

Submission to the Draft National Clinical Quality Registry Strategy 2019-2029 Consultation



Submission summary

This year there will be more than 56,000 strokes in Australia¹, and there are more than 475,000 stroke survivors living in our community¹, many with an ongoing disability. Unless action is taken, it is estimated by 2050 the number of strokes experienced by Australians will more than double to almost 133,000 strokes annually¹, and there will be one million stroke survivors living in the community.¹

Stroke Foundation is a national charity that partners with the community to prevent stroke, save lives and enhance recovery. We do this through raising awareness, facilitating research and supporting stroke survivors. Stroke Foundation is dedicated to empowering health professionals to deliver high quality best-practice care to stroke patients. We advocate for better systems, processes and resources to help health professionals deliver world class stroke care.

Clinical quality registries (CQRs) play a critical role in continuous quality improvement, improving patient outcomes and compliance with evidence-based guidelines. An evaluation of Australian CQRs has demonstrated these registries have a number of important benefits. This includes greater survival for patients and improvements in quality of life after treatment.² In addition, they represent value for money, returning between two and seven dollars for every dollar invested.²

When stroke was identified by the Australian Commission for Safety and Quality in Health Care (ACSQHC) as a priority clinical domain for national CQR development in 2016³, an Australian CQR for stroke had already been in operation for a number of years.

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.⁴ This CQR is used to collect data on patient admissions for stroke and transient ischaemic attack from participating hospitals across Australia. In addition, follow-up of patients three to six months after their hospital admission, and data linkage with the National Death Index, collects valuable data about patient outcomes. This data is used to guide quality improvement interventions in hospitals, reduce variations in care delivery and, ultimately, reduce preventable deaths, disability, and recurrent stroke. The AuSCR now has 83 hospitals contributing data in six states, with more than 80,000 episodes of acute care and in excess of 36,500 completed follow-ups of patient reported outcomes at 90-180 days following admission.

The AuSCR initiative is undertaken by a four member multidisciplinary consortium of which Stroke Foundation is a part. Other members include The Florey Institute of Neuroscience and Mental Health, The George Institute for Global Health, and the Stroke Society of Australasia. Stroke Foundation is represented on the AuSCR Management and Steering Committees, and with The Florey Institute of Neuroscience and Mental Health, shares responsibility for the maintenance and operation of the Australian Stroke Data Tool (AuSDaT). The AuSDaT is a web based tool which is used to collect patient data for the AuSCR, as well as other stroke programs, including Stroke Foundation's National Stroke Audit.

As the voice of stroke in Australia, Stroke Foundation welcomes the opportunity to comment on the draft National Clinical Quality Registry Strategy 2019-2029.

As well as drawing on the experience of the AuSCR, there is an opportunity to learn from international experience. For example in Sweden, significant government investment over two decades in the development of National Quality Registries (NQRs) and health information technology infrastructure, has contributed to major gains in a number of clinical areas including stroke.

Outlined below are the **key elements** Stroke Foundation believes are needed as part of a **national, coordinated and strategic approach to the development of CQRs**.

- Australian Governments to invest in the development of a coordinated national registry program, which will include:
 - A *set of national CQR standards* based on the ACSQHC operating principles and technical standards.
 - An *independent accreditation scheme* for national CQRs, with different accreditation levels assigned to registries depending on the number of national CQR standards they meet.
 - A *sustainable funding model*, which should:
 - identify multiple sustainable public and private sources for support of registry operations
 - determine funding of *new national CQRs*, based on their ability to address high priority clinical domains as outlined by the ACSQHC, as well as key gaps in registry coverage
 - determine funding of *established CQRs that have achieved sustainable operation*, based on their ability to address high priority clinical domains, as well as attain the highest national CQR accreditation level, requiring achievement of all national CQR standards
 - include a minimum 5-year funding term for organisations contracted to develop and operate national CQRs.
- Australian Governments to mandate that under national healthcare standards, Australian hospitals are required to contribute data to approved national CQRs as a requirement of their hospital accreditation.
- Australian Governments to invest in hospital infrastructure to support national CQR data collection.
- Australian Governments to work towards a national, streamlined ethics application and approval process, and harmonisation of Federal and State and Territory privacy legislation.
- In order to make CQR data more *accessible* and *understandable*, Australian Governments should require national CQRs to:
 - Share data more widely, by extending reporting to all relevant clinicians, hospital boards and management teams, funders and accreditors.
 - Provide registry data to clinicians and other key stakeholders in a more timely fashion.
 - Present registry data as clearly as possible, accompanied by analysis and presentation that assists understanding, so clinical teams can see how they are performing compared with their peers, and how they can improve.
 - Make registry data easier to manipulate for quality improvement purposes.

