospitals and retained in their internal server.
	Data collection	Hospital staff input data via standardised forms.
	Data analysis	The CorHealth analyse data to report procedure volumes and identify opportunities for quality improvement.
	Reporting	Standard Reports are sent to hospitals and the MOHLTC periodically.
	Quality improvement	Hospitals are provided access to their data continuously for internal analysis. Data provided to the MOHLTC for analysis.
Danish Database for Biological Therapies in Rheumatology (DANBIO)	**Purpose**	To monitor clinical quality of treatment using selected quality indicators for patients with rheumatoid arthritis in Denmark.
	Year	Established 2000.
	Hosting organisation	Hvidovre Hospital.
	Funding source	Funded by the five regions since 2006. Grants from the pharmaceutical industry.
	Scope	National. Mandatory reporting since 2006.
	Governance	Independent Steering committee of experts. Overseen by the National Board of Health and the Danish Data Protection Agency.
	Data hosting	Database uses Linux and FreeBSD as the server platform. Controlled by the Health Data Authority.
	Data collection	Online database since 2006. Patient reported PROMS (via touch screen) and clinician reported measures. Updated annually at follow up appointments.
	Data analysis	Data analysis is carried out to assess data to target goals and standard indicators established by the DANBIO steering committee.
	Reporting	Report 2015 available in English. Peer-reviewed articles.
	Quality improvement	Quality indicators set within the registry and monitored through annual patient updates. Feedback loop part of design. Outcomes reported by hospital and region annually.

Registry name	Description	Detail
The Danish Head and Neck Cancer Database Group (DAHANCA)	**Purpose**	To improve clinical outcomes for patients with head and neck cancer through multidisciplinary care.
	Year	Established 1976.
	Hosting organisation	Danish Clinical Quality Program – National Clinical Registries (RKKP).
	Funding source	Government since 2011. The Danish Head and Neck Cancer Database (DAHANCA) is financed by the Danish government through the RKKP and the Danish Multidisciplinary Cancer Groups.
	Scope	National. Compulsory reporting.
	Governance	Operated by the DAHANCA who select members for the Steering Committee. Overseen by the RKKP governance structure.
	Data hosting	Online via secure central web-based database (OCX). Paper forms available for health professionals to submit to the DAHANC.
	Data collection	Health professionals provide data for patients with head and neck cancers prospectively. Inclusion, On study, Recurrence, Primary treatment, Control during treatment and comorbidities are reported.
	Data analysis	National quality registries must specify improvement goals for each individual indicator in the registry. Information is used to monitor the rate of improvement in effectiveness, patient safety and access.
	Reporting	Annual reporting in Danish. Participating oncology centres have access to and ownership of their own data.
	Quality improvement	All National Quality Registries have standard quality improvement feedback loops that feed information back to hospitals and regions.

Registry name	Description	Detail
Dutch Audit for Treatment of Obesity (DATO)	**Purpose**	To improve the quality of bariatric surgery in the Netherlands.
	Year	Established 2014.
	Hosting organisation	The Dutch Institute for Clinical Auditing (DICA).
	Funding source	The umbrella organization of nine health insurers in the Netherlands, BZorgverzekeraars Nederland, provides the funds for national clinical audits.
	Scope	National. Mandatory. All 18 Dutch bariatric centres participate.
	Governance	Scientific committee and a clinical audit board (CAB) monitor the goals and quality of the registry. Representative are selected from all 18 bariatric centres.
	Data hosting	The DICA online secure interface.
	Data collection	Hospital input via extraction of data from existing patient electronic records, and clinician input through the DICA interface.
	Data analysis	Provides standardised report and quality indicators via a secure online interface, 'my DATO', which hospitals can access to analyse their own data. Updated weekly.
	Reporting	The DICA produces an annual report (in Dutch). Research access with permission. Peer-reviewed articles.
	Quality improvement	Constant feedback to hospitals through myDATO interface. Every two years, the DICA facilitates monitoring of data quality by an external organisation.

