ACSQHC Consultation: CQR Framework for Clinical Quality Registries

Submission on behalf of the Australian Clinical Trials Alliance Registry Special Interest Group

Submitted on 31 March 2023

Submitted

ABOUT YOU

1. You are invited to provide your contact details however providing your contact details is optional and the survey can be completed anonymously.

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2. Are you responding on behalf of an organisation?

☐ No

☒ Yes

If yes, what is the name of the organisation? ACTA Registry Special Interest Group (CQR SIG)

3. What is your role?

☐ Clinical Director/Head of Department

☐ Executive (CEO, President, Executive)

☐ Member/representative

☐ Policy Officer

☒ Other (please specify) Co-chair of the Registry SIG and Professor at Monash University

4. Which best describes the capacity in which you are responding?

- ☐ Allied Health Professional
- ☐ Consumer/patient/carer
- ☐ Funder
- ☐ Government representative
- ☐ Manager/administrator
- ☐ Medical practitioner
- ☐ Nurse
- ☐ Other clinician/ health professional
- ☐ Private sector representative
- ☒ Researcher/academic
- ☐ Safety and Quality professional
- ☐ Other (please specify)

5. Are you currently involved in a clinical registry or a CQR?

- ☒ Yes
- ☐ No

OVERALL IMPRESSIONS

The *Framework 2nd edition* provides future-focussed guidance to jurisdictional health departments and CQR custodians to support well-designed CQRs operating under, or moving towards national arrangements to meet their core purpose. That is, work towards achieving national reporting and the return of information to patients, clinicians, health service providers, health insurers, governments and the community on the appropriateness of health care in high-priority clinical conditions, medical devices, therapies and interventions. Please review the document and then answer the following questions about your overall impressions.

Note, questions about the content of specific sections appear later in the survey.

6. Does the current draft provide you with the information you need to implement the requirements of the *Framework 2nd edition*?

☐ Yes
☒ No

If no, how can it be improved? We are interested to hear your thoughts on the content, structure and format of the draft.

Thank you for the opportunity to provide feedback on the revisions to the Framework 2nd edition. ***The Australian Clinical Trials Alliance Registry Special Interest Group (ACTA Registry SIG)*** *aims to represent all clinical registries in Australia, of which there are currently over 100 on the Commission's Register of Clinical Registries. Currently 70 clinical registries are members of the ACTA Registry SIG. The Registry SIG provides opportunities for professional development, including leading an annual conference. It also aims to provide a united voice for clinical registries in responding to national consultation that affects the CQR sector. This response has been informed by consultation of over 60 CQR professionals within the ACTA Registry SIG, and is endorsed by members of the ACTA Board.*

The ACTA Registry SIG acknowledges the importance of the ***CQR Framework****, both in* ***guiding best practice development*** *and ongoing administration of clinical quality registries, as well is its future role in* ***informing accreditation of CQRs****. The ACTA Registry SIG believes that accreditation of CQRs may be a very valuable tool in further integrating securely funded CQRs into health service and clinician performance review and clinical governance frameworks. However,* ***achieving this will require efforts not only from individual CQRs, but also from across the sector****, most importantly from health services, jurisdictions, regulators, agencies such as the Commission itself, and the Commonwealth Department of Health. It is important that this is recognised in the Framework, and that strategies to address health system barriers and enablers are considered within the Framework recommendations. It is also critical that the Framework clearly supports the* ***Commonwealth Department of Health's National CQR and Virtual Registry Strategy****. This could be made more explicit if the revised Framework were clearly* ***aligned to the Strategy's Pillars****.*

We note that updates to the Framework have been intended every 5 years or so (2008, 2014 & commencement of current revisions in 2019). ***Our response to the Framework focuses on (1) what is achievable to support best practice for CQRs within the next 5 years, and (2) what enablers are required from the sector to achieve this.***

7. Is the language used in the draft appropriate and applicable to your organisation?

☐ Yes
☒ No

If no, what specific suggestions do you have for improving the language?

The Framework should be clear what is included within the scope of the document as a CQR*. It has utilised a recognised definition in the Introduction, and should aim to be consistent with this. It is appropriate to recognise that the majority of entities that meet this definition are stand-alone (disease or procedure-specific) CQRs.*

*We note that some of the terminology, particularly in Attachments 1 and 2, shows a lack of understanding of CQRs and that they are separate entities from Health Services. In particular, the language includes '**Health Service CQRs'** suggesting that CQRs are established within Health Services. We also note that the draft Security Compliance Guidelines recommends use of NF86, the national e-authentication framework. This is a **hospital-focused document**, and not necessarily appropriate or most relevant to CQRs.*

*The Framework has mentioned in the introduction, the concept of **registry maturity**, and that this will inform the development of an **accreditation** framework, as is the case with international accreditation frameworks. However, maturity is not mentioned again throughout the documents. It is strongly recommended that **each component** of the Framework note how it may vary based on registry maturity.*

8. Noting that the *Framework 2nd edition* will underpin the development of an approach to accreditation for CQRs, do you have any suggestions for strategies to support CQR operators to implement the requirements?

*As noted in the introduction and throughout this response, CQRs are generally small activities, comprising in the vast majority of cases, fewer than 10 EFT of paid staff. They have limited capability to deliver many of the elements of the framework in isolation. They must be **enabled through actions on behalf of primarily Health Services and Jurisdictions**, through leadership of primarily the **Commission and the Commonwealth Department of Health**. These are discussed in more detail in the further feedback.*

9. Please indicate which of the following documents you would like to provide feedback on. Please select all that apply.

- [x] Framework for Australian Clinical quality registries Second Edition
- [x] Summary paper containing CQR case studies
- [ ] Attachment 1: Australian CQR logical design and infrastructure guideline Second Edition
- [ ] Attachment 2: Australian CQR security compliance guideline Second Edition
- [ ] None

10. Please indicate which of the following Framework sections you would like to provide feedback on. Please select all that apply.

- [x] Strategic and operating principles for national CQRs
- [x] Governance

☑ Health data for safety and quality improvement

☑ Logical architecture and design

☑ Security compliance

☑ Reporting

☑ Outlier management and oversight

☐ None

STRATEGIC AND OPERATING PRINCIPLES FOR NATIONAL CQRS

Please review the sections on *Strategic Principles* (1.1) and *Operating Principles* (1.2) and then answer the following questions.

11. Is the information presented clear and easy to understand?

☐ Very clear
☐ Somewhat clear
☒ Somewhat unclear
☐ Not clear at all

12. How could the content be expressed or designed to better support you or your organisation to implement the guidance provided in the Framework 2nd edition?

