

**RACS SUBMISSION IN RESPONSE TO THE ACSQHC CONSULTATION REGARDING:
*THE FRAMEWORK FOR AUSTRALIAN CLINICAL QUALITY REGISTRIES – 2ND EDITION***

INTRODUCTION

Although the benefits of full case ascertainment and complete data collection are widely acknowledged (ACSQHC's own *Economic evaluation of clinical quality registries*¹ provides useful detail on the economic benefits of greater coverage), the Framework does not set out the essential strategies which will lead to such a goal (RACS acknowledges the Framework is not intended to describe a detailed plan for the sector).

This submission is broken into two sections: A and B.

Section A describes strategies which should be considered to achieve the goal of full case ascertainment and complete data collection in priority registries.

Section B provides general comments about the Framework.

SECTION A:

STRATEGIES TO ACHIEVE FULL CASE ASCERTAINMENT AND COMPLETE DATA COLLECTION IN AGREED PRIORITY CLINICAL QUALITY REGISTRIES

It is RACS' view that Australian governments and other stakeholders should implement a variety of interlinked strategies with the goal of achieving full (national) case attainment and complete data collection in *agreed priority clinical quality registries* (CQRs), including ones relevant to surgery as well as other areas of medicine.

These strategies include the following:

1. Reaching agreement amongst stakeholders on which surgical (and other) registries to prioritise for full case attainment

Governments should work with colleges, specialty societies and other clinical stakeholders on the identification of existing registries or clinical domains requiring registries for priority development.

The existing ACSQHC 'Prioritised list of clinical domains for clinical quality registry development'², is a starting point.

There will be some registries which may be more conducive to early development towards full case attainment, for example the Australasian Shunt Registry, Binational Colorectal Cancer Audit, Australasian Vascular Audit, Australasian Pelvic Floor Procedure Registry, BreastSurgANZ Quality Audit, Australian and New Zealand Emergency Laparotomy Audit, Prostate Cancer Outcomes Registry - Australia and New Zealand, and the Australian & New Zealand Thyroid Cancer Registry.

There may be value in identifying a small number of registries for a pilot project which would involve implementing the strategies outlined here only in relation to them. Were high/full case attainment achieved under this pilot the strategies could be applied more broadly.

2. Streamlining approval processes

A major restraint on the roll out of CQRs is site approval. RACS acknowledges this issue is widely understood, and notes that, 'streamlining site governance, patient

¹ <https://www.safetyandquality.gov.au/sites/default/files/migrated/Economic-evaluation-of-clinical-quality-registries-Final-report-Nov-2016.pdf>

² <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/prioritised-list-clinical-domains-clinical-quality-registry-development-final-report>



consent and research ethics processes', is a 'priority action' in the *National CQR Strategy 2020-2030*.

RACS acknowledges it is a complex policy area, but is of the strong view that a legal mechanism enabling automatic, system-wide and cross jurisdictional ethics approval for prioritised CQRs would be key to fast-tracking the achievement of full (national) case attainment.

3. Making health service participation mandatory and ensuring attendant funding for public health services

Full case attainment and complete data collection will be impossible without a mandatory requirement for public and private health services to participate. RACS notes that 'Action 1.28' of the NSQHS Standards requires health service organisations to identify potentially unwarranted variation, and regularly review and improve the appropriateness of clinical care³. However, participation in specific registries is not currently mandated as an element of this 'action'. RACS would support a consultation on the potential for the tightening of NSQHS or clinical care standards (or other mechanisms) so as to mandate participation by health services in *specific prioritised registries or registries in particular clinical domains*.

Although it would not result in universal participation by health services, as an additional lever RACS could consider adding CQR compliance to its hospital/training accreditation process.

For *public* health services, mandatory participation would need to be accompanied by funding for administration, as well as the systematic integration of prioritised clinical quality outcomes data with national and jurisdictional health information systems. This will be a large task as in some public hospitals, relevant records exist only on paper.

4. Provisioning priority registries with sustainable funding

Even if the seamless integration of health information systems were achieved, the clinical bodies managing prioritised surgical (and other) registries will also require specific funding support for administration. As noted in the *National CQR Strategy 2020-2030*, 'funding for clinical quality outcomes datasets is provided on an ad hoc basis by a range of public, private and non-government stakeholders, with varying funding models and levels of commitment in place, and no clear strategic approach or consistency.'⁴

A frequently cited barrier to the greater success of registries is the time spent by administrators seeking what is often non-reoccurring, and relatively short-term funding from a variety of funders.

RACS broadly supports the funding model outlined in the *National CQR Strategy 2020-2030*⁵ of 'sustainable funding in partnership with multiple beneficiaries'. However, RACS notes that funders, particularly those with a financial interest should not influence the purpose or functioning of CQRs.

