30 March 2023

Dr Bernadette Aliprandi-Costa
Manager, Safety and Quality Improvement Systems and Intergovernmental Relations
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
Sydney NSW 2001

Sent via email: CQR@safetyandquality.gov.au

Dear Dr Aliprandi-Costa

Re: Australian Commission on Safety and Quality in Health Care Consultation on the Framework for Australian clinical quality registries, Second Edition

Thank you for inviting public responses to your proposed updated Framework.

Background to our responses

Stroke is a major cause of death and disability. It is estimated that 445,000 survivors of stroke are living in our community - many with ongoing disability.[1] In Australia, inequitable access to, and provision of, best-practice treatments is a major cause of health disparities. Patient outcomes (death/disability) could be improved following stroke, as well as other events, if there was less variation between hospitals in the provision of best-practice care.[2]

Clinical quality registries (CQRs) play a critical role in continuous quality improvement, improving patient outcomes and compliance with evidence-based guidelines.[3] For example, monitoring the use of thrombolysis in acute care settings across Australia lead to improved outcomes for many stroke patients, particularly those in rural and regional areas. In addition, CQRs represent value for money, returning between two and seven dollars for every dollar invested.[3] In 2016, the Australian Commission on Safety and Quality in Health Care (the Commission) identified stroke as a priority clinical domain for national CQR development, due to the 'serious consequences of poor quality care, high burden of disease, and moderately high cost to the system'.[4] Despite its recognised importance and need, funding to support a national stroke CQR has been challenging to secure and fragmented, and currently the Federal Government does not contribute any funding towards support for this national CQR.

Established in 2009, the Australian Stroke Clinical Registry (AuSCR) is a collaborative national effort to monitor, promote and improve the quality of acute stroke care. This CQR is used to collect data on patient admissions for stroke and transient ischaemic attack (TIA) from participating hospitals across Australia. In addition, follow-up of patients after their hospital admission, and data linkage with the National Death Index (NDI), collects valuable

data about patient outcomes. The data are used to guide quality improvement interventions in hospitals, reduce variations in care delivery and, ultimately, reduce preventable deaths, disability, and recurrent stroke. Importantly, the consecutive collection of patient care data as part of the AuSCR has permitted unique insights from across the country on the effects of the COVID-19 pandemic on acute stroke care[5, 6], which have been used to inform Australian governments.

The AuSCR program is undertaken by a consortium led by the Florey Institute of Neuroscience and Mental Health, and two leading non-government organisations, Stroke Foundation and the Stroke Society of Australasia. Support for analysis and reporting is provided by stroke epidemiologists from Monash University. Collectively, these organisations represent a broad section of the Australian clinical and scientific stroke community.

The AuSCR now has 63 hospitals across six states and territories contributing approximately 20,000 new episodes of care each year. In addition, the AuSCR has more than 160,000 episodes of care recorded, and has received in excess of 74,000 completed follow-up surveys of patient reported outcomes (www.auscr.com.au).

The AuSCR and its consortium partners, Stroke Foundation and the Stroke Society of Australasia, welcome the opportunity to provide input into the development of the Framework for Australian CQRs, Second Edition.

Our responses below address several areas of focus in this consultation.

A sustainable funding model for Australian CQRs

CQRs require significant and long-term investment. There are substantial resource requirements for CQRs that collect identifiable patient datasets, use an opt-out approach, and collect patient-reported outcome measures (PROMs). Since CQRs are frequently viewed as 'infrastructure', there are significant challenges in attracting competitive research grants from funding bodies to support their core operational activities and database systems, and relying on research grants is highly risky and inappropriate for a national priority resource. For many Australian CQRs, securing ongoing funding is a year-by-year proposition that inefficiently consumes a significant amount of time.