Recommendation

Consideration should be given to funding a demonstration project, using one or two established CQRs, such as the AuSCR, which address a high priority clinical domain and meet a high proportion of the national CQR standards that will underpin a national accreditation scheme. The purpose of the demonstration project will be to identify and address barriers to the implementation of the National CQR Strategy. In addition, the project will identify and highlight the key elements of high impact, high value national CQRs.

1. National CQRs are based on clinician/patient partnerships (p25)

- **What key actions would facilitate:**
 - **clinician/patient partnerships?**
 - **the development of CQR PROMs and PREMs?**
 - **greater clinician/patient interaction with CQRs?**
 - **the development of interactive CQRs?**
 - **What other key actions would facilitate CQR contribution to patient centred care?**

There is an increasing focus on patient centeredness in registries, which is consistent with our growing understanding of the importance of active partnerships between patients, clinicians and researchers in driving improvements in healthcare services, patient outcomes and research. However in Australia, and internationally, many registries have limited patient involvement in their design, oversight, or operations.⁵ Patients are often not consulted about their priorities regarding outcomes for data collection.⁶ In addition, patients do not usually have access to registry data, and as a consequence are unable to utilise this data to support self-management or shared decision-making.

There are however indications things are beginning to change. For example, in the United Kingdom (UK), the Healthcare Quality Improvement Partnership (HQIP) has an explicit patient and public involvement policy, and now includes patient representatives when developing specifications for its registries.⁷ Similarly in the United States (US), the ImproveCareNow network for inflammatory bowel disease engages patients and families together with care teams and researchers in the design, governance and operation of its registry, facilitating improved awareness of what is important to patients.⁸

In Sweden, registry management teams in NQRs use **a variety of strategies to engage with patients**⁹:

- For registries with existing patient associations a common feature is to have one or two representatives from that association on the steering committee. When no relevant patient associations are established there are alternative ways to ensure patient representation.
- Registry representatives' are regularly invited to patient associations' meetings to present current registry information.
- Patients participate in the design of registry questionnaires, information materials and guidelines.

Registry representatives noted the positive impact of active patient and patient organisation participation, in particular the increased awareness on behalf of registries as to the type of information patients may need.⁹ One of the key barriers to participation from the patient's perspective was understanding registry output data, particularly for patients with impaired cognitive skills. This highlighted the **need to make registry data more understandable for patients**.⁹

The AuSCR actively involves consumers in its governance structure, design and development, and consults Stroke Foundation's Consumer Council in the development of consumer friendly summary

reports of clinical audit data for dissemination of key stroke care quality indicators. This helps consumers to participate in local advocacy for improvements in stroke care.

An increasing number of countries, including the UK, Sweden and the Netherlands^{10,11}, are beginning to incorporate patient-reported outcome measures (PROMs) into clinical registries alongside clinical measures.¹² PROMs reflect the patient's perspective as they provide data directly reported by the patient or the patient proxy. In Australia, a number of clinical registries, including the AuSCR, the Victorian Severe Trauma Registry, the Victorian Prostate Cancer Registry and the Arthroplasty Clinical Outcomes Registry in New South Wales, are collecting and reporting on PROMs. 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. Importantly however, one of the concerns of employing PROMs in monitoring the quality of care, is the lack of an established standard on what change in PROMs scores should be achieved by an intervention.¹³ International societies have begun publishing recommendations on how to integrate PROMs into registries, which may provide useful guidance for Australian CQRs looking to introduce these measures.

New **patient centred registries** are being developed, in which data, including patient outcomes and experiences, are continuously monitored and available to clinicians and patients in real time. A generalisable model for a **registry based, patient centred learning system** has been developed, which brings together patients and families with clinicians and care teams to form a partnership for coproducing health improvement and research.¹⁴ In this system¹⁴:

- *Data 'feed forward' systems* enable patient reported and clinical data to be made available continuously both for patients, and at the point of care for tracking health and planning care.
- Patients are able to share their perception of health, function, and wellbeing with their care team in real time.
- Patients can select measures that matter to them and enter their data outside clinical encounters, enabling them to monitor and continually assess their health.
- *Decision support 'dashboards'* with graphs of patient level data over time enable patients and clinicians to detect relations between symptoms and interventions.
- Registry data are returned to both the patient and the clinician in *meaningful summary reports* showing trends over time.

