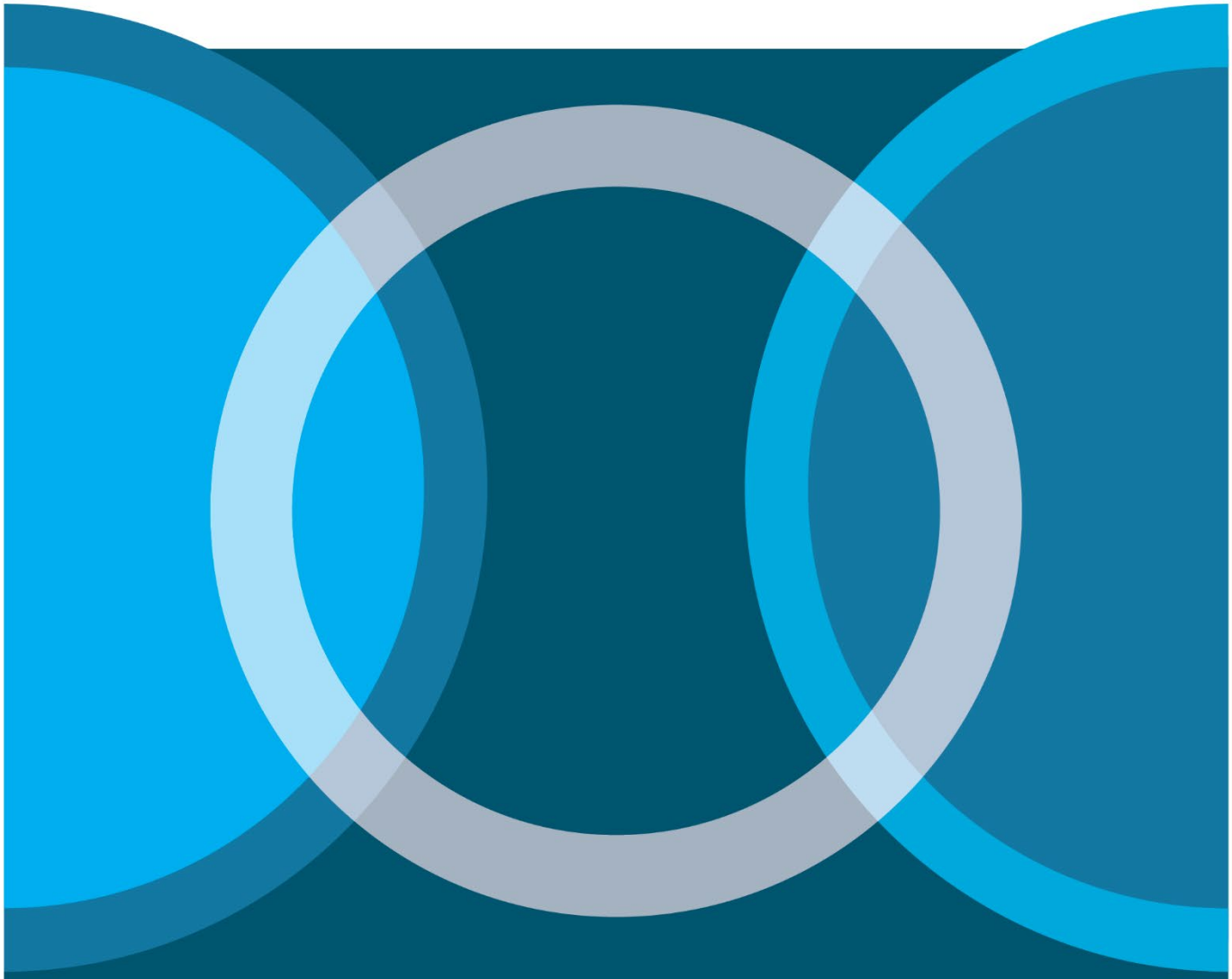
AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



National consultation and feedback 2023

Framework for Australian clinical quality registries – Second Edition

October 2023

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Introduction

The draft *Framework for Australian clinical quality registries second edition* (the Framework second edition), developed by the Australian Commission on Safety and Quality in Health Care (the Commission) with input from the CQR Framework Review Advisory Group, outlines the future state for Australian national CQRs, and provides guidance to support CQRs to work towards achieving best practice governance, logical design, security and privacy compliance, reporting and outlier measurement.