2. ***Strategic Principles*** *– The majority of the Strategic Principles are appropriate, although it is not clear how CQRs will be able to participate in the national health information agenda (Principle 5).*
3. ***Operating Principles*** *– We are uncertain of the need to separate CQRs into 2 models based on operational design. New operational models may emerge in the future, and as long as the CQRs undertake their core functions, we are unsure how defining the 2 models assists the Framework. A generic approach would make sense, allowing for the evolution of technology and the external environment.*

*The **Data Collection** section recommends that CQRs source data directly from clinical information systems/EMRs (this is also stated in the Aims section (1) that clinical data is "collated" from "health systems" and "longitudinal health outcome data" is obtained from "data linkage from other health data holdings"). Extensive **feedback** has been provided by the ACTA Registry SIG during the consultation that:*

- *Not all health services (HS)s nor providers of healthcare have EMRs, particularly private and rural/regional hospitals which comprise over half of hospital care delivery and private specialists*

- *CQR data elements are not routinely included within HS EMRs*
- *EMR data suffers from poor standardisation, completeness and quality*
- *Data extraction from HS EMRs is costly, time-consuming and frequently not feasible due to the EMR issues identified above. To do this on a routine basis for all HSs for existing CQRs would be a major undertaking that would need support at both the Commonwealth and jurisdictional levels, sustained funding for priority CQRs and resources and funding for CQR infrastructure development.*

*The ACTA Registry SIG recognises the data collection burden of CQRs, however there needs to be **short to medium term solutions** to address these, until Australian HSs are at a higher level of EMR maturity (suggestions below).*

*Further, use of **FHIR** and **NLP** technologies are essentially in the research stage and their quality and feasibility are not yet proven for their use in CQRs. These techniques are also costly and require technical expertise which does not currently exist in most HSs.*

*Similarly, while we support the use of **IHIs**, these are not yet in widespread use, so they cannot be mandated for CQRs.*

There is limited information on the use of PROMs in CQRs in this Framework. ACTA Registry SIG recognizes that HSs, jurisdictions, CQRs and researchers are all seeking to utilise PROMs, and that data linkage of PROMs between these organisations is not straightforward. There is an opportunity to streamline this space, particularly in the public sector.

In addition, the section on ensuring data quality (1.2.6) provides limited standards or frameworks on data quality. A multitude of frameworks exist within research and clinical data contexts that address data quality and the use of consistent language (eg difference between validity, accuracy and completeness). These frameworks should be referenced and preferably suitable quality frameworks recommended to the community of CQRs.

13. Do these sections contain all the information you need to implement the requirements?

☐ Yes
☒ No

If no, what information do you think is missing?

We suggest removing reference to Model 1 and Model 2 and instead focusing on a core CQR definition and capabilities. These describe the current situation, but having two or more systems (e.g. jurisdictional stand-alone registries) are inefficient and problematic for national reporting. Issues arise as to data ownership and willingness to share.

We suggest greater incorporation of references to the private health sector throughout the Framework. There is very little specific reference to the private sector, although private providers undertake approximately 50% of health care services, and the private sector more broadly is a significant stakeholder in CQRs including providing funding.

*Page 17 (1.2.7 Organisation and governance) calls for accountability and transparency for the '**investment of public funds'**. However, many CQRs receive funding by private sector organisations including pharmaceutical companies, device companies, clinical craft group societies etc. Their contributions to CQRs should be made explicit in the document, and their role in reporting and outlier management acknowledged.*

The data integration requirements with private providers of healthcare (at a HS and individual clinician level) are a major challenge for CQRs and they can't be overlooked in these documents.

As mentioned above, we recommend the inclusion of a specific section on quality framework(s) that are suitable for CQRs (eg Commonwealth Govt, COSMIN, frameworks from academic literature).

14. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in these sections?

***Strategies to improve data collection for CQRs include**:*

- *Recommending mandatory participation in high-priority CQRs (e.g. as has recently been legislated for the Dust Diseases Registry)*
- *Encouraging HSs to incorporate CQR data collection into routine HS audits and QA/QI activities. This could be on a pro-rata basis e.g. a HS which is contributing to 30 CQRs allocates 3 x the resources compared to a HS which is contributing to 10 CQRs.*
- *CQR participation by HSs could be assessed during NSQHS accreditation.*
- *Encouraging public HSs to support the use of some clinician non-clinical time for CQR data collection*

There is a potential opportunity to streamline PROMs collection and use across the various PROMs collections (at jurisdiction, HS and CQR level), noting that data linkage from the broad range of existing systems is complex.

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GOVERNANCE

The section on *Governance* (1.3) aims to ensure that the appropriate clinical, technical, operational and administrative arrangements are in place to meet the requirements of the *Framework 2nd edtion,* and the information needs of the community. Please review this section and then answer the following questions.

15. Is the information presented clear and easy to understand?

☐ Very clear
☐ Somewhat clear
☒ Somewhat unclear
☐ Not cler at all

16. How could the content be expressed or designed to better support you or your organisation to implement the guidance provided in the Framework 2nd edition?

The language is corporate focused, and not necessarily aligned to that of a collaborative Quality Assurance/Improvement activity. It also does not reflect the small size of most CQRs centres/secretariats, nor the large amount of in-kind support provided to CQRs.

17. **Does this section contain all the information you need to implement the requirements?**

☐ Yes
☒ No

If no, what information do you think is missing?

The Framework appropriately recognises that the CQR must be associated with a legal entity, which usually includes an organisation, and may include a Board. CQRs do not usually have or monitor the performance of a CEO (pg 19). Standalone CQRs usually have a ***small secretariat of paid staff, and a wider group of participants*** *including clinicians, health services, consumers and other stakeholders including regulators, governments, craft group colleges and socieites, consumer organisations etc. Many participants provide* ***in-kind support*** *without which the CQR would not be possible. This* ***broad CQR community is not represented*** *in the discussion of organisational structure and governance, nor in the CQR workforce section, and is an omission.*

The CQR workforce section does not acknowledge the ***academic leadership*** *- a major source of in-kind support - that oversees many CQRs in conjunction with clinical leadership. It also doesn't acknowledge particular expertise in communications and engagement, including consumer engagement, the ethics and governance workforce, data collection and data entry workforce; design and publication staff, or* ***events and conference/workshops/courses that CQRs undertake to educate their workforce and showcase their output to create change for impact****.*

18. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in this section?

See above.