Registry name	Description	Detail
Electronic National Renal Registry (NRR) Formerly The Malaysian Dialysis and Transplant Registry	**Purpose**	To determine the disease burden, outcomes and factors influencing End Stage Renal Disease (ESRD) and Renal Replacement Therapy (RRT) in Malaysia, to facilitate research on RRT and ESRD, and to maintain the national renal transplant waiting list.
	Year	Established 1992.
	Hosting organisation	The Malaysian Society of Nephrology (MSN) and the National Kidney Foundation Malaysia.
	Funding source	Owned by the MSN. Funded by the Government Ministry of Health (MOH) through the Clinical Research Centre (CRC). Also receives funding from corporate and not-for-profit sponsors.
	Scope	National. Clinicians from hundreds of clinics across Malaysia contribute voluntarily to the register.
	Governance	Owned by the MSN. The Electronic National Renal Registry (NRR) Advisory Board liaison between the MSN and the CRC/MOH. Steering Committees for each register. Expert panels advise.
	Data hosting	Online database NRR hosted by the MSN.
	Data collection	Clinicians submit and update detailed information for all patients with ESRD. Necessary for patients to be included in the national renal transplant waiting list (eMOSS).
	Data analysis	The NRR compares outcomes achieved with 'gold standards' or comparative benchmarks for specific health outcomes, to determine disparities.
	Reporting	Publish annual report, available publicly (in English). Statistical Summaries available to clinicians. Data available to the CRC for analysis.
	Quality improvement	Clinicians access data continuously through statistical summaries on NRR. Data used by the CRC and the MOH to evaluate ESRD and RRT treatment outcomes in Malaysia.

Registry name	Description	Detail
National Bowel Cancer Audit (NBoCA)	**Purpose**	To improve the quality of care and survival of patients with bowel cancer, and to ensure that care meets requirements outlined in the National Health Service (NHS) cancer plan.
	Year	Established 2005.
	Hosting organisation	The NHS Digital.
	Funding source	The NHS England and the Welsh Government.
	Scope	National, covering all relevant services in England and Wales. Voluntary, patients can opt out of participation.
	Governance	Clinical advisory group and working group, overseen by the Gastro-Intestinal (GI) Audit Board.
	Data hosting	Clinical Audit Platform (CAP) – NHS Digital.
	Data collection	Clinicians input data for newly diagnosed patients. Further data are collected using the patients NHS number via Hospital Episode Statistics.
	Data analysis	Funnel plots are used to compare five key outcomes. Outliers are reported directly to hospitals.
	Reporting	Short reports published throughout the year. Annual reports publicly available. All clinical outcome data available on the gov.data website.
	Quality improvement	Publishes outcome data as part of the Clinical Outcomes Publication programme. Detailed Outlier and Cause for Concern policies.

Registry name	Description	Detail
National Cardiovascular Data Registry (NCDR) Includes: ▪ Chest Pain – MI Registry ▪ AFib Ablation Registry ▪ CathPCI Registry ▪ ICD Registry ▪ IMPACT Registry ▪ LAAO Registry ▪ PVI Registry ▪ STS/ACC TVT Registry ▪ Diabetes Collaborative Registry ▪ PINNACLE Registry.	**Purpose**	To help hospitals and private practices measure and improve the quality of cardiovascular care they provide by ensuring evidence-based care, improving patient outcomes and lowering health care costs.
	Year	Established 1997.
	Hosting organisation	The American College of Cardiology (ACC).
	Funding source	Users (health clinics) pay for service. The National Cardiovascular Data Registry (NCDR) provides funding grants for research projects.
	Scope	More than 2,400 hospitals and over 8,500 outpatient providers worldwide participate in one or more of the ACC's 10 registries.
	Governance	Oversight by a management board and the Science and Quality Oversight Committee, reporting to the ACC Board of Trustees. Each registry has a steering committee and three subcommittees: research and publications, clinical support team, and quality improvement.
	Data hosting	Online via the ACC website, secure login (access included in fee). A NCDR certified software vendor, a NCDR compatible data abstraction provider or a free web-based data collection tool can be used to submit data.
	Data collection	Data are submitted on a quarterly basis by healthcare providers. For some registries, relevant registry data fields can be extracted direct from a participants' Electronic Health Record.
	Data analysis	Data are summarised and compared with aggregated national data for quality benchmarking, which are provided to health services for internal analysis.
	Reporting	Facilities receive quarterly reports of their own data. Some data reported publicly for consumers on the NDCR website with hospital permission.
	Quality improvement	Benchmarked outcome reports provided to health services for internal quality improvement. Confidential Data Quality Reports are provided at the time of data submission. Annually, participants are randomly selected for on-site audits.