A fundamental shift is needed to recognise CQR core programs as essential to systematically monitoring the quality and appropriateness of care, driving continuous improvements in patient outcomes, and ultimately delivering value to the health system. As data collecton, reporting and quality improvement are an integral part of the National Health Reform Agreement (addendum 2020-25), there is a clear need for a sustainable Federal funding model for national, prioritised CQRs. This should be Federally-supported, as the Federal govenement has an obvious interest in obtaining value for money in Activity Based co-funding. Federal coordination would reduce the risk of State-based data system fragmentation. This has obvious efficiencies, and will significantly reduce the amount of time registry teams are required to spend in order to secure funding.

Many of the elements in the Framework will be infeasible or unachievable without adequate resourcing and security of ongoing funding. These include the development and

maintenance of data infrastructure, staffing (e.g. governance management), reporting requirements, the standardised collection of PROMs, and achieving interoperability with hospital electronic medical records (EMRs). We will require sector-wide innovation to achieve the necessary data integration.

In the most recent Stroke Foundation National Stroke Audit Acute Services Report, there were 115 contributing hospitals that admitted over 40 patients per year.[7] Therefore, with adequate funding, there is scope for the AuSCR to continue to grow and involve more hospitals. Currently, the AuSCR team is faced with a significant workload, and uncertainty, when negotiating budgets with each state and territory jurisdiction with contracts that are often short-term (1-year). There is no funding to upgrade the data platform to meet the objectives of the Framework in reducing the data collection burden for clinicians.

The ideal funding scenario

We feel that a partnership model between the Commonwealth and the jurisdictions would be the ideal funding model for CQRs. The Commonwealth could provide ongoing, sustainable support for the infrastructure required for data capture, reporting and national benchmarking, and each jurisdiction could support the provision of registries in their areas with longer-term (3-5 year) contracts, that adequately cover the costs of running a registry and the requirements of the Framework.

We have recently been quoted a cost of between $1-3 million for the development of a bespoke registry platform that will meet the future vision desired for CQRs. We have sought grant funding to support this (which is highly uncertain), but would expect government funding for core 'state of the art' data infrastructure, including systems that enable interoperability, that will be required of registries. Although it is one of the most advanced systems available, our current platform is not flexible enough to easily allow for the addition or changing of variables. Importantly, this current platform does not provide the level of reporting required by clinicians and governments/funders, and is nearing capacity in terms of reporting on the large volume of episodes within it. The system is now nine years old, and there is an urgent need to refresh the software and design.

Feasibility of the Framework for Australian CQRs, Second Edition

While we acknowledge that the Framework is future-focused, we are concerned about the feasibility of a number of elements of the Framework should this be the basis for registry accreditation in the future.

Although we have made some progress with Application Programming Interfaces (APIs) (for example in Western Australia, where the state-based Western Australian Stroke Data Tool links via an API to the AuSCR), most hospitals do not have the infrastructure or resources to enable them to extract data and set up APIs to import data securely and directly into registries.

Some hospitals are still using paper records, rather than EMRs, and there are many different patient management and EMR systems. Therefore, there is no one-size-fits-all approach,

and costly bespoke options may be required for each health service. In addition, EMRs often lack the completeness and detail that the registry requires, so the direct transfer of data from EMRs to registries may present issues with data quality, and could still require some manual data entry or data cleaning.

Ethics and governance approvals

Although the Framework acknowledges the limitations of working within a research framework, rather than a routine health service safety and quality framework, no guidance is provided on moving off this traditional pathway. Obtaining and maintaining ethics and governance approvals are a significant burden on CQRs in terms of workload, and in some health services, the costs for amendments. These burdens have been identified as a key barrier to the development of registries in Australia. The ethics requirements for CQRs can differ greatly between states and even between individual hospital ethics committees. Steps are being made, particularly in Western Australia and Queensland, to move to a more streamlined approach to ethics and governance approvals, by clearly designating CQRs as a key part of quality improvement. Further government leadership, support and guidance to move away from the traditional research pathway is required. Streamlining of the ethics and governance requirements for registries, in order to maximise their operational efficiency, should be addressed at a national level. CQRs should not have to deal with these issues on their own.