This report summarises the findings of a national survey, targeted consultation sessions and written submissions conducted with stakeholders to gather feedback on the updated draft Framework second edition.

About the consultation

The public consultation period took place from 17 January 2023 to 10 May 2023. Consultation documents for the draft Framework second edition included:

Draft Framework for Australian clinical quality registries Second Edition – This document provides the draft Framework second edition strategic and operating principles and guidance on CQR governance arrangements, national reporting requirements and approach to outlier management.

Draft Australian CQR logical design and infrastructure guideline Second Edition – This document provides guidance on best-practice CQR logical design, development, and operation through effective health service level and jurisdictional models.

Draft Australian CQR security compliance guideline Second Edition – This document provides guidance on national CQR compliance with privacy and security.

Summary paper and case studies – This document outlines the revision process and four case studies on clinical registries working towards the requirements of the draft Framework second edition.

The purpose of the consultation process was to determine if the draft Framework second edition provided the information stakeholders need to implement CQRs in their organisation and how CQR operators could be supported to implement the requirements of the draft Framework second edition.

Stakeholders across Australia were contacted by email and requested to submit feedback on the draft Framework second edition. The consultation was also promoted via the Commission's website and social media platforms; as well as by members of the Commission's CQR Framework Review Advisory Group.

Those contacted included state and territory health departments, CQR operators, medical colleges and societies, medical research institutes, public and private hospitals and consumer groups. Stakeholders were invited to provide their feedback on the draft Framework second edition via one or more of the consultation activities described below.

National survey

A national survey was conducted between 17 January 2023 and 31 March 2023. Data was captured via an online survey, with a small number of respondents opting to complete the

survey by submission. In total, there were 104 respondents of which 101 completed the online survey, and three responded via submission.

Virtual workshops

A series of virtual workshops were held for the purpose of gathering feedback on the drafts. Each consultation was framed by a brief on-screen presentation providing context for the discussion, after which the draft and accompanying documents were presented and discussed, section by section. In total, 15 virtual workshops were held with 168 participants between 1 March 2023 and 5 April 2023.

Submissions

Stakeholders also had the option of providing feedback on the draft Framework second edition via a written submission. Some stakeholders used the survey questions as a structure for their submissions. Others provided open responses.

STAKEHOLDER GROUP	NUMBER OF SUBMISSIONS
Registry sector	7
Consumer advocate	5
Jurisdiction	5
Medical colleges / societies	4
Research sector	3
Peak body	3
Hospital Public (n=2) Private (n=1)	3
Industry	3
Government agency	2
TOTAL	**35**

Qualitative analysis

Feedback generated across all activities went through a process of qualitative analysis to arrive at a set of overall themes for the consultation. Webinar transcripts, submissions, and survey responses were reviewed and coded by a minimum of two team members, and results shared and compared. The resulting codes and categories were decided by consensus.

Summary of consultation feedback

Across all consultation activities, there was widespread endorsement of the draft Framework second edition, and the emphasis on the role CQRs play in driving improvements in healthcare; establish expectations around how CQRs should be managed and operated nationally; and drive digital modernisation so that CQRs meet their core purpose within a learning healthcare system. That is,

> *"…achieve national reporting and the return of information to patients, clinicians, health service providers, health insurers, governments and the community on the appropriateness and effectiveness of health care in high-priority clinical conditions, medical devices, therapies and interventions."*

Participants in virtual workshops, submissions and respondents to the national survey were asked to provide their overall impressions of the draft Framework second edition. Amongst a generalised positive response to the intent and aspirations of the draft Framework second edition, discussion from participants was focussed on the following themes:

- Overall, there was stakeholder support for the intention and aspirations of the draft Framework second edition. Participants across the consultation had a variety of perspectives on the strengths of the draft Framework second edition, including positioning CQRs as national health infrastructure; creating opportunities for CQRs to learn from and support each other; providing access to health information and facilitating feedback loops; creating opportunities to drive quality improvements and, aligning with work being done by jurisdictions to modernise CQRs

- Participants who were in favour of moving CQRs from a research framework to a quality improvement framework were primarily focussed on current constraints relating to ethics approvals and health service authorisation via the Site-Specific Assessment (SSA) which limits timely approval to collect, share, link and use health information data

- Some participants expressed concerns regarding the concept of shifting CQRs from a research framework to a quality improvement framework, in particular about practical aspects, such as consent requirements. Others raised concerns about the limitations of data collected through health services, the lack of guidance around establishing or managing a CQR in this context, and the possibility of diminishing the quality of analysis and interpretation.

