Medical colleges have an obligation to ensure full participation in Clinical Quality Registries

Robert J Aitken[1]
Julian A Smith[2]
Guy J Maddern[3]

1 Sir Charles Gairdner Hospital, Perth, WA.
2 Monash University, Melbourne, VIC.
3 University of Adelaide, Adelaide, SA.

robert.aitken@health.wa.gov.au

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Clinical Quality Registries (CQR) systemically collect health-related information that can be used to monitor, benchmark and improve patient care. Historically, most have been quality assurance activities that collected data over a year and reported up to another year later. Near real-time, longitudinal quality improvement CQRs are now preferred,[1] and there is abundant evidence that CQRs improve outcomes and are cost-effective.[2-4]

The cornerstone of a successful CQR is data quality.[5,6] Although only a minority of CQRs are managed by medical colleges, almost all will have college representatives on their management committee. We argue that colleges should use their position to ensure high quality data, which requires full participation, high case ascertainment and data completeness. Poor quality data can provide misleading reassurance, perhaps leading to incorrect conclusions. A participation rate of at least 95% is recommended.[6] In many countries, authorised CQRs are mandated.[2] As the loss of even a small number of cases can have an impact on results, many audits in the United Kingdom have an exemption to patient opt-out provisions.[7] The importance of data quality is so critical that CQRs should report compliance.[1] Since 2014, the Australian Commission on Safety and Quality in Health Care (the Commission) has published a series of documents related to CQRs. The most recent was the revised 2024 Framework.[1] This mirrored the federal Department of Health, Disability and Ageing 2020–2030 CQR strategy.[8] The barriers to participation have been repeatedly identified in these and many other publications.[6,9] They include inadequate ethics approval process; the variable, inconsistent and often unreasonable demands of site-specific approval; the constraints of qualified privilege; the barriers to data sharing; and the disproportionate imbalance of preventing the potential leak of individual patient data against the much greater community gain. The lack of secure, protected funding has been particularly problematic.

These barriers have not been addressed in any practical manner.[6,9,10] CQRs cannot function properly without substantial clinician involvement, which is usually provided in addition to their normal clinical duties. The failure of governments to address barriers is frustrating, disheartening and, ultimately, a deterrent to clinician involvement.[10] As a result, participation in Australian CQRs is very poor. The Commission's website currently lists 122 CQRs, of which 16 are purely or predominately surgical.[11] Only two of these have achieved the 95% participation standard.[12,13] A suitable high profile example is the Australian and New Zealand Hip Fracture Registry, which commenced in 2012, but in 2024 reported that less than 90% of Australian hospitals participated.[14] Many surgical CQRs have compliance rates of less than 50% (data from annual reports or project managers). At least eight of the 16 CQRs have been granted federal or state funding.

In their response to the draft 2023 CQR Framework, both the Royal Australasian College of Surgeons (RACS) and the Australian Clinical Trials Alliance advocated mandatory participation in priority CQRs.[15,16] The Commission's response was that there should be further exploration related to linking hospital accreditation and individual continuous professional development (CPD).[17]

Detecting and then managing unwarranted variation (outliers) is a central role of CQRs. The Commission's 2024 Framework outlier policy borrowed heavily from the UK Health Quality Improvement Programme (HQIP). HQIP revised its outlier guidance in January 2024 such that CQR governance bodies are now required to report hospital or clinician non-participation to the Care Quality Commission — the external independent regulator.[18] The 2024 Framework copied this updated HQIP outlier guidance, but changed the requirement to reporting non-participation to the relevant health service organisation, who would know, or should have already known, of the non-participation. In no other safety-critical industry would it be acceptable for an organisation to report non-participation in safety activities to itself.

Two editorials published in 2024 specifically and critically addressed the problem of poor participation in surgical CQRs. One of the editorials stated that the societal benefit from participating in CQRs made providing treatment without audit unethical.[19] The second editorial reminded surgeons of their professional responsibility to critically assess their performance, benchmarked against their peers.[20] These ethical and professional responsibilities are equally applicable to hospitals and jurisdictions.

Although the Commission's Framework places the responsibility of managing participation on the CQR governance body, it provides it with no authority. Indeed, its changes to the HQIP Outlier Guidance has arguably watered down their authority. Likewise, a professional college has no authority to override the barriers to participation that governments have failed to address.

It is abundantly clear that voluntary participation in Australian CQRs has failed.[11,14] However, medical colleges and their members have an important role in addressing this failure. A key step would be that the profession mandate participation in their specialty CQRs and that non-participation would be associated with significant consequences.

The Framework gives the medical colleges an opportunity to advocate to the Commission and

support it linking CQR participation to hospital accreditation and individual CPD.[17] It would also permit the medical colleges to address the serious concerns expressed by the Hon Geoffrey Davies in a series of lectures he delivered to the surgical community in the aftermath of the Bundaberg hospital inquiry.[21]

The first step would be to formalise the conduct of the hospital's monthly mortality and morbidity meeting. There are already longstanding guidelines for conducting these meetings and they should be meaningfully enforced as part of hospital accreditation.[22] This would include a minimum 80% consultant attendance. If the hospital is the training site, the medical colleges have an obligation to know the quality of patient outcomes and enforce its quality, which would be audited by the Australian Council on Healthcare Standards.