Registry name	Description	Detail
Network for Improving Critical care Systems and Training (NICST)	**Purpose**	To improve the quality of care available for acute and critically unwell patients globally.
	Year	Established 2013.
	Hosting organisation	The Network for Improving Critical care Systems and Training (NICST).
	Funding source	Private donations and international research grants.
	Scope	National. ICUs from both government, and semi-government healthcare facilities have been recruited.
	Governance	Overseen by the Ministry of Health, Sri Lanka and the Information and Communications Technology Agency.
	Data hosting	Data are stored in secure servers. Access is curated.
	Data collection	Voluntary. Data are entered through a secure cloud-based mobile or desktop portal.
	Data analysis	Diagnosis mapped to the Acute Physiology and Chronic Health Evaluation (APACHE IV) to enable risk adjustment, benchmarking and the potential for international comparison. Anonymised aggregate data are provided to centres in monthly reports.
	Reporting	Contributing sites have access to all data submitted from their ICU. Information on completeness of reporting is displayed monthly through each participating centre's own dashboard.
	Quality improvement	Dashboards enable users to highlight specific trends and sort the aggregate information by week, month or by admission characteristics.

Registry name	Description	Detail
New Zealand Cancer Registry (NZCR)	**Purpose**	To provide information on the incidence of, mortality from, cancer and to provide a basis for cancer survival studies and research programmes.
	Year	Established 1948.
	Hosting organisation	The New Zealand Ministry of Health.
	Funding source	The New Zealand Ministry of Health.
	Scope	National.
	Governance	Overseen by the New Zealand Ministry of Health and New Zealand Cancer control Agency.
	Data hosting	The New Zealand Ministry of Health.
	Data collection	It is mandatory for health services to report any new cancer diagnosis. Data collected include demographic information and information relating to the tumour.
	Data analysis	Data are analysed by a specialist team of cancer coders. Two clinical coding systems are used by the New Zealand Cancer Registry: The WHO International Statistical Classification of Diseases and Related Health Problems (ICD) to classify the tumour site, and the WHO International Classification of Disease for Oncology (ICD-O) to tumour morphology.
	Reporting	Cancer data and statistics are reported online on the Ministry of Health website. Cancer data are also reported in cancer related publications, such as the *New Zealand Cancer Action Plan 2019–2029*.
	Quality improvement	Cancer data are feedback to clinicians, District Health Boards, researchers, the Ministry of Health and the public, via publicly available statistics information and reports.

Registry name	Description	Detail
All New Zealand Acute Coronary Syndrome Quality Improvement Programme (ANZACS-QI)	**Purpose**	To support secondary care clinicians to implement appropriate, evidence-based guidelines to manage acute coronary syndrome (ACS).
	Year	Established in 2012.
	Hosting organisation	Data management is provided by the National Institute of Health Innovation.
	Funding source	The All New Zealand Acute Coronary Syndrome Quality Improvement Programme (ANZACS-QI) is funded by the New Zealand Ministry of Health.
	Scope	National. Forty-one public hospitals that admit ACS patients contribute information.
	Governance	The ANZACS-QI governance group on behalf of the Cardiac Society of Australia and New Zealand.
	Data hosting	Data are hosted by the National Institute of Health Innovation.
	Data collection	Data are collected using an ANZACS-QI web form, that collects demographic, risk factor, investigation, management and in-hospital outcome data for all patients admitted with a suspected ACS.
	Data analysis	Linkage of registry datasets to measure processes (drug dispensing, cardiac procedures and monitoring, and outcomes, for example, CVS hospitalisation and death).
	Reporting	Real-time reporting of evidence-based indicators using the ANZACS-QI web form allows for hospital-level quality improvement. Monthly, quarterly and annual summary reports containing national agreed indicator data generated and distributed.
	Quality improvement	The indicators reported allow for comparison of District Health Boards and national averages.