The future-focussed approach of the draft Framework second edition was discussed across the consultation. Most participants saw this as an inevitable and valuable update, but there were mixed views about if and how CQRs would be supported to make the transition, if and how greater interoperability would be supported across the sector, and whether the draft Framework second edition was inclusive of the most up-to-date technologies.

Concerns were raised about the ability of some CQRs to implement the requirements of the draft Framework second edition, including what supports/enablers may be provided, such as consideration of mandatory CQR participation and mandating interoperability support from other stakeholders, including Electronic Medical Record (EMR) and Electronic Health Record (EHR) providers.

The role of consumers in the draft Framework second edition was discussed throughout the consultations, including their contribution to governance arrangements and management of CQRs, the collection of consumer-relevant data, and consumer access to the outputs of CQR activity. Several participants noted that some consumers are anxious if not cynical about the purpose of data collection activities. Others noted that meaningful consumer engagement must be built into CQRs. Others emphasised the need for inclusivity of diverse identities, and diverse health conditions. Underpinning these conversations was a strong sense that consumers should be a priority in the ongoing development of the draft Framework second edition and that the diversity of consumers and their health experiences should be understood and integrated into the draft Framework second edition.

Across the consultation period, participants in virtual workshops, submissions and the national survey were asked to provide feedback on the draft *Reporting* section. Overall, participants agreed that reports are an essential and valuable output for CQRs. There was consistent feedback around the need to revise the reporting schedule to allow for variations in CQRs. There was also strong support for the idea that digital dashboards were a desirable alternative to conventional, text-based reporting.

The draft Framework second edition requires that national CQRs have an effective outlier policy in place. Overall, participants endorsed the requirement for CQRs to have an outlier policy. However, multiple participants indicated that, while they supported outlier 'measurement' activity, they did not believe CQRs should be responsible for outlier 'management'. Participants also debated the proposed technical approaches to outlier measurement and raised concerns about how outlier identification policies may affect individual clinicians.

The views of the sector were also sought on a proposed CQR accreditation scheme. There was little support for the implementation of accrediting CQRs until national infrastructure and custodial arrangements were put in place. Some participants asked for clarity on the relationship between the National Safety and Quality Health Service (NSQHS) Standards and the draft Framework second edition, and any possible accreditation scheme for CQRs in the future. A suggestion included a mapping document that connects the aims of the draft Framework second edition to the NSQHS Standards**.**

Regarding ongoing advocacy and collaboration for the draft Framework second edition*,* some participants discussed the need for the draft Framework second edition to have advocates and recommended actively engaging with key stakeholders in health to secure their support (such as engaging senior decision-makers, engaging medical colleges and clinical societies). Other participants in the consultation process indicated their interest in working collaboratively with the Commission to develop and implement the draft Framework second edition*.*

Regarding the document structure, across the consultations, there was mixed feedback on the level of detail provided in certain sections. In some areas it was raised by some participants that the detail was too deep and too prescriptive. In other areas, it was raised that the guidance provided was not detailed enough. As consultations progressed, it was discussed that a solution might be to develop the core document as a set of principles, and to produce companion documents aligned with each of these principles to support CQRs to implement the requirements.

The majority of participants positively endorsed the language used in the draft as being appropriate and applicable to their organisation. When prompted for suggestions on how to improve language, some referred to the need for clarity of terminology and definitions (including clarifying the definition of a CQR, clarifying the definition of data custodian, clarifying the meaning of national arrangements, and clarifying the definition of CQR maturity). Additional suggestions for improving the language included ensuring that the language is inclusive of diverse identities, is accessible and relevant and consistent in the level of detail (prescriptive vs general guidance).

Regarding strategies to support implementation, some of the suggestions related to providing training or resources that CQR personnel could use to identify and address gaps. The majority focussed on the need for CQRs to be funded and/or resourced to meet and maintain the requirements of the draft Framework second edition. This aligns with overall concerns about how CQRs will be supported to transition to the future state for Australian national CQRs.

Summary of consultation themes

Across the consultation period, participants in virtual workshops, submissions and the national survey were asked to provide their overall impressions of the draft Framework second edition, and then offered the opportunity to provide further comment on individual

sections of the draft Framework second edition. The following themes were raised prominently throughout all areas of discussion.