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HEALTH DATA FOR SAFETY AND QUALITY IMPROVEMENT

The section on *Health data for safety and quality improvement* (1.4) covers the requirements for data governance arrangements. These apply whether the CQR is operating within centrally hosted jurisdictional infrastructure, or if it is operating on a platform hosted and maintained by an existing health service organisation or third-party service provider, such as a university. Please review this section and then answer the following questions.

19. Is the information presented clear and easy to understand?

☐ Very clear
☐ Somewhat clear
☒ Somewhat unclear
☐ Not clear at all

20. How could the content be expressed or designed to better support you or your organisation to implement the guidance provided in the *Framework 2nd edition*?

Section 1.4 Health data for safety and quality improvement *discusses a small set of legislation, regulation and policy related to health data collection. This includes:*

- *The National Infrastructure Model (undefined)*
- *The NHIA and national data governance arrangements (which provides for collaboration between national and state agencies to share health data, and of which CQRs are not a party)*
- *The DATA Scheme (which is not implemented and, as yet, is unclear which of the Commonwealth datasets will participate)*
- *National data governance arrangements (which uses the AIHW Data Governance Framework as the exemplar)*
- *Data Governance Principles (which appear to be more corporate oriented)*
- *Five Safe's Data Sharing Framework*

Missing from this section is a comprehensive description of the legislative and regulatory requirements – it does not make sense to include the DATA scheme but not include the My Health Records Act (2012), The National Health (Privacy) Rules 2021, Privacy Act (1988) and the remaining jursdictional acts.

The data governance roles described are not fit for purpose for CQRs – there is no "data owner" in CQRs. There are people who have responsibilities and rights but there is no "ownership". Similarly "data custodian" and the responsibilities attributed to them is not consistent the AIHW's use of the term (which was held up as the exemplar) and the DATA schemes use of the term.

The section on Five Safe's Framework for data sharing appears to be out of context here and poorly labelled.

21. Does this section contain all the information you need to implement the requirements?

☐ Yes
☒ No

If no, what information do you think is missing?

*Section 1.4 aims to describe **how CQR data should be integrated into state and national datasets**, however it does not effectively do this. There are no specific initiatives listed that will support data collection or sharing for CQRs at this point in time. Even if fully enabled, these activities may be able to enhance collection and sharing of a small subset of CQR data. There is no reference to privately held hospital data, nor data from clinicians' private rooms.*

22. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in this section?

*To achieve maximum impact, **CQR data should be integrated into jurisdictional and national data governance Frameworks (aligned with the National CQR Strategy 10-year timeframe).** This could include the use of CQR data to complement reporting from:*

- *Jurisdictions*
- *AIHW*
- *National Cancer Registry*

CQR datasets should also be integrated into EMRs, particularly jurisdictional or group hospital EMRs where possible. This is a substantial project that requires support and leadership across the health sector.

LOGICAL ARCHITECTURE AND DESIGN

The section on *Logical architecture and design* (1.5) provides an overview of the functionality and system requirements of a CQR, and describes the infrastructure that would support CQR information design and data model and generic business functions of national CQRs. Please review this section and then answer the following questions.

23. Is the information presented clear and easy to understand?

☐ Very clear
☐ Somewhat clear
☐ Somewhat unclear
☒ Not clear at all

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24. how could the content be expressed or designed to better support you or your organisation to implement the guidance provided in the *Framework 2nd edition*?

Logical Architecture and Design – this response relates to Section 1.5 as well as the separate Attachment 1.

Our response to this document has been informed by technical advice from Monash University's eSolutions team that manages the University's data infrastructure. Our understanding is that the development of this document and the Security Compliance document were outsourced by the Commission to a third party commercial provider with whom the Commission has previously contracted services. It is unclear whether this provider has any experience in establishing or managing a CQR. We believe that this lack of input or co-design with the sector is a limitation of this document.

*The **Document's Purpose** states (pg 7):*

Specifically, the design has been developed to:
• Drive towards international best practice for clinical outcome data collections and reporting
• Deliver efficiencies and interoperability in data collection and exchange
• Promote standardised approaches to CQR design that support the strategic and operating principles for a national approach to Australian CQRs (refer to the Framework for Australian clinical quality registries, Second Edition)
• Reduce the time and cost of developing future CQRs through the provision of a generalisable and reusable design on centrally hosted national infrastructure
• Standardise data elements and definitions to facilitate benchmarking, comparisons, and data exchange wherever possible.
The logical design provides a model for CQRs to leverage centrally hosted infrastructure (including, but not limited to, cloud-based infrastructure), to promote consistent operating systems and data structures which are uniform and standardised in Australia, creating significant efficiencies, interoperability with other information systems, and easier assessment of CQR security.

The evidence from which this model was determined to be best practice is not clear. The main recommendations of this document are essentially that (1) CQRs should aim to collect data digitally from health service EMRs and (2) CQRs are hosted on a single national platform. For a range of reasons both these aims are not achieveable within the expected duration of this Framework (i.e. 5 years).

These barriers have been stated before and include primairly:

- *A lack of health system EMR maturity compared with internationally. Very few Australian health serivces have EMR maturity at a level '7' – the highest level, compared with overseas. Many private and rural/regional health services do not have EMRs at all.*
- *Australian EMRs are many and disparate. While some jurisdictions such as Queensland, SA and NSW have a more standardised approach, there still remain variations at a health service level. Other jurisdictions and the private sector utilise multiple EMR providers.*
- *The quality and completeness of EMR data varies, and in general is poorer than CQR data. Key CQR data items for measuring clinical indicators are not present in most EMRs.*

*As a general comment, the **Framework documents very much conceptualise CQRs as a database**. While the database and its hosting and security and data collection and reporting technology are all important, CQRs are not about the database. Successful CQRs have been built on fit for purpose open source software such as RedCAP.*

The key components of a CQR are that it is clinician led and patient-centric, such that it creates a clinical (and where applicable) patient community of practice that seeks to make ongoing improvements to processes and outcomes of care. Achieving improvements requires change at the individual practitioner and health service level.

***Databases do not of themselves achieve change; they are a tool that clinicians and registry experts use to facilitate change in a data-driven independent environment of trust and peer support. Describing CQRs as a set of business functions fails to recognise the existing strength of CQRs and why the current model has been so successful, and continues to be highly regarded by clinicians.** EMR analytical software such as Dr Foster has been invested in by state governments who have tried and failed to create useful information regarding outcomes.*

EMR data still remains primarily collected to provide activity information, and is not fit for purpose for quality and safety monitoring. Hospitals currently undertake many manual data collections and audits to provide quality and safety metrics for ACHS and other quality indicators, as for most hospitals the data just isn't in the EMR. This will not be rectified within the next 5 years.