RACS notes that the funding model of the Australian Orthopaedic Association National Joint Replacement Registry⁶ (AOANJR) is one that may be able to be emulated in some cases. But, many registries will not have the support of an industry with a direct financial interest in gaining outcomes data, as is the case with the AOANJR.

³ <https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance-standard/clinical-performance-and-effectiveness/action-128>

⁴ <https://www.health.gov.au/sites/default/files/documents/2021/02/national-clinical-quality-registry-and-virtual-registry-strategy-2020-2030.pdf>

⁵ [https://www1.health.gov.au/internet/main/publishing.nsf/Content/F092FB9BBFDA4CBACA2583CB000505FE/\\$File/National%20Clinical%20Quality%20Registry%20and%20Virtual%20Registry%20Strategy%202020-2030%20to%20Web%2013%20Dec%202021.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/F092FB9BBFDA4CBACA2583CB000505FE/$File/National%20Clinical%20Quality%20Registry%20and%20Virtual%20Registry%20Strategy%202020-2030%20to%20Web%2013%20Dec%202021.pdf)

⁶ <https://www.health.gov.au/resources/publications/national-joint-replacement-registry-cost-recovery-implementation-statement-1-july-2022-to-30-june-2023?language=en>

Currently the very successful prostate cancer outcomes registry only exists due to support from the 'Movember' charity. A patient charity should not be left to maintain such a critical piece of health infrastructure.

Because the ultimate beneficiaries of registries are patients, it is appropriate that governments and private health insurers be the primary contributors.

5. Implementing measures to drive full participation by surgeons and other clinicians

5.1 Use of Registration Standards or Continuing Professional Development (CPD) to require participation

RACS requires its Fellows to participate in one peer-reviewed audit as an element in CPD (as well as to participate in Australian and New Zealand Audit of Surgical Mortality (ANZASM) where there has been a patient death). This does not mean they must participate in a specific registry. Rather the audit can be a clinical unit audit, specialty group audit, registry, total audit, or selected audit, as long as it is peer reviewed and at least 10 hours per annum.

RACS' requirements are in line with the AMC's 'CPD Homes' Criteria for Accreditation which do not require Accredited CPD program providers to mandate participation in a specific type of audit. There is also a requirement in the Criteria for Accreditation that CPD be provided at a reasonable cost to practitioners.

The CPD Homes model also enables practitioners to choose from a variety of CPD providers.

Thus, while the way RACS implements its CPD program encourages participation in registries as a means of audit, the nature of the existing CPD Homes model means RACS' CPD is not currently an appropriate means of mandating participation in specific registries.

RACS notes that the provision of 'complete and accurate data to clinical registry(s) that are relevant to the (cosmetic surgery practitioner's) scope of practice'⁷, is a requirement under the new Registration Standard for Endorsement for Cosmetic Surgery.

Consideration could be given to the wider implementation of such a model for clinicians whose scope of practice fell within the scope of priority registries.

Were changes made to mandate participation either through changes to the CPD Homes model, or through changes to Registration Standards, RACS would work with regulators to achieve compliance by its Fellows.

Note however that any new measures mandating participation should not be rolled out without first mandating health service participation. It will be impossible for clinicians to participate without full participation and support of the health services in which they work.

5.2 Commitment to the confidentiality of individual surgeon/clinician data

Prior to last federal election a bill was tabled which would have created surgeon 'league tables' with data on individual surgeon performance. While RACS supports the public release of appropriately risk-adjusted outcomes data on surgical performance at a team, institutional or national level, RACS does not support release of reports on individual surgeon performance⁸.

Patient outcomes are often system-based issues rather than related to individual performance.

In addition, without appropriate risk adjustment and/or if poorly communicated, outcomes measures may tell an entirely incorrect and unfair story about a clinician.

⁷ <https://www.medicalboard.gov.au/News/2023-04-03-cos-surgery-update.aspx>

⁸ <https://www.surgeons.org/about-racs/position-papers/public-reports-on-surgical-outcomes-and-performance-2015>

As an example, it is widely acknowledged that perhaps the most highly regarded kidney cancer surgeon in the United Kingdom ranks poorly against other surgeons. This is due to the fact that this surgeon tackles cases referred by other surgeons who either do not want to tackle those cases or who do not have the skillset.

It is hard for the patient and lay person to fully understand these nuances in case data.

Public release of clinician-level data would thus mean that clinicians are incentivised to provide less complete information about their procedures to clinical quality registries, and to shift complex clinical cases.

RACS understands that 'Australian national CQRs' operating in conformance with the model set out in this Framework would keep data 'confidential', and only share particular data with particular groups - Individual clinician data would only be available to the contributing clinician, unit-level data would only be available to the contributing unit, etc.

RACS believes that this model is appropriate, striking the right balance between openness and transparency, and confidentiality.

On a related issue, anecdotal evidence indicates that qualified privilege is becoming more difficult to obtain for clinical quality registries.