Registry name	Description	Detail
The Pancreatic Surgery Registry (StuDoQ|Pancreas)	**Purpose**	To improve surgical quality and outcomes for pancreatic surgery in Germany.
	Year	Established 2013.
	Hosting organisation	The German Society for General and Visceral Surgery (DGAV).
	Funding source	The DGAV collects participation fees from clinicians participating in all StuDoQ registries.
	Scope	National. All clinics in Germany and Austria are invited to participate. Voluntary.
	Governance	The DGAV Executive Board of the DGAV StuDoQ Registry oversees the StuDoQ|Pancreas Steering Committee. The DGAV employs professional personnel to maintain the registry.
	Data hosting	Database. Clinician entry. Online. Server physically located in the DGAV headquarters.
	Data collection	Clinicians enter data via online browser-based interface.
	Data analysis	The registry was developed as a tool for risk-adjusted quality assessment in pancreatic surgery. The DGAV carries out statistical analysis of data. Benchmarking key part of analysis.
	Reporting	No annual report. However, clinics that participate are granted continuous access to deidentified registry information and analysis. Data are not provided to third parties.
	Quality improvement	Evaluated using the German Network Health Services Research Checklist for the evaluation of clinical registries. Annual evaluation of data with benchmarking sent to participating clinics.

Registry name	Description	Detail
Performance, Effectiveness, and Costs of Treatment episodes in Stroke (PERFECT Stroke)	**Purpose**	To measure the cost-effectiveness of treatment and to create a comparative database that allow comparisons between hospitals, hospital districts, regions and population groups.
	Year	Established 2004.
	Hosting organisation	It is co-ordinated by the Centre for Health and Social Economics (CHESS) within the National Institute for Health and Welfare (THL).
	Funding source	Government. Social Insurance Institute and the THL.
	Scope	National.
	Governance	Steering committee of experts and CHESS staff oversee the database.
	Data hosting	CHESS staff extract and collate data from existing patient registries. No clinician or health service involvement.
	Data collection	Data extracted from Finnish National Hospital Discharge Register.
	Data analysis	Indicators identified in data. Risk-adjusted indicators are compared between hospital districts and hospitals.
	Reporting	Annual report for health services, in Finnish. Peer-reviewed articles by researchers using database information.
	Quality improvement	Benchmark data updated annually, used to inform performance indicators for health services.

Registry name	Description	Detail
Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART) Includes: ▪ Swedish Coronary Angiography and Angioplasty Registry (SCAAR) (1998) ▪ Swedish Cardiac Surgery Registry (1992) ▪ Swedish Transcatheter Cardiac Intervention Registry (SWENTRY) (2010, formerly TAVI) ▪ Swedish Register of Information and Knowledge about Swedish Heart Intensive Care Admissions (RIKS-HIA) (1992) ▪ Secondary Prevention after Heart Intensive Care Admission (SEPHIA) ▪ Swedish National Cardiogenetic Registry (under construction).	**Purpose**	To support the development of evidence-based therapy for cardiac disease by providing continuous information on patient care needs, treatments, and treatment outcomes. The long-term goal is to reduce morbidity and mortality and improve cost-effective patient care.
	Year	Established 2009.
	Hosting organisation	The Uppsala Clinical Research Center, Uppsala University.
	Funding source	Government funding and not-for-profit health organisations including the Swedish Association of Local Authorities and Regions, the Swedish State, the Swedish Heart-Lung Foundation, the Swedish Society of Cardiology, the Swedish Society of Thoracic Radiology, the Swedish Society of Thoracic Surgery and the Swedish Heart Association
	Scope	National. All (72 in 2018) hospitals in Sweden that provide care for patients with cardiac diseases participate.
	Governance	The SWEDEHEART steering committee. Working groups for each registry.
	Data hosting	The SWEDEHEART online secure web-based interface.
	Data collection	Treating physicians report each procedure online via a web-interface directly from their health service. Compulsory questions are asked, and the patient's history of similar procedures is displayed in real time.
	Data analysis	Data can be linked to national patient registries and compared with general population statistics in Sweden. Information can be collated and analysed at a hospital, national or individual patient level. Comparisons between hospitals are produced. Researchers require permission from steering committee to access data.
	Reporting	Annual report, 2018 latest. Available in English. Annual summary reports for all registries. Peer-reviewed articles (68 published in 2018).
	Quality Improvement	The SWEDEHEART Quality Index (2011) – includes 11 indicators for quality improvement. Monitor visits approximately 20 hospitals each year to audit.