Research paradigm to quality improvement paradigm

Moving CQRs from a research paradigm to a quality improvement paradigm, with data collected at its source and shared with registries by agreement, is a change that attracts both positive and negative sentiment. Participants in favour of the shift referred to:

1. The potential to drive system-wide improvements in safety and quality
2. The removal of research-based ethics constraints, providing timely access to data
3. Greater efficiencies, including addressing duplicative data collection efforts
4. Establishing feedback loops to clinicians and hospitals and jurisdictions to support a learning health care system
5. Using the information collected to educate and engage the community, and ensure they have the information they need to make decisions about their own health care.

Those concerned about the shift queried:

1. How ethical issues including patient consent and privacy would be managed
2. How the gaps between the data routinely collected by health service organisations and the more bespoke data requirements of researchers would be addressed
3. What mechanisms could be put in place to ensure that data was provided to registry operators by health services
4. How existing CQRs would be supported to implement the requirements of the draft Framework second edition.

Preparing for a digital future

Participants broadly acknowledged and supported the intent of the draft Framework second edition to describe the future state for CQR operations in the context of a digital health system. However, many raised concerns about how existing registry workforces would be supported to adapt to the new requirements around data infrastructure, and data governance. Commentary from participants included:

1. Concerns that existing workforces lack the expertise and resources to establish new future-focused systems, and manage them ongoing
2. Concerns around how smaller and less mature CQRs would be supported to make the transition to the proposed operating models
3. The belief that government funding was essential to support the transition
4. The recommendation that certain interoperability standards must be mandated to ensure that data can be appropriately shared by CQRs
5. Suggestions that a national, government-funded infrastructure be introduced as a platform to enable the future operations of all CQRs.

Consumer roles in CQRs

Multiple participants recommended that consumers, their perspectives, their interests, and their needs, be at the centre of CQR activity under the draft Framework second edition. Specific commentary included:

1. The critical importance of representing all communities and all conditions in the nation’s CQRs, including addressing the current barriers
2. The need to embed consumers in governance structures

3. The responsibility to ensure consumers have meaningful and easy access to the information collected, with guidance on what it means for the health system and their personal health care decision.

Improvements to the draft document

In terms of how the draft Framework second edition could be improved as a document, key themes among participant feedback included:

1. Restructuring the main document to feature high-level principles only, with detailed information contained in companion documents
2. Ensuring the clarity and consistency of terminology and concepts
3. Ensuring that examples and scenarios are relevant across a range of CQRs
4. Ensuring that the various frameworks referenced in the document are relevant across a range of CQRs, and in alignment with the principles and requirements of the Framework second edition.

Key insights: Strategic principles & operating principles

Participants broadly endorsed the *Strategic principles*, using descriptors including ‘sensible’, ‘reasonable’ and ‘sound’.

Feedback on the *Operating principles* was more mixed. Alongside positive endorsements, there were some concerns about the clarity of some terms and concepts, and an interest in having some specific operational details addressed.

Strategies suggested by participants for implementation

1. An over-arching vision statement that frames the *Strategic principles*
2. Clarity on whether CQRs are considered to be operating within a research framework, or a quality improvement framework, and the implications of that approach, especially on consent and ethics
3. Explicit recognition of ‘health system improvement’ as one of the aims of the draft Framework second edition
4. Guidance on Indigenous data sovereignty and data governance
5. Guidance on how to undertake consumer-engagement / co-design, especially with Aboriginal and Torres Strait Islander people and communities
6. More emphasis on the core definition and capabilities of CQRs, and less reliance on specific CQR models, to future-proof the draft Framework second edition
7. More information about the roles and responsibilities of private sector health services, and private sector funding of CQRs
8. Guidance on the collection and use of patient experience data, particularly in relation to disabled people and communities
9. Guidance on integration of data from primary care.

Key insights: Governance

Participants broadly endorsed the principles of the *Governance* section, but also called for more detailed guidance, particularly as it relates to smaller and less mature CQRs, and university-based CQRs.

Strategies suggested by participants for implementation

1. Providing more guidance around patient consent considerations

2. Addressing out-dated, inflexible IT systems in hospitals
3. Providing more guidance on updating/redefining the role of data 'owners'.

Key insights: Health data for safety and quality improvement

Offered the opportunity to provide suggestions on how the content could be better expressed, some respondents suggested:

a. Covering the data governance requirements of the two proposed operating models separately
b. Providing more detail around the legislative and regulatory requirements.