There are advantages to qualified privilege. In RACS's view, amongst other benefits, it can result in increased cooperation and candour amongst peers, increased candour in accurately reporting outcomes, and the potential to increase case ascertainment - assisting in complete data entry.

Absence of qualified privilege has been cited as a reason why some clinical quality registries do not have greater participation.

At the same time RACS acknowledges that there are valid reasons to restrict qualified privilege. Indeed, RACS recently successfully obtained a change to qualified privilege for ANZASM, in order facilitate appropriate data sharing with jurisdictions for quality improvement in multidisciplinary care.

Thus, in order to encourage participation in priority registries the availability or otherwise of qualified privilege should be managed flexibly.

SECTION B:

GENERAL COMMENTS ABOUT THE FRAMEWORK

Governance

There should be more of an emphasis on the need for *national* governance arrangements. The fractured nature of the Australian health system has meant that registries attempting to have national coverage themselves have fractured governance arrangements, including differing rules around access to data in different jurisdictions.

Data collection

RACS welcomes the fact that the Framework outlines a data set that is desirable, and the intent to measure things that actually make a difference to patients.

There is a desire to collect as much data as possible from routine data collections at hospitals. RACS supports this, however this is currently unrealistic for many reasons including Australia's level of digital sophistication.

Aims like "Data collection should be automatic and electronic" may not be achievable for many reasons, e.g:

- Patient outcomes are collected from patients with varying literacy
- Some records are only on paper (i.e. in some public hospitals)

Data linkage is a goal but it is unclear how possible this is nationally without a strong national strategy to achieve this.

Specialist societies and Colleges may be able to provide advice about how to get more from what is available e.g. LOS, return to theatre, readmission rates etc

Appropriate processes for internal data validity checks are somewhat unclear.

Collection of PROMS data on a routine rather than research basis will be difficult and expensive, often requiring independent data managers rather than clinicians to enter the data.

CQRs need to be constructed in a robust fashion so that if e.g. the provider of software goes out of business the data and registry can continue.

Outliers

The 'Outlier policy' has not been suitably refined for Australian conditions, as it is based on UK HQIP guidelines that may differ in the Australian context. Data quality is a key requirement, so the current barriers to full case ascertainment and data quality will impact this.

The definition of an 'outlier' triggering an investigation is inconsistent in the document and the methods for identifying outliers require clarification and refinement i.e. 2 SD (too many alerts not practical) vs 3SD (may not be a large enough group). A suggestion may be to use control (and run) charts where 2 or 3 consecutive points above the alert level of 2SD, for example, may be the trigger. The document describes using funnel plots (these are becoming obsolete due to the demands of the necessary frequent risk adjustment). The use of run charts, which show trends over time, is not mentioned in the document. The Framework emphasises near real time reporting, at every 3 months. Statistical process control chart or run charts can do this easily, funnel plots cannot.

Australia operates a very different health system to the UK, with a public and private mix for most clinicians who work across a number of sites where the case-mixes may differ. An outlier policy is best to reflect the entire practice of the individual, but this will be difficult for a range of reasons – data sharing from different sites (privacy considerations include issues across state and territory borders as well), availability of this data in a timely manner, and how to enforce private hospital participation.

The Framework is silent on the right to work while a health professional is under investigation, but this should occur in all but the most exceptional cases because of the potential for poor data e.g. false alerts.

How would the cost of outlier review be covered? There is also a question around indemnity for reviewers undertaking such investigations.

RACS encourages the Commission to develop recommendations within the Framework for best practice processes to support individual clinicians and Units requiring improvement to meet performance standards.

Reporting

Overseeing the interpretation of reports is best managed at the Specialist Society level.

The host/guardian should be responsible for ensuring local health services have access to their own data, comparisons at least de-identified, regarding various benchmark KPIs.

As noted in section A, RACS understands that 'Australian national CQRs' operating in conformance with the model set out in this Framework would keep data 'confidential', and only share particular data with particular groups/individuals. RACS agrees with this model.

RACS is concerned that poorly communicated outcomes data may cause prejudice against rural hospitals in favour of large metropolitan hospitals and have the perverse impact of undermining efforts to build health access in rural areas. The release of Australian national CQR data should be managed bearing in mind policy priorities such as ensuring continued access to health services in rural areas. An ultimate outcome of a successful system of national CQRs providing data about outcomes to jurisdictions should not be the further consolidation of services in metropolitan areas.

Reporting frequency

With the current level of CQR engagement the reporting frequency suggested in the document will be challenging due in part to the timely access/receipt of data. There needs to be some guidance on the meaning of 'real-time' reporting, with a balance between doing so frequently to ensure practice improvements with over-reporting.

Is there a way to recognise different levels of sophistication of CQRs i.e. gold, silver, bronze levels where bronze level is operating at the minimum requirements? This would reflect the time it takes a CQR to reach full sophistication.

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