*The '**CQR Solution Design'** section of the document (**Section 3**) is not clear in describing data collection and transfer from a health service to a CQR. The diagrams are poorly labelled and the terminology used is unclear. For example Figure 2 (pg 14) is titled 'CQR conceptual system services' and shows a diagram of various datasets such as PAS and pathology reports moving through an Integration Layer and out to jurisdictional and domain-specific registries. The accompanying text (pg 15) states 'in theory, the framework will enable the establishment of a CQR at health care organisations of any level. To optimise the number of CQR instances, it is recommended that, whenever possible, a CQR needs to be established at the highest level of the organisation (e.g. Group, Health Service or state and territory)'.*
*It is our understanding on reading this, as well as further diagrams and text throughout Section 3, that the **integration layer** referred to is developed and provided **within each health service**, which then on-provides the data to CQRs. **There is no information regarding how this data is fed into CQR systems from the health service.** However, there exist two main mechanisms for this (1) the data is pushed automatically from the HS end to the CQR database or (2) the data is pulled by the CQR from the HS. To date this transfer of data where it exists, is via a manual process (pulling). While we are aware of instances of this sort of transfer being established at a a few individual health services, the model is not currently resourced or funded to be applied across the health system. . It also does not accommodate the situation where additional data is held at the clinician level, which is the case in most private hospital settings.*

*While 'The Road Map (**Section 3.3**) acknowledges 'it is a fact that the level of maturity of e-health system adoption is vastly different across all the hospitals in Australia,' it ignores the implications of this by adding, 'however, the motivation of establishing a CQR is always encouraged regardless of the adoption level.'*

*Figure 3 describes an **Implementation Roadmap,** which has 4 steps; (1) start digitisation (2) increase maturity (3) develop interoperability capability and (4) subscribe to jurisdictional/national CQR. The latter proposes that 'the health service organisation may choose to either host the CQR on their local infrastructure or subscribe to the CQR service from the jurisdictional infrastructure'. **This reads as CQRs should be hosted by individual health services or by jurisdictions.** There is no mention of independent third parties such as Universities or Institutes. In general we do not recommend individual HSs hosting CQRs for privacy and security reasons, as HSs are regularly subject to data breaches. There are also potential privacy issues associated with a HS hosting other HS idenditied data.*

***Section 4 Information Design** 'provides a standardised starting point for the design and implementation of an Australian CQR (pg 20) and provides general information which may be useful to new CQRs'. **Section 5 Infrastructure Design** 'describes at a high-level design for the deployment of CQR applications at the proposed **centrally hosted infrastructure**,' also described as '**CQR-as-a-service**.' This model is not defined in the document, and it is not clear what the centralised infrastructure would consist of or where it would be based.*

*This section notes 'The recommendation as at date of publication of the Framework is that **new CQRs should be established on the CQR-as-a-service platform**, and 'all CQRs on legacy infrastructure should have a roadmap that provides a plan to move off the legacy architecture model.' While such a model has potential advantages, it would require significant investment of funds by the sector, and would not be possible for CQRs to fund individually.*

*While Section 5.1 states that 'Under Model 1, centrally hosted jurisdictional CQR, a single provider network or cloud provider may be used to host CQR-as-a-service.' **There is no information relating to Model 2 (standalone CQRs), which in general seem to be an afterthought throughout much of this document, yet is currently the more widely used model.***

***Section 7 National digital health infrastructure and software industry standards** – 7.1 Infrastructure overview 'describes the centrally hosted infrastructure that is relevant to Australian CQRs (pg 36).' This comprises (1) Healthcare identifiers and (2) Provider identifiers, (3) National Authentication Service for Health (NASH), (4) clinical information specifications and terminologies, and the (5) Health Information Gateway. These have all been developed with the primary purpose of sharing healthcare data between providers for clinical care purposes, not for CQRs that are generally external to health services.*

(1) and (2) and (5) are not yet in routine use in the health system; (3) is not relevant to CQRs, and (4) often is not granular enough for many CQR data items. Given the limited EFT and funding of most CQRs, combined with the lack of EMR maturity of a majority of health services and across the health system, Table 1 Technical Standards Overview (pg 39) is not a fit for purpose standards framework. Essentially the same applies to Appendix A – Business Requirements. There are few if any CQRs that would be able to meet these requirements within the next 5 years.

25. Does this section contain all the information you need to implement the requirements?

☐ Yes
☒ No

If no, what information do you think is missing?

As discussed above, the proposed model relating to standalone disease/procedure specific CQRs that operate across both the public and private sectors, which comprise the majority of Australian CQRs, is unclear both regarding where and how the 'integration layer' is to be incorporated within the data transfer from HS to CQR, and what the enablers are that would drive this integration. Additionally, Australian HSs across the board are not at a sufficient level of EMR maturity to support a model of EMR data transfer to CQRs, and this is likely to be a 10-year timeframe.

26. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in this section?

We recognise that data collection for CQRs is a significant burden for HSs, and that is usually unfunded which may have implications for CQR data quality and completeness. Until the health sector has greater EMR maturity and interoperability, there are short to medium term approaches that can enhance data collection and quality.
These include:

- *Expectations for HSs to collect data for high priority CQRs (e.g. an early definition could be those that are funded by Commonwealth and/or State governments or Agencies, and those that are on the Commission's Prioritised domains ; later it could be those that are accredited). Expectations could be made explicit in the Commission's National Safety and Quality Health Service Standards, that HSs must participate in these defined high-priority CQRs, as appropriate to each HS.*
- *Jurisdictional agreements with HSs could include a requirement to support some data entry for CQRs. This could be funded by a mix of internal HS and jurisdictional/Commonwealth funds.*
- *The new Medical Board of Australia Guidelines require 25 hours per annum of individual performance review, and CQRs provide an appropriate way of achieving this when benchmarked reports are provided to sites and/or clinicians. This could be promoted by the MBA, Colleges and*
- *The ACSQHC could define data standards for Health Services as part of HS accreditation, which include (1) processes to approve CQRs via a QA pathway at the HS or HS group level, (2) requirements for HSs to work towards interoperability with external CQRs.*

We also appreciate current issues with a lack ***of data standardisation for CQRs*** *and we are open to working with governments regarding developing a more standardised approach for CQR data moving forward where possible. We also note that one of the strengths of CQRs as shown during the COVID pandemic, is the* ***adaptability of data collection****. During COVID many CQRs were able to pivot to collect additional items regarding COVID and changing models of care. Any standardised approach to data collection should still have*

flexibility *to allow for dataset adaptation in a timely way to respond to* ***external environmental change.***

SECURITY COMPLIANCE

The *Security compliance guideline* (1.6) provides the national data security standards and a checklist for Australian CQRs. Please review this section and then answer the following questions.