Participants expressed a level of confidence in the draft *Health data for safety and quality improvement* section using descriptors such as 'robust' but noted the value of expanding the section to explicitly address the governance arrangements and technical considerations required to ensure safe and successful data collection and data sharing, in pursuit of safety and quality improvement.

Strategies suggested by participants for implementation

1. Training
2. Support for integrating data from the private sector
3. Support for CQRs to pursue data agreements with jurisdictional data holders
4. Adopting FAIRERR data principles (Findable, Accessible, Interoperable, and Reusable, Ethics, Responsibility and Reciprocity) to prioritise sharing and use of data.

Key insights: Logical architecture and design

Considerations of logical design and infrastructure are a specialised area. Accordingly, there was limited feedback on the *Logical architecture and design* section, and the companion document, *Attachment 1: Australian CQR logical design and infrastructure Second Edition*.

Submissions and survey responses from groups and organisations familiar with these considerations were the main source of commentary, provided an overall endorsement for the *Logical architecture and design* section, and the companion document, *Attachment 1: Australian CQR logical design and infrastructure Second Edition.*

Strategies suggested by participants for implementation

1. Ensuring that concepts are consistent and clearly cross-referenced between the *Logical architecture and design* section, and the companion document
2. Introducing expectations/mandates for health services to collect data for CQRs in high-priority areas
3. Promoting CQR engagement as a contributor to professional development / performance review requirements
4. Building data standards into health service accreditation.

Key insights: Security compliance guideline

Considerations of security compliance are a specialised area. Accordingly, there was limited feedback on the *Security compliance guideline* section, and the companion document, *Attachment 2: Australian CQR security compliance guideline Second Edition*

Those that did participate in this part of the consultation were highly sensitive to risk and had an appetite for strong requirements and practical guidance.

Strategies suggested by participants for implementation

1. Ensuring that this section of the draft Framework second edition is user-friendly, and applicable to a broad range of CQRs
2. Development of a centralised resource dedicated to supporting the security compliance of all CQRs.

Key insights: Reporting

Participants agreed that reports are an essential and valuable output for CQRs. There was consistent feedback around the need to revise the reporting schedule to allow for variations in CQRs. There was also strong support for the idea that digital dashboards were a desirable alternative to conventional, text-based reporting.

Strategies suggested by participants for implementation

1. Taking a more flexible approach to reporting requirements.

Key insights: Outlier measurement and oversight

Overall, participants endorsed the performance measurement role of CQRs, and the requirement for CQRs to have an outlier policy, as documented in the *Outlier measurement and oversight* section of the draft Framework second edition.

Multiple participants indicated that, while they supported outlier 'measurement' activity, they did not believe CQRs should be responsible for outlier 'management'. Participants also debated the proposed technical approaches to outlier measurement, and raised concerns about how outlier identification policies may affect individual clinicians.

Strategies suggested by participants for implementation

1. Including in the NSQHS Standards a requirement for health services to review CQR reports, and address outlier issues
2. Developing processes within each jurisdiction by which a CQR can escalate outlier concerns.

Overall findings

Finding 1: Stakeholders supported the draft Framework second edition for its intent to reframe national CQRs within a quality improvement framework and to provide the strategic and operating principles for National CQRs.

Stakeholders supported the purpose of the draft Framework second edition to provide the strategic and operating principles; guidance on governance arrangements; reporting, logical design and security compliance for governments and jurisdictional and national CQR operators.

Stakeholders also recognised the benefits of detailed guidance on logical design system architectures and outlier measurement and suggested these be provided as companion documents. Separating the draft Framework second edition and companion documents would ensure the focus of the draft Framework second edition remained on the strategic and operating principles, governance, reporting and security and privacy compliance. Several stakeholders articulated concerns regarding how health data provided to registry operators were stored, managed and shared. Stakeholders also reflected their concerns regarding how health data are held in sperate siloed systems and stored over a long period of time, and what systems and processes are in place to ensure legacy systems are maintained appropriately.

The draft Framework second edition is underpinned by national and jurisdictional legislation and the highest level of data security requirements expected of health data custodians.