The second step would be that, at each meeting, participating practitioners confirm they have completely entered all data into any relevant CQR, including any national mortality audits. This would ensure timely data entry, facilitate data completeness, allow early discussion of any variation and, thus, permit near real-time quality improvement, which are all requirements of the Framework. Existing examples of near real-time (monthly or quarterly) quality improvement reporting can be found in the UK National Hip Fracture and Emergency Laparotomy CQRs and the Australia and New Zealand Emergency Laparotomy Audit – Quality Improvement (ANZELA-QI). HQIP and Australian states are increasingly reporting near real-time. Such real-time reporting will still need to be supplemented by careful analysis and interpretation.

The third step would be for medical colleges to require completion of their CPD program within two months of the end of the CPD year. Failing that, the practitioner would have to apply for an exemption, and, if granted, the CPD should then be completed within an additional reasonable period. This is the CPD standard expected of the legal profession. If tradespeople flying to a mine do not have current safety certificates, for example, they are not permitted to board the plane, far less enter the mine site. There is no reason why medical practitioners should be held to a lesser standard.

The final step would be the publication of participation compliance by named hospitals. This would be consistent with CQRs that already publish identifiable hospitals[14] and is a requirement of the Framework. The threat to a practitioner's CPD compliance and a hospital being disaccredited would provide both practitioners and hospitals with powerful incentives to participate.

There will undoubtedly be protests. Each medical college should state it is responding in anticipation of the likely obligations that will be imposed[17] by the Commission and jurisdictions and its wish to demonstrate unequivocal support for CQRs. Concerns about costs should not be a barrier to action, given the Commission's own evidence that CQR are cost-effective.[3,4] In other safety critical industries, participation in safety activities is not dependent on funding. Whether government and jurisdictions then support the medical colleges will provide clear evidence of their real interest in CQRs.

There are strong precedents. The monthly staff meeting was one of the five components of the 1917 American College of Surgeons (ACS) Minimal Hospital Standardisation (MHS) program.[23] Over the next 20 years, it became the primary endeavour of the ACS and was the basis of the Joint Commission on Accreditation of Hospitals, now the Joint Commission.[24] Many current CQRs were initially established by the ACS in the 1920s.

The first report of the MHS program was presented to the ACS Regents in October 1919. In March 1920, only five months later, an editorial in the *Medical Journal of Australia* (*MJA*) argued that if "possible in America, it must be possible in Australia" and that Australian hospitals should be given a year to "remedy existing defects" and it would then be in the "public interest if lists of hospitals were published".[25] This was the first of more than 20 editorials, meeting reports, and special and other articles that the *MJA* published over the next seven years, in which it advocated for the introduction of the MHS into Australia. The MHS program was strongly supported by the RACS founders and was included in its original constitution. As its centenary approaches, the RACS and the other medical colleges should deliver the vision of these founders.

Competing interests: Robert Aitken is a member of the Western Australia Department of Health Mortality Committee and a member of the Australian and New Zealand Audit of Surgical Mortality (ANZASM) Management Committee. He is the Clinical Director of the Western Australian Audit of Surgical Mortality (WAASM) and Chair of the Australian and New Zealand Emergency Laparotomy Audit – Quality Improvement (ANZELA-QI) working party. He is a member of Australian Commission on Safety and Quality in Health Care Emergency Laparotomy Clinical Care Standard Topic Working Group. Julian Smith is the Chairman of the Australia and New Zealand Cardiac and Thoracic Surgery Research Institution, which is the corporate entity overseeing the three clinical quality registries of the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (adult cardiac, thoracic and congenital), and a former member of the Royal Australasian College of Surgeons (RACS) Council. He is Editor-in-Chief of the *Australian and New Zealand Journal of Surgery*. Guy Maddern is the Surgical Director of Research Audit and Academic Surgery at RACS, and Chairman of ANZASM.

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1 Australian Commission on Safety and Quality in Health Care. Australian Framework for National Clinical Quality Registries 2024. Sydney: ACSQHC, 2024. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/australian-framework-national-clinical-quality-registries-2024 (viewed Oct 2024).

2 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. https://www.safetyandquality.gov.au/sites/default/files/2021-11/evidence-check-governance-accreditat

ion-and-quality-assurance-of-clinical-quality-registries-final-report-nov-2021.pdf (viewed July 2025).

3 Australian Commission on Safety and Quality in Health Care. Economic evaluation of clinical quality registries: final report. Sydney: ACSQHC, 2016. https://www.safetyandquality.gov.au/sites/default/files/migrated/Economic-evaluation-of-clinical-quality-registries-Final-report-Nov-2016.pdf (viewed Oct 2024).

4 Lee P, Chin K, Liew D et al. Economic evaluation of clinical quality registries: a systematic review. *BMJ Open* 2019; 9: e030984.