27. Is the information presented clear and easy to understand?

☐ Very clear
☒ Somewhat clear
☐ Somewhat unclear
☐ Not clear at all

28. Does this section contain all the information you need to implement the requirements?

☐ Yes
☒ No

If no, what information do you think is missing?

This response is to Section 1.6 as well as the separate Attachment 2.

The Australian CQR security compliance guideline Second Edition *is a 68-page document that* ***aims*** *'to provide the security compliance checklist and guidance for Australian CQRs' (pg 7). It is 'intended to be used by individuals and organisations wishing to assess the compliance of a new or established CQR against appropriate security standards and techniques current as at November 2022.'*
It is not clear whether this is designed to be used by CQRs themselves as a self-assessment, or by Health Services, or by an accrediting agency. Some clarity regarding this would be useful to properly assess how fit the document is for the proposed audiences. It is likely that a more streamlined, simpler version would be more fit for purpose if it is to be used by a broad range of organisations.

Section 3 Infrastructure models and risk profiles*; It is not clear why the two CQR models are specified here. We would imagine that the principles of good infrastructure security would apply regardless of the CQR operational model.*

Page 12 notes that 'This Guideline assumes that CQRs hosted centrally will be subject to greater inherent security risk than stand-alone CQRs,' and this is noted in the higher risk profile of this operational model on page 16-20. It is disappointing therefore that this document still seeks to promote centrally-hosted CQRs as the preferred model (e.g. 'centrally hosted jurisdictional model (future state) pg 17) even though it is noted to have a greater inherent risk.

The document proposes one infrastructure model for Standalone CQRs, however there are actually multiple infrastructure models. These include:

*1. Data collection infrastructure (**database software**) developed by the **CQR or** by a **third party***
*2. Database **hosted on a server** managed by the **CQR** organisation (e.g. Monash University) or on a server managed by a **third party** (e.g. AWS, Azure)*

There may be various combinations based on the above. This is not adequately captured in 3.3 (pg 13) or Figure 3 (pg 14). This is important because a CQR may need to have separate contractual arrangements with both a software provider and a hosting provider, and these need to clearly articulate the roles and responsibilities of each party relevant to CQR operations and security. Both infrastructure types have different technological and governance risks and processes to manage. There are also risks associated with data sharing technologies e.g. APIs, SFTP that should be specifically noted. Some registries still use paper data collection, and some health services don't use EMRs. The risks associated with this would be appropriate to include.

*The basic premise of **Section 4.2 Assessing Compliance**, seems to be that Centrally Hosted Jurisdictional CQRs are not ISO 27001 or ASD certified. This is intriguing, as many funders expect CQR data infrastructure to be ISO 27001 certified or at least compliant. It would be useful to explain the rationale for this decision. The document says, (pg 26), that 'It is expected that few organisations within Australia will have ISO 27001 or ASD certification'. In this case, isn't an alternative for CQRs to be required to be ISO 27001 compliant, if they are not certified, instead of creating a de novo checklist?*

In this case it would also be useful to explain the difference between ISO 27001 certified vs compliant in the document, e.g.

***ISO 27001 compliant** means that the organisation (CQR) has self-assessed against the ISO standards and believes it to be compliant with these.*
***ISO 27001 certified** means that organisational (CQR) compliance against the ISO standards has been confirmed by an external auditing/certifying organisation.*

***Section 5 Security Compliance Checklists for CQR 'Good Practice'**. It is noted that the embedded Excel documents in 5.1 – 5.3 are not able to be accessed (the checklists).*

Overall, we question the need for detailed guidance regarding security (Section 6). Ideally this document would identify existing recognised security standards for CQRs (e.g. ISO 27001 certification or compliance), that would each CQR to determine if they have access to the capability and functionality to meet these standards. If not, the CQR may need to seek a provider that can provide the required functionality and capability. Noting this may be a source of significant costs particularly to small CQRs, which may limit their ability to ultimately be accredited.

29. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in this section?

It is unclear what organisations (e.g. CQRs, health services, an accrediting agency/the Commission, CQR funders/the Commonwealth/Jurisdictions) would use this document? We

suggest a more streamlined document that is developed through specific user feedback to make sure it is fit for its determined purpose.

This section (and document) would be strengthened if the value of all infrastructure models was appropriately recognised and one model is not promoted over another, particularly when the central jurisdictional model is noted to have higher security risks.

Note types of risks associated with various CQR infrastructure, including both the database software, the hosting environment, data transfer technologies (e.g. APIs, SFTP) and even paper data transfer.

Consider using terms ISO 27001 certified vs compliant or explain the rationale for the need for an alternative compliance checklist.

Use existing security standards that can advise CQRs of what the high-level expectations are, so that they can determine whether they are able to meet these standards, or need to seek an alternative provider, which may be cost prohibitive for small CQRs.

REPORTING

The section on *Reporting* (1.7) outlines the requirements for timely data reporting and analytics. Please review this section and then answer the following questions.

30. Is the information presented clear and easy to understand?

☐ Very clear
☐ Somewhat clear
☒ Somewhat unclear
☐ Not clear at all

31. How could the content be expressed or designed to better support you or your organisation to implement the guidance provided in the *Framework 2nd edition*?