Reporting

The number and timing of reports listed in the Framework is infeasible, and in many instances not clinically meaningful. One example is the requirement for quarterly reports to health services. The AuSCR currently includes 'live' reports (real-time based on the data in the system) within the Australian Stroke Data Tool (AuSDaT) (see below), and we are working towards more interactive dashboards. However, formal reporting to hospitals requires complete data, where data quality processes have been completed and statisticians are able to run detailed analysis (e.g. to derive variables). This process is time-consuming, and it is not possible within our current staffing and resources to provide high-quality reports to health services more regularly.

We wish to seek clarity regarding the term 'real-time' reporting. Staff from hospitals participating in the AuSCR have access to on-demand 'live' reports of their data currently in the registry, and may search for certain date ranges and compare their data to peer, state or all hospitals. Data for reporting is reviewed for quality and completeness, variables are derived, and rules for handling missing or conflicting data are applied. Before annual reporting, data are linked with the NDI for completeness of outcome reporting. Therefore, these reports cannot be 'real-time'.

In addition, hospital staff often rely on clinical coding to identify and/or complete their AuSCR records, which can take weeks to finalise, and data sent to the registry can be delayed by 3 months or more.

Moreover, linkage with the NDI is costly (approximately $5,000) and time-consuming. Therefore, linking registry data to the NDI more frequently than what is currently done (annual basis) is infeasible. A model whereby CQR data, like the AuSCR, is integrated into enduring linkages managed at the Federal level, e.g. the National Integrated Health Service Information Analysis Asset, may see linkages to the NDI (among other assets) occur more frequently at lower cost.

In terms of outlier reporting, a distinction needs to be made between performance indicators for hospital processes of care (e.g. discharge medications) versus performance indicators related to patient health outcomes (e.g. mortality or readmissions). Clinical judgement is also needed to interpret the appropriateness of hospital processes of care depending on the patient circumstances and clinical scenario (e.g. patients who are being transferred to another hospital for surgical procedures). Case-mix (risk) adjustment should only be used when comparing patient health outcomes between hospitals. It is also important that covariates selected for risk adjustment are done so carefully. These should meet the requirements of a true confounder. We recommend risk adjustment should only be used when comparing patient health outcomes between hospitals, and not for comparing processes of care. Instead, subgroup analyses and stratification could be used to investigate differences in processes of care between hospitals.[8]

However, if appropriate adjustments are made, we strongly believe that reporting should eventually be mandatory and public facing, similar to some international registries (for instance https://www.strokeaudit.org/). Reports could be provided against the National Standards where they exist (e.g. Acute Stroke Standard). As data collection and quality improvement are mandatory requirements under the National Health Reform Agreement, State hospitals providing stroke care should be publicly accountable. The Framework should promote, and provide for, public reporting of data.

Governance

The AuSCR has a Steering Committee comprised of relevant stakeholders, including representatives from each of its consortium partner organisations, as well as individuals with lived experience of stroke. In addition, there is an AuSCR Management Committee, all members of which have clinical backgrounds in medicine, nursing, or allied health, which is responsible for the day-to-day operation of the AuSCR with oversight from the Steering Committee. Importantly, it is the Steering Committee, rather than the Board of The Florey Institute of Neuroscience and Mental Health as the data custodian and legal entity, which has oversight of governance and sets the strategic direction for the registry.

While the governance arrangements outlined in the Framework do not align with the AuSCR's current governance structure, we do agree that the proposed model is sound and may offer numerous benefits, helping to strengthen support for the registry's functions. In 2022, we commissioned an independent review of the governance and operational aspects of the AuSCR. We will consider the recommendations from this review when the report is received in May, and their alignment with the final Framework.

Patient Reported Outcome Measures (PROMs)

PROMs, which reflect the patient's perspective, as they provide data directly reported by the patient or the patient proxy, are increasingly being captured by registries alongside clinical measures. These measures provide a bio-psycho-social perspective on health, and have the potential to help clinicians improve the quality of patient care by moving beyond traditional outcomes such as mortality and morbidity.