Stakeholders agreed the levers underpinning the change were appropriate and aligned with cross-government policies and work underway including the:

- Australian Government Department of Health and Aged Care (the Department) *National Strategy for Clinical Quality Registries and Virtual Registries 2020-2030*[1]
- Department *National Health Reform Agreement (Addendum 2020-2025)* [2]
- Department Health Data and Digital Transformation Collaborative (at the time of this consultation)
- Department CQR Interoperability Working Group (at the time of this consultation)
- Department Healthcare Identifiers Framework Project[3]
- Australian Digital Health Agency (ADHA) National Healthcare Interoperability Plan
- ADHA National Digital Health Strategy and Road Map (under review at the time of this consultation).

Additional levers (as stated in the draft Framework second edition) include:

  - Reporting on the appropriateness and effectiveness of health care is considered an important part of healthcare safety and quality improvement; a patient and consumer right[4] ; an essential professional requirement[5] and health data custodian obligation [6,7]
  - Health information aggregated via agreement with data custodians for quality improvement informs compliance with National Safety and Quality Health Service

[1] Maximising the Value of Australia's Clinical Quality Outcomes Data: A National Strategy for Clinical Quality Registries and Virtual Registries 2020-2023

[2] National Health Reform Agreement (Addendum 2020-2025)

[3] Healthcare Identifiers and the Healthcare Identifier Service

[4] *Freedom of Information Act* 1982

[5] Australian Health Practitioner Regulation Authority (AHPRA)

[6] Private Health Insurance Act 2007 (Addendum 2019)

[7] National Health Reform Agreement (Addendum 2020-2025)

Standards[8], adherence to evidence-based care guidelines and standards and supports clinician/patient decision making.

Finding 2: There was little support for the implementation of accrediting CQRs until national infrastructure and custodial arrangements were in place. A checklist against the principles in the draft Framework second edition could be used to facilitate a self-assessment in the first instance. Stakeholders suggested including key actions against the principles of the draft Framework second edition that CQRs could be assessed against to help ensure that they perform at a designated level.

Stakeholders understood that any entity or individual applying to access and hold health data is required to request approval from the health data custodian. Stakeholders also recognised that those clinical registries established and operating within a research paradigm need to comply with the requirements of their ethical approval which is underpinned by the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (the National Statement)[9].

Stakeholders were supportive of Human Research Ethics Committees (HRECs) taking into consideration how clinical information collected by clinical registries would be reported to broad stakeholder groups and returned to the health custodian to support safety and quality improvement in health service provision.

Stakeholders supported the provision of actions to enable governments and CQR custodians to self-assess for compliance with the guidance provided in the draft Framework second edition in the first instance. Stakeholders had concerns about how an accreditation scheme would operate until national infrastructure and custodial arrangements were put in place.

For clinical registries operating within a research paradigm, stakeholders also supported the independent assessment of currently operating registries for adherence to their HREC approval by the institution that provided the HREC approval.

Stakeholders welcomed support for jurisdictional health departments to increase their level of health digitisation and prioritisation of interoperability between health systems to facilitate jurisdictional level reporting.

There was broad support for the mechanism for the collection of clinical quality outcomes data in national prioritised clinical domains to occur via collaborative agreement such as the Information-sharing model agreement (as referenced in the ADHA National Healthcare Interoperability Plan). This approach would not preclude current CQR operators from providing CQRs as a service to health departments.

Stakeholders supported a national approach and implementation of national digital health infrastructure, that would be led by the Department in partnership with the ADHA, jurisdictional health departments and the private sector in alignment with the National Healthcare Interoperability Plan and the National Data Strategy and Roadmap (currently under development by ADHA at the time of this consultation).

[8] National Safety and Quality Health Service Standards Action 1.28

[9] National Statement on Ethical Conduct in Human Research (2023)

Finding 3: Stakeholders supported the draft Framework second edition providing a definition of CQRs as reflected in the Australian Government *National Strategy for Clinical Quality Registries and Virtual Registries*

Stakeholders noted the diversity of clinical registries and quality audits currently being conducted in Australia[10]. Clarity was sought on the definition of a CQR; stakeholders recognised that while the guidance provided within the draft Framework second edition may be considered by any group that has established, or would be looking to establish a clinical registry, not all clinical registries are, or will be nationally prioritised clinical registries.

Stakeholders supported the draft Framework second edition providing a definition of CQRs that reflected the definitions provided in the National Strategy[1]:

A CQR 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 benchmarks and significant outcome variance, and inform improvements in healthcare quality. The governance function is central as it oversees registry operation and resource application, ensures accountability, establishes the data set required to meet the needs and objectives of the CQR, and establishes key policies around, for example, the identification and management of outliers[1].