Section 1.7 Reporting
Reporting is a key function of CQRs, *and is one factor that differentiates CQRs from other clinical registries, audits, cohort and longitudinal datasets. We acknowledge that currently there is a diversity in frequency and content of CQR reports, particularly reports to sites, and that it is useful for the Commission to seek to standardise this to some extent. However we make the following observations:*

'Real-time reporting' (as recommended on page 29) generally utilises data that has not been cleaned or risk-adjusted*. It is most useful for providing* ***operational/activity information*** *to clinicians and health services. It is recommended* ***that benchmarked reports are provided on data that has been cleaned, verified where possible and risk adjusted****. This data is more robust and is the data from which any* ***outliers*** *should be determinated. In general, these reports may become available from around 6 months after the period that they are monitoring, depending on the timeliness of data entry. It is noted that many state and national datasets currently report final benchmarked data many years after*

the event (e.g. AIHW, Consultative Council data). ***By comparison, CQR reporting is generally very timely.***

The section also states (pg 29) that 'annual reporting of aggregate or summary information is insufficient to meet the needs of the sector for safety and quality improvement.' However this depends on the particular CQR. For monitoring outcomes of a chronic disease such as diabetes, annual benchmarked reporting may be perfectly adequate. However monitoring outcomes of high volume high risk procedures may be more appropriate on a quarterly basis, given the risks of not identifying issues in a timely way. Where CQRs or HSs have low volumes of episodes, reporting more frequently than annually may not be clinically meaningful. ***The type and frequency of reporting should be relevant for the individual CQR and be determined by the CQR Steering Committee****.*

Currently many CQRs do not provide reports to all jurisdictions, and in many instances jurisdictions do not necessarily have an identified contact or process to receive and review these reports. If jurisdictonal reporting is to be a requirement, ***then jurisdictions need to clearly identify to whom these go to within jurisdictional health departments****.*

The proposed schedule of reporting is onerous, and requires a team of analysts and statisticians, particularly if ad-hoc reporting becomes significant. CQRs may need to charge a fee for bespoke reporting to enable cost-recovery where possible.

Clinical interpretation may be appropriate for review of annual and potentially site reporting, however depending on the scale and scope of the CQR, this can be a significant burden to clinicians and cost to the registry. Clinician time should be used juridciously.

Not all CQRs provide clinician reports, primarily to ensure engagement particularly in the absence of a mandatory participation requirement.

The type of statistical analysis required depends on the nature of the CQR. While process control charts may be appropriate to high volume high risk procedures (e.g. cardiac), they may not apply to low volume or chronic diseases/procedure CQRs (e.g. diabetes or transplants) or where few sites participate.

Inclusion of cost-effectiveness, cost-utility and cost-benefit data regarding CQRs is an important undertaking that should be done periodically at a system level. There is no rationale for this on an annual basis, and costs may be prohibitive for small CQRs.

32. Does this section contain all the information you need to implement the requirements?

☐ Yes
☒ No

If no, what information do you think is missing?

Real-time reporting *is primarily for operational purposes to review* ***activity****.*

Benchmarked, risk-adjusted reports *take time to produce, nevertheless CQR reports are often more timely than similar reports from jurisdictional and national government organisations.*

The Steering Committee should determine the type and frequency of reports, as well as the most appropriate types of analyses*. In general, the requirements for specific reports are extensive and may not all be required or feasible within the staffing of CQRs, many of which have less than 1 EFT of statistician or data analyst.*

Jurisdictions should have a clearly identified process for receipt and review of CQR reports.

CQRs may need to ***charge fees for bespoke*** *reports.*

CQRs should use clinician time in reviewing reports judiciously *to minimise time and cost burden. Clinician-level reports should not be required in the absence of mandatory participation as it may reduce clinician engagement in CQRs.*

Cost-effective analysis of CQRs should be undertaken periodically at a system level.

Reporting recommendations should be high level and be achievable even for CQRs with less than 1 EFT of funded statistician time.

Automation of reporting *via fit-for-purpose registry platforms, where HSs can access interactive dashboards of their live data may reduce the requirement for statistician time in the future.*

33. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in this section?

See above. In general, reporting requirements should be flexible, high level, specific to the needs of the particular CQR, and in line with the level of CQR maturity and resources.

OUTLIER MANAGEMENT AND OVERSIGHT

The section on *Outlier management and oversight* (1.8) outlines the requirement for CQRs to develop and implement a performance measurement policy to identify outliers and provide opportunities to support quality improvement. Please review this section and then answer the following questions.

34. Is the information presented clear and easy to understand?

☐ Very clear
☐ Somewhat clear
☒ Somewhat unclear
☐ Not clear at all

35. How could the content be expressed or designed to better support you or your organisation to implement the guidance provided in the *Framework 2nd edition*?

Section 1.8 Outlier measurement and oversight..

It is important to recognise that the primary function of benchmarked reporting is to allow HSs to understand how their processes and outcomes of care compare to others, especially their like/peer HSs. This has been shown to lead ***in overall improvement in outcomes across both poor performing and highly performing CQRs****. This results in lifting the performance across the sector, and benefits individuals who participate across many individual HSs.*

Outlier identification is a specific use of benchmarked reporting *where 'outliers' are identified and prompted to undertake a review of their processes and outcomes of care. Outliers may not be common, nor may they be an indication of serious adverse outcomes. It is important that the primary focus of reporting is recognised to be* ***quality improvement****, and not the singling out of individual HSs to be criticised or blamed.*

Outlier identification ***at site level*** *is generally made via the use of* ***risk-adjusted funnel plots,*** *although other statistical methods are also available. This is a valuable tool in enabling clinical Unit Heads and hospital leadership to review their performance when it is below expected levels to identify and address any potentially contributing factors.*

However, outlier identification at ***a clinician level*** *is more complex. Currently most CQRs do not require mandatory participation, and it is recognised that some clinicians may remain reluctant to engage in CQRs if they believe that their individual outcomes will be the subject of scrutiny or review. The current legislative environment exacerbates this, as CQRs may be subject to FOIs, legal subpoenas, and are not commonly granted qualified privilege status.* ***Thus clinician-level outlier reporting in the absence of mandatory participation may not be feasible in some CQRs****.*

It should also be noted that there is very little literature regarding appropriate outlier analysis mechanisms for CQRs. Questions such as how does the number of participating sites, or the volume of cases at each site, or the frequency of the outcome occurring, impact on outlier determination, have not been researched (for reference, Monash University currently has a PhD student undertaking this). Further, ***some outcome measures such as mortality*** *require more timely attention and action than others such as e.g****. reporting of cancer stage****. Ultimately, the* ***clinician leadership/Steering Committee should determine the method and frequency of reporting outliers from each CQR****.*

A recent publication in the area of stroke recommended that risk-adjustment only be used when comparing patient health outcomes and NOT for comparing processes of care. This is because if a care processes is standard for a particular population, every patient should receive this irrespective of age, sex, etc. (Yu et al, 2022).

The proposed outlier management timeline may also be infeasible given many registries rely on statisticians external to their core staff to run outlier analysis.

Also, experience from multiple CQRs has shown that escalation beyond the hospital level may be difficult to achieve. It may be difficult to find a contact within a jurisdiction who could

*be notified. For **private hospital groups**, it is less clear what the role of reporting to the jurisdiction is. **Guidance from the Commission in defining and supporting a system-wide approach to outlier escalation and review is required.***

36. Does this section contain all the information you need to implement the requirements?

☐ Yes
☒ No

If no, what information do you think is missing?