Registry name	Description	Detail
Swedish Hip Arthroplasty Register (SHAR) Svenska Höftprotesregistret	**Purpose**	To improve care provision for patients who undergo hip arthroplasty in Sweden. To provide continuous quality assurance through activity analysis with the aim of giving patients the best possible care.
	Year	Established 1979.
	Hosting organisation	Centre of Registers Västra Götaland.
	Funding source	Government. The Swedish Association of Local Authorities and Regions and Region Västra Götaland.
	Scope	National. All Swedish hospitals that preform procedure contribute to register.
	Governance	Region Västra Götaland oversees registry. The Board and Steering Group are appointed in consultation with the Swedish Orthopaedic Association.
	Data hosting	Online. Secure online data access server. Provided by the Centre of Registers Västra Götaland.
	Data collection	Health professionals input demographic information, diagnosis, surgical technique and type of implant used, if repeat surgery. Patient reported outcome measures (PROMs) are collected through patient questionnaires before an operation and one, six, and 10 years post operation.
	Data analysis	Completedness analysis completed annually, overall and by hospital unit. PROMs data analysed in annual report. Statistical analysis available continuously via website.
	Reporting	Annual report, 2017 latest. Available in English and Swedish. Peer-reviewed articles – 20 in 2018, 29 so far in 2019.
	Quality improvement	Continuous publication of statistics. Clinicians can compare their results with those of other hospital units. Implant manufacturers can review the effectiveness of their devices.

Glossary

Clinical quality registry (CQR): An organisation which systematically monitors the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify outcome benchmarks, significant outcome variance, and inform improvements in healthcare quality[9].

Governance: Governance is a set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal and HR) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance.

Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of the different participants in the organisation to achieve the organisation's objectives. In the National Safety and Quality Health Service (NSQHS) Standards, governance includes both corporate and clinical governance.

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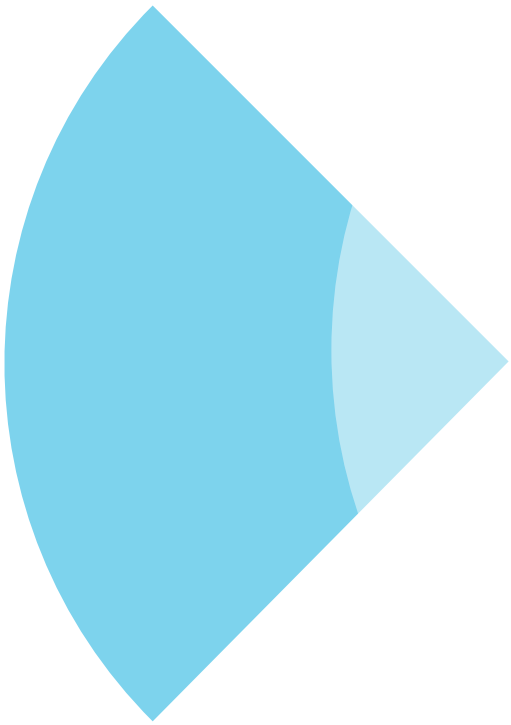

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

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

PHONE: (02) 9126 3600

@ACSQHC

safetyandquality.gov.au