A high functioning, mature CQR, is a CQR:

- *With strong governance arrangements in place*
- *With a data management system that complies with privacy and security requirements associated with personal health information*
- *With a high level of coverage of the relevant patient population*
- *That provides regular risk-adjusted, benchmarked feedback to clinicians*
- *That publicly reports fit-for-purpose information, and*
- *With policies in place to guide the identification and management of outliers and to respond to requests for access to CQR data[1].*

Finding 4: Data governance arrangements and including data sovereignty practices is key to ensuring data quality for reporting on health care variation

Consultation participants highlighted the importance of expert oversight in the management of databases/data lakes and expertise within data analytic teams to ensure the accuracy of the collected data, prior to the calculation of quality indicators and the generation of reports or publications.

Finding 5: National CQRs should have consumer involvement in CQR design and the ongoing operations and evaluation of the CQR

Community stakeholders recommended that consumers, their perspectives, their interests and their needs, be at the centre of CQR activity under the Framework second edition. Community stakeholders supported the need for consumers to have the opportunity to contribute their perspectives on their healthcare experiences, and to review, correct or clarify the data submitted to clinical registries.

Community stakeholders emphasised the need for inclusivity of diverse identities, and diverse health conditions in the nation's CQRs, the need to embed consumers in governance structures, and the responsibility to ensure consumers have meaningful and

[10] Australia Register of Clinical Registries

easy access to the information collected, with guidance on what it means for the health system and their personal health care decisions.

Finding 6: Concerns remain in relation to data security and the management and reporting of data breaches

Stakeholder concerns regarding data security and data breaches was high across the consultations, both in terms of implementing the appropriate data security safeguards, and registry custodians adhering to their responsibilities in managing and reporting data breaches.

Stakeholders also raised concerns regarding increased data security risks in relation to the length of time that health data are held by registries, and to particularly large datasets, with some suggesting that these risks could be addressed via a Commonwealth data archive.

Health administrators expressed a level of discomfort in how health data from their institutions, following approval for release, was being held, used, and managed by CQRs, and whether appropriate security arrangements were in place.

Finding 7: The use of Healthcare Identifiers should be mandatory for all national CQRs

CQRs should implement the Healthcare Identifiers within their systems to enable reporting at the level of the jurisdiction and facility and sharing information to enable the provision of quality and accurate information with key stakeholder groups including jurisdictional health departments, governments, Commonwealth agencies (including the Commission, ADHA, Australian Institute of Health and Welfare (AIHW)), funders, health service organisations and clinicians, in a format and time frame that would inform health service improvement and shared clinical decision-making.

Finding 8: CQRs should facilitate public reporting of patient safety and quality outcomes

Stakeholders also endorsed the principle of public reporting of clinical quality outcomes data, suggesting that it should be accompanied by information to support health service organisations address unwarranted variation.

Stakeholders supported registries develop consumer-based tools to assist consumers in using the information as part of shared clinical decision-making.

Finding 9: There should be further exploration of pathways that could be used to make CQR participation mandatory

Such as linking participation to health service accreditation, and/or professional development requirements for individual clinicians.

Finding 10: A communication strategy should be developed to build awareness amongst the community on how health data is collected, managed, and used and reported to inform improvements in health care and patient outcomes through clinical quality registries

Building awareness of the community of the value of reporting of clinical data as opposed to data being used for costing and funding purposes is needed. A communications strategy could also focus on building health literacy amongst the community.

Finding 11: A costing and impact analysis could be undertaken to assess the cost of the implementation of a national infrastructure change

To determine low, medium, and high-cost implications (regarding level of funding and additional resources required to meet best practice requirements) for CQRs should be assessed by a partnership with national agencies such as the ADHA and the AIHW and Commonwealth, state and territory governments. Such an analysis would need to be considered by the jurisdictions, Health Chief Executives and Health Ministers.

Stakeholders also supported increased transparency regarding the return of investment of public funds into registries.

Revision of the Framework for Australian clinical quality registries

As referenced in the Australian Government National Strategy for Clinical Quality Registries and Virtual Registries[11], a high functioning, mature CQR, is a CQR:

- With strong governance arrangements in place
- With a data management system that complies with privacy and security requirements associated with personal health information
- With a high level of coverage of the relevant patient population
- That provides regular risk-adjusted, benchmarked feedback to clinicians
- That publicly reports fit-for-purpose information, and
- With policies in place to guide the identification and management of outliers and to respond to requests for access to CQR data[1].