*Outlier identification and management is a small part of benchmarking, and should be undertaken within an **overall supportive environment that seeks to identify and address issues without blame.***

***The Commission should clarify the escalation process beyond the hospital level, and actively support this through its engagement with HSs and Jurisdictions**.*

37. Do you have any suggestions for strategies that would support CQRs to implement the requirements detailed in this section?

We recommend the following:

- *The Commission work with the Commonwealth and Jurisdiction Departments of Health regarding **mandating priority CQRs** – this could include Commonwealth, Agency and Jurisdictional-funded CQRs, CQRs from the Commission's priority list, as well as any other CQRs identified as high priority.*
- ***CQRs determine the method and frequency of reporting outliers** based on their disease/procedure profile, size, and requirements. **Timelines** should also be adjusted accordingly, and CQRs should not be held accountable where external parties delay escalation e.g HS review/response of the outlier, or jurisdictional review.*
- ***The Commission include in its National Safety and Quality Standards for Health Services, the requirement for HSs to review CQR reports when received, and to address issues identified and report these to the CQRs**. This would include the **Commission's Inter-jurisdictional Committee** working to create identified units/staff within each jurisdiction to whom CQRs can escalate hospital outliers as per an escalation policy.*

SUMMARY PAPER

The *Summary Paper* includes four case studies of CQRs that are working towards aligning with the national arrangements and meeting the requirements of the *Framework 2nd edtion.* Please review the document and then answer the following questions.

38. Please share with us any specific aspects of the case studies that you found useful.

N/A. The case studies are too few and brief to provide useful guidance.

39. How could the case studies be improved? We are interested to hear your thoughts on the content, structure and format of the case studies, and on the appropriateness of the CQRs featured.

*It is recommended that the Framework contain an **Executive Summary** for ease of reading and to consolidate specific guidance and recommendations.*

*It is recommended that prior to the use of Case Studies, that the 'Summary' contain an **overview of the activity and impact** of the CQR sector in Australia, and highlights the data quality gaps in the current system that have led to the development of CQRs over the last 30 or so years .It is recommended that the 'Summary' note that **Australia is an international leade**r in CQRs, and that economic reviews of CQRs consistently show a **health economic benefi**t.*

*We noted some **confusion regarding terminology** and what activities would be considered 'in-scope' regarding the Framework, such as government-hosted datasets, national clinical audits and research databases. We believe that the general principles of **CQRs as clinician-led, patient-centred activities which aim to enhance the quality and safety of healthcare through regular collection and reporting of data to participants,** remains a fit for purpose definition.*

*While we agree that all guidance documents should be future-focused, we believe that the Framework should propose interim strategies over the next few years to support these principles. This would also align with the **10 year timeframe of the National CQR Strategy until 2030**.*

*The Summary paper highlights sector concerns regarding CQRs as primarily related to data collection, data governance and IT systems, and lack of standardisation. We understand this feedback was primarily provided by health services and jurisdictions (although this is not explicitly stated in the Framework). It would be good to also note **concerns of the CQR sector as also key stakeholders,** that should be included in the Framework, such as:*

- *the need for sustainable funding models,*
- *a recommendation for CQR participation to be mandatory for priority CQRs*
- *health service support for data collection,*
- *the current ethics and governance approval process that is not fit for purpose, and*
- *the need for a process to escalate CQR performance issues beyond the health service if no action is taken*

PROCESSES

Within a research paradigm there are already established processes for obtaining approvals to conduct cohort studies. For health data to be collated and reported within a safety and quality framework, the *National Health Information Agreement* would be the preferred mechanism for gaining approval from the data custodian.

40. Do you think this mechanism is fit for purpose?

☐ Yes
☒ No

If no, what other mechanism of agreement accessing and analysing and reporting on health data for safety and quality health care improvement is preffered?

The NHMRC Statement states that CQRs and other QA activities ***need to be reviewed by an 'appropriately constituted group' within each HS organisation.*** *This does not need to be by a Research Governance Office, however this has become the norm by default. Yet when CQRs are onboarded by RGOs, they face many obstacles, including lack of RGO understanding of CQRs particularly opt-out processes; duplication and completion of unnecessary paperwork that is not suitable for CQRs, and is based on a clinical trial paradigm. This leads to frequently long delays in HS approvals which can take months or years****, resulting in many years to onboard CQRs nationally****.*

Implementing ***amendments to CQRs****, such as the collection of additional variables to align with changing clinical guidelines, may be delayed many months as ethics and governance approvals are sought at each participating site.*

Additionally, when CQRs are approved via the RGO pathway, frequently this means that the HS Clinical Governance Unit is not aware that the HS is contributing data and does not have routine access to reports or data. ***Thus, the full potential of the CQR is not being realised.***

Even when HSs are interested in approving sites via an alternative pathway, there is not an existing process to do this.

Monash University was funded in 2022-23 by the Commonwealth Department of Health to undertake a ***Streamlining CQR Approval Project (SCrAP) to address this issue****. The Project commenced in April 2022 and aimed to implement a sample of CQRs with a sample of HSs via a pilot process via the Clinical Governance Unit or equivalent of the HS. The Project team and a developed Steering Committee (including an observer from the Commission) developed a set of supporting resources:*

1. *A draft* ***CQR policy for Health Services***
2. *A* ***CQR-Health Service Contract Template and Schedule***
3. *A* ***CQR Lead Role Description for Health Services***
4. *A* ***Good CQR Practice Guide*** *(in development)*

*These resources were **well received** and had extensive review by participating HSs and CQRs. However, **implementation has been difficult**. A survey is currently being undertaken to understand barriers and enablers to this process, but feedback so far has been primarily related to **HSs seeking formal approval/recognition that this is a legitimate alternative to RGO approval for CQRs**. The other barrier has been time and the project being **a lower priority** compared with competing day to day operational priorities. While the final report is still being drafted, it is likely to make the following recommendations:*

1. *That the **NHMRC** provide formal guidance to the Commonwealth that CQR onboarding by HS processes other than via the RGO is appropriate.*
2. *That the **Commission** endorse the developed SCrAP resources and process as an appropriate alternative to RGO approval.*
3. *That the Commission raise awareness of the SCrAP process with the **jurisdictions**.*
4. ***Mandatory participation** in Government or Agency funded CQRs will also assist HSs in prioritising implementation of the SCrAP (or other) alternative pathway for approval.*