5 Boyle JR. Future of surgical registries. *Br J Surg* 2021; 108: 741-741.

6 Brown WA, Ahern S, MacCormick AD, et al. Clinical quality registries: urgent reform is required to enable best practice and best care. *ANZ J Surg* 2022: 92; 23-26.

7 NHS England. Programmes to which the National Data Opt-Out should not be applied. https://digital.nhs.uk/services/national-data-opt-out/programmes-to-which-the-national-data-opt-out-should-not-be-applied (viewed Oct 2024).

8 Australian Government Department of Health and Ageing. Maximising the value of Australia's Clinical Quality Outcomes data. A national strategy for Clinical Quality Registries and Virtual Registries, 2020–2030. Canberra: Commonwealth of Australia, 2020. https://www.health.gov.au/resources/publications/a-national-strategy-for-clinical-quality-registries-and-virtual-registries-2020-2030?language=en (viewed Oct 2024).

9 Ofri A, Spillane AJ. The complexities of establishing a surgical multi-centre registry in Australia: challenges, and possible solution. *ANZ J Surg* 2024; 94: 1444-1446.

10 Maddern G. Clinical quality registries: is government listening? *ANZ J Surg* 2023: 93; 2782.

11 Australian Commission on Safety and Quality in Health Care. Australian Register of Clinical Registries. https://www.safetyandquality.gov.au/publications-and-resources/australian-register-clinical-registries (viewed Oct 2024).

12 South Australian Health and Medical Research Institute. The Australian Orthopaedic Association National Joint Replacement Registry. Adelaide: SAHMRI, 2024. https://aoanjrr.sahmri.com (viewed Oct 2024).

13 Royal Australasian College of Surgeons. Surgical mortality audits. https://www.surgeons.org/research-audit/surgical-mortality-audits (viewed Oct 2024).

14 Australian and New Zealand Hip Fracture Registry. Annual report of hip fracture care 2024. Sydney: ANZHFR, 2024. https://anzhfr.org/registry-reports/ (viewed Oct 2024).

15 Royal Australasian College of Surgeons. RACS submission in response to the ACSQHC consultation regarding the Framework for Australian clinical quality registries, 2nd ed. https://www.surgeons.org/-/media/Project/RACS/surgeons-org/files/advocacy/RACS-submission-to-Registries-Framework-Consultation_.pdf?rev=f809960886b4410680f005f51d4f6d90&hash=2132C960DEB01D89979C29EFCB3FC1CA#:~:text=RACS%20broadly%20supports%20the%20funding,purpose%20or%20functioning%20of%20CQRs (viewed Oct 2024).

16 Australian Clinical Trials Alliance. ACSQHC consultation: CQR Framework for clinical quality registries. Australian Clinical Trials Alliance Registry Special Interest Group. 31 March 2023. https://clinicaltrialsalliance.org.au/wp-content/uploads/2023/04/ACTA_CQRFrameworkResponse_FINAL.pdf (viewed Oct 2024).

17 Australian Commission on Safety and Quality in Health Care. National consultation and feedback 2023. Framework for clinical quality registries, 2nd ed. Sydney: ACSQHC, 2024. https://www.safetyandquality.gov.au/sites/default/files/2024-08/framework-for-australian-cqrs-second-edition-consultation-2023-summary-report.pdf (viewed Oct 2024).

18 Healthcare Quality Improvement Partnership. NCAPOP Outlier Guidance. Identification and management of outliers. London: HQIP, 2024. January 2024. https://www.hqip.org.uk/wp-content/uploads/2024/02/HQIP-NCAPOP-Outlier-Guidance_21022024.pdf (viewed Oct 2024).

19 Harris IA, Close JC, Armstrong E. Barriers to clinical audit. *ANZ J Surg* 2024: 9: 1436.

20 Stoney JD, Smith PN. Power of arthroplasty registries in orthopaedic surgery. *ANZ J Surg* 2024: 9: 1437-1438.

21 North J, Murphy K, Beaumont G. Self-regulated trustworthiness: reality or myth? *ANZ J Surg* 2023: 93: 1126-1127.

22 Royal Australasian College of Surgeons. Surgical audit guide, 5th ed. Melbourne: RACS, 2021. https://www.surgeons.org/-/media/Project/RACS/surgeons-org/files/reports-guidelines-publications/manuals-guidelines/surgical-audit-and-peer-review-guide.pdf?rev=8c6d405564b84c5ea96e6991a9378b86&hash=F2595498AB95EE4DC227237D11875F26 (viewed Oct 2024).

23 American College of Surgeons. Seventh year book, 1920. The College, 1920; pp 13-17.

24 Joint Commission. History of the Joint Commission. Oakbrook Terrace (IL): Joint Commission, 2025. https://www.jointcommission.org/who-we-are/facts-about-the-joint-commission/history-of-the-joint-commission/#:~:text=Founded%20in%201951%2C%20The%20Joint,the%20highest%20quality%20and%20value (viewed Oct 2024).

25 Hospital standardization. *Med J Aust* 1920; 1: 263-264. https://doi.org/10.5694/j.1326-5377.1920.tb39898.x ■