Clinical quality outcomes datasets is a universal term inclusive of CQRs and other mechanisms like virtual registries (i.e., those that draw data from existing platforms, such as state-based Electronic Medical Records (EMRs) or data lakes and data warehouses). These datasets include a combination of clinical and patient-derived data for a particular clinical domain, which are designed to report timely, actionable and risk-adjusted benchmarked data back to clinicians, health providers and other stakeholders for the purposes of quality improvement[1].

To date, CQRs have played an important role in collating and analysing health data that are captured in various health systems and data bases. However, many are impacted by the burden associated with establishing sound data collection methods, establishing and implementing data governance arrangements and developing and maintaining dedicated information systems. This is due in part, to CQRs operating within a research paradigm and not within a routine health service safety and quality reporting framework.

Additional barriers to achieving the purpose of CQRs and effective national reporting include disparate clinical registry system architectures, operating systems and data structures which

[11] National Clinical Quality Registry and Virtual Registry Strategy, Commonwealth Department of Health 2020

are neither uniform nor standardised in Australia. This creates significant inefficiencies, hampers interoperability with other information systems, and complicates the assessment of CQR system security.

Despite best efforts, due to these constraints, it can be challenging for clinical registries to routinely provide information back to clinicians, health service organisations, jurisdictional health departments, health insurers and the community with sufficient detail and frequency on the population of interest to support safety and quality improvement.

In line with the international evidence[12] and greater digitisation of the health records, the guidance provided in the revised draft Framework second edition aligns with best practice as listed below:

- Complete, high quality 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[13]. This includes contemporary database technology and quality assurance processes and national accreditation of CQRs

- Successful national CQRs have organisational governance arrangements; receive some government funding and are coordinated between national, state and territory governments and stakeholder groups[14,15]

- 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

- 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 service organisations and monitor outcomes
    - Include public reporting of clinical outcomes and hospital performance
    - Facilitate continual access to, or ownership of data by health service organisations 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.

To realise the value of CQRs, the draft Framework second edition provides contemporary, future- focussed guidance to assist CQRs achieve their core purpose within a learning health system framework.

[12] Australian Commission on Safety and Quality in Health Care. Evidence check – Governance, accreditation, and quality assurance of clinical quality registries: a report prepared by the Rosemary Bryant AO Research Centre for the Australian Commission on Safety and Quality in Health Care. Sydney: ACSQHC; 2019.

[13] Evans SM, Bohensky M, Cameron PA, McNeil J. A survey of Australian clinical registries: can quality of care be measured? Internal Medicine Journal. 2011;41(1a):42–8.

[14] Ahern S, Evans S, Hopper I, Zalcberg J. Towards a strategy for clinical quality registries in Australia. Aust Health Rev. 2019;43(3):284–7

[15] Wilcox N, McNeil JJ. Clinical quality registries have the potential to drive improvements in the appropriateness of care. Med J Aust. 2016;205(S10):S21–S6

The focus of the draft Framework second edition is for national CQRs on prioritised conditions[16] and procedures where:

1. There are serious consequences to the patient associated with poor quality of care
2. Unwarranted variation in outcomes can be identified and addressed
3. An evidence-based sequence of care improves patient outcomes (or there is a need to capture national data to develop an evidence base for care)
4. There is a significant cost burden associated with the condition/procedure/device
5. The clinical condition/event is able to be systematically recognised, and
6. Where the information requirements for a successful CQR can be met.

The updated guidance in the draft Framework second edition may be used by public and private health administrators, jurisdictional health departments and registry data custodians including CQR operators via a strengths-based[17] approach. The draft Framework second edition is also relevant for clinicians, medical colleges, governments, funders (in the private and public sector), the community and anyone with an interest in health outcomes, monitoring and reporting on variation in practice and health system improvement.

Conclusion

Across all consultation activities, there was widespread endorsement of the draft Framework second edition, and the emphasis on the role CQRs play in driving improvements in healthcare; establish expectations around how CQRs should be managed and operated nationally and drive digital modernisation so that CQRs meet their core purpose within a learning healthcare system.

[16] The Australian Commission on Safety and Quality in Health Care. Prioritised list of clinical domains for clinical quality registry development: Final report. Sydney: ACSQHC; 2016.

[17] Consider what aspects of the registry meet the requirements of the Framework second edition and plan for future improvements overtime.