ABOUT YOU

41. Which of the following best describes where you are located?

- (•) Metropolitan
- ( ) Regional
- ( ) Rural
- ( ) Remote
- ( ) Not applicable
- ( ) Other (please specify)

42. In which state or territory are you based?

- ( ) ACT
- ( ) NSW
- ( ) NT
- ( ) SA

- ○ TAS
- ○ QLD
- ◉ VIC
- ○ WA
- ○ Other (please specify)

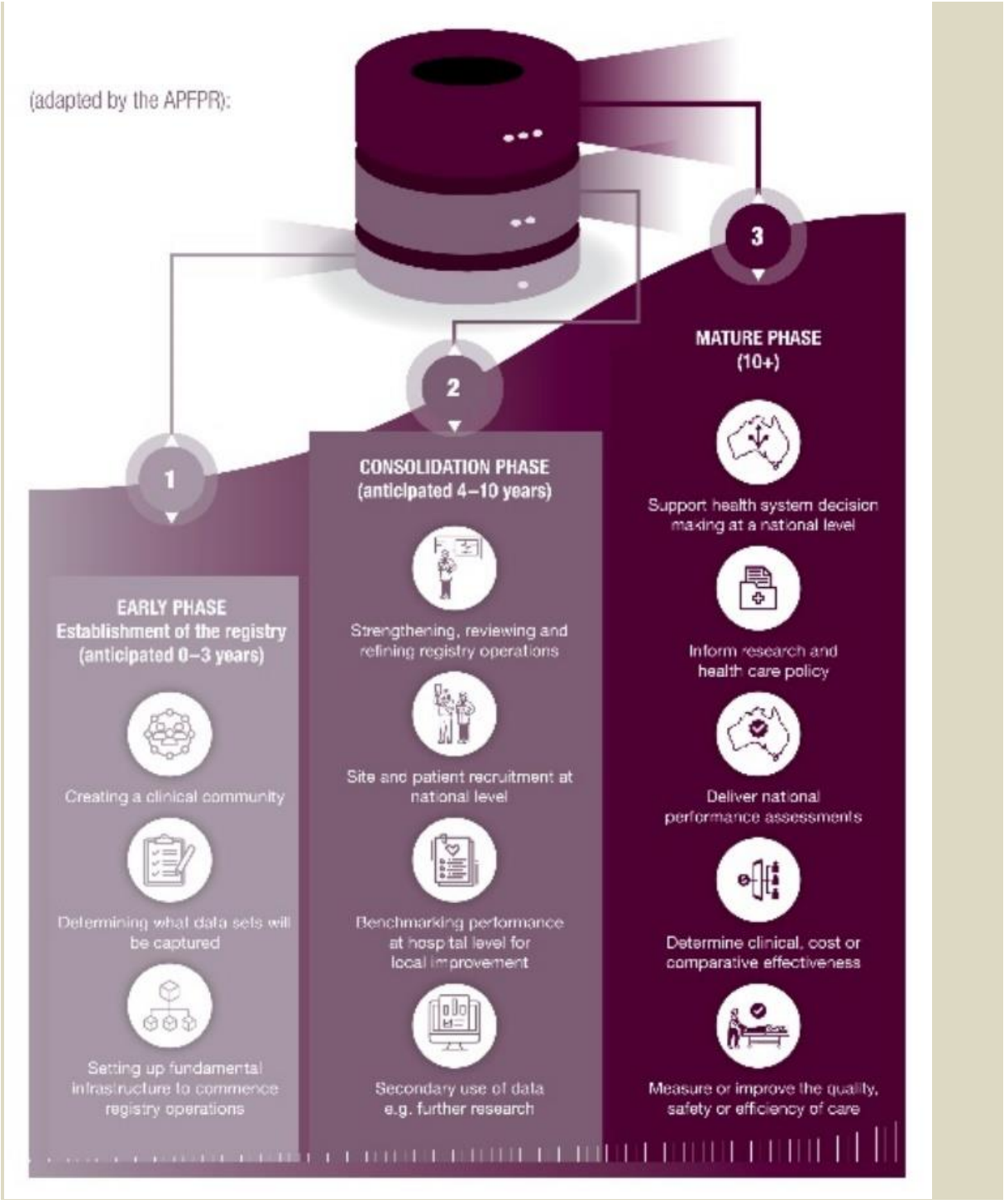
- ○ Prefer not to say

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY

43. If you have any final and additional feedback on the documents, please provide it here.

We provide two suggested additional areas of focus for the Framework below:

1. ***CQRs are consumer-centred:***
   - *Australian national CQRs should be* ***designed in partnership with consumers, Aboriginal and Torres Strait Islander people and linguistically diverse communities*** *to ensure the collected data reflects their experiences, and to ensure these groups receive information in a way that is appropriate for them.*
   - *Several CQRs have been designed with or are operating with* ***close collaboration with consumers****. As an example, the Australian Pelvic Floor Procedure Registry (APFPR) has consumer representation (both in relation to lived experience and consumer advocacy) on its Steering Committee, as well as a Consumer Advisory Group to provide feedback on registry activities and ensure they are informed by the needs of patients with pelvic floor conditions. The Australian Dementia Network Registry also has consumer representation via Dementia Australia at Steering Committee level and also within working/advisory groups. These advisory groups have co-designed patient and carer surveys, and provided input into the Annual Reports.*
   - *CQRs provide an opportunity for national consumer-friendly,* ***data-driven information for consumers regarding their specific disease/procedure outcomes****, which otherwise is generally jurisdiction-based. However, resourcing for consumer engagement and resource/information development for consumers may not be available for all CQRs.*
2. **Monash University has developed a graphic that highlights the key maturity phases** of CQRs, and the current phase timeframes, based on site ethics and hospital governance barriers leading to delayed national coverage, as well as the timeframes required for CQRs to obtain long term follow up data. We recommend the Framework articulates the key components and phases of CQR maturity and recognises the timeframe ranges in its expectations of CQR capability.


(adapted by the APFPR):
1
2
3
EARLY PHASE
Establishment of the registry
(anticipated 0–3 years)
Creating a clinical community
Determining what data sets will be captured
Setting up fundamental infrastructure to commence registry operations
CONSOLIDATION PHASE
(anticipated 4–10 years)
Strengthening, reviewing and refining registry operations
Site and patient recruitment at national level
Benchmarking performance at hospital level for local improvement
Secondary use of data e.g. further research
MATURE PHASE
(10+)
Support health system decision making at a national level
Inform research and health care policy
Deliver national performance assessments
Determine clinical, cost or comparative effectiveness
Measure or improve the quality, safety or efficiency of care