While AuSCR does collect PROMs, collecting these outcomes at two or more time points, as specified in the Framework, is infeasible for our registry and more than likely for other CQRs. The AuSCR collects PROMs at one time point, between 90-180 days post-admission for stroke/TIA. This is a standard/recommended time point post-stroke, where symptoms are stable, and is used widely in stroke research. Given the AuSCR receives information on approximately 20,000 episodes of care per year, providing comprehensive follow-up is labour intensive and a significant cost to the registry. Approximately 65 to 70 percent of eligible AuSCR registrants complete follow-up, and we would not be able to collect PROMs at a second time point without a significant increase in funding. We believe the current single timepoint in the AuSCR is appropriate for the stroke population. We also believe that PROMs should be fed back to clinical teams in a timely way to further support quality improvement. Currently, clinicians can see these data in our system, but are not immediately alerted when these records are complete for viewing or where certain responses might flag the need for a hospital to review a patient. We are currently working on an MRFF funded project to assess the feasibility of an AuSCR prompted, hospital-led, follow-up service for respondents reporting poor quality of life metrics.
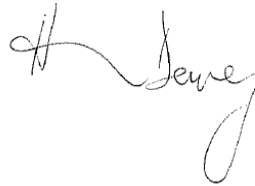
Summary

Failure in care delivery for stroke is costly for both the patient and the health system.[9] The inefficient use of limited healthcare resources represents significant risk for health services and governments. The revised Framework is an important step towards national reporting, and the development of a national standard, for CQRs. As a Stroke Community we strongly support the Commission's focus on data collection, reporting and quality improvement. Our response has highlighted the critical need for a sustainable funding model for Australian CQRs which will underpin the Framework, as well as elements of the Framework that are currently infeasible for the AuSCR and likely many other Australian CQRs. We appreciate and thank the Commission, and the Advisory Group, for undertaking this work. We do note that those on the Advisory Group represent important acute care groups (including stroke), but recognise that the subacute sector plays an important role in quality care and follow-up, and therefore should also be represented in any future updates. We look forward to hearing about the outcomes of this consultation, and further refinement of the Framework.

Thank you for the opportunity to provide input into this consultation.

Yours sincerely

Professor Dominique Cadilhac
Data Custodian
AuSCR and AuSDaT

Professor Helen Dewey
Chair
AuSCR Management Committee

Dr Lisa Murphy
CEO
Stroke Foundation

Professor Timothy Kleinig
President
Stroke Society of Australasia

References

1. Deloitte Access Economics. 2020. No postcode untouched, Stroke in Australia 2020.

2. Cadilhac DA, Andrew NE, Lannin NA et al. Quality of acute care and long-term quality of life and survival: the Australian Stroke Clinical Registry. Stroke. 2017. 48:1026-1032.

3. Australian Commission on Safety and Quality in Health Care (ACSQHC). 2016. Economic evaluation of clinical quality registries: final report. Sydney: ACSQHC.

4. Australian Commission on Safety and Quality in Health Care (ACSQHC). 2016. Prioritised list of clinical domains for clinical quality registry development: final report. Sydney: ACSQHC.

5. Cadilhac DA, Kim J, Tod EK et al; AuSCR COVID-19 Reporting Consortium Group. COVID-19 pandemic impact on care for stroke in Australia: Emerging evidence from the Australian Stroke Clinical Registry. Front Neurol. 2021. 12:621495.

6. Cadilhac DA, Kim J, Cloud G et al; AuSCR COVID-19 Reporting Consortium Group. Effect of the Coronavirus disease 2019 pandemic on the quality of stroke care in stroke units and alternative wards: A national comparative analysis. J Stroke. 2022. 24:79-87.

7. Stroke Foundation. 2021. National Stroke Audit – Acute Services Report 2021. Melbourne, Australia.

8. Yu AYX, Bravata DM, Norrving B et al. Measuring stroke quality: Methodological considerations in selecting, defining, and analyzing quality measures. Stroke. 2022. 53:3214-3221.

9. Kim J, Andrew NE, Thrift AG et al. The potential health and economic impact of improving stroke care standards for Australia. Int J Stroke. 2017. 12:875-885.