This system is significant for people with chronic conditions, who rely on self monitoring and self management to deal with their condition.

In this system, efficiently collecting valid patient reported and clinical data in busy practices across different electronic platforms is a potential challenge; however, the developers of the system suggest **utilising a third party, internet based solution** to¹⁴:

- extract selected clinical data elements from the electronic health record and the clinician
- collect self reported measures from patients using validated tools
- instantly display all data in the dashboard.

The developers suggest this can be achieved using secure, privacy protected processes.¹⁴

In a system such as this, it is critical that models of consent are responsive enough to respect patients' preferences, and deal with changes that may occur over time with regard to the purposes for which data may be utilised, as well as who may access and utilise the data.¹⁴

2. National CQRs are quality assured, efficient and cost effective (p26-27)

- **What key actions would facilitate:**
 - **the development of a CQR standard and accreditation scheme?**
 - **national CQR communication and collaboration?**
 - **streamlining of external barriers such as ethics approval, site governance and data collection processes?**
- **What other key actions would facilitate a quality assured, efficient and effective CQR sector?**

A CQR standard and accreditation scheme

The findings of a 2011 national survey to determine the capacity of Australian clinical registries to accurately assess quality of care, found many existing registries needed to be expanded in order to be capable of benchmarking outcomes on a national scale.¹⁵ Of 28 registries surveyed, most were found to require modifications to provide useful and reliable information for quality improvement purposes.¹⁵ Thirteen of the 28 registries (46 percent) recruited less than 80 percent of the eligible population. Twenty-three surveyed registries (82 percent) did not formally audit reliability of coding at the clinical level, and five (18 percent) did not collect the information required for basic risk adjustment of outcome measures.¹⁵

These findings highlight the need for a coordinated national registry program to ensure registries comply with appropriate technical and operating principles. This program should include an independent accreditation scheme for CQRs and the development of national CQR standards.

In Sweden, NQRs are categorised according to certification level, to indicate how well-developed each registry is, and its assumed usability for research and clinical improvement. The certification level, along with registry size and complexity, is an important criterion for national funding. The certification system is comprised of nine criteria¹⁶:

1. Variables link to evidence-based clinical guidelines.
2. Data feed national benchmark reports.
3. Improved healthcare results are presented and data are validated.
4. Achieves high coverage.
5. Registry offers online presentation and feedback.
6. Identifies important indicators and areas in need of improvement.
7. Registry data is used for research.
8. Capability to collect data.
9. Has a strategy for the analysis and feedback of data.

The most developed registries are at certification level 1, and meet all nine criteria.¹⁶ Registries with certification level 2 meet criteria 4 to 7, while registries with certification level 3 meet criteria 8 and 9.¹⁶

In 2008, the ACSQHC published 'Operating Principles and Technical Standards for Australian Clinical Quality Registries', aimed at improving the ability of registries to collect high-quality data, and facilitate capacity to benchmark performance across institutions.¹⁷ The document describes the principles that should be used to govern the structure, governance and operations of Australian CQRs, as well as the technical standards that should be used in the development and operation of these registries.¹⁷

The **operating principles and technical standards** outlined in the ACSQHC document¹⁷ **provide a guide for the development of a set of national CQR standards**. Registries would need to comply with the standards in order to gain national accreditation, as judged by an independent body. The **independent accreditation scheme for CQRs**, similar to the scheme operating in Sweden, would assign different levels of accreditation to registries depending on the number of standards they meet.

As mentioned above, registry coverage is one of the criteria used to determine certification of NQRs in Sweden. In Australia, participation in registries is voluntary, so data may not be complete or representative, impacting on its accuracy and utility. For example there may be major omissions of specific geographic areas, such as poor Western Australian participation in the AuSCR.

A report by the Grattan Institute has highlighted **opportunities to improve registry coverage, and thus the accuracy of CQR data in Australia**, for example by making funding of registries conditional on the registry enrolling at least 90 per cent of relevant patients (or providing evidence of a valid sampling process), as is the case in Denmark.¹⁸ Therefore, **high registry coverage should be included as a national CQR standard against which registry accreditation will be determined**.

National CQR communication and collaboration

The most effective way to encourage national CQR communication and collaboration is to tap into existing informal collaborative networks and centres of expertise in the area of registry science. **Under the auspices of a national registry program, these networks could be formalised and scaled up**, acting as a resource for the registry community, linking different groups working in the area across the country, and fostering support and learning. Outlined below are two centres of expertise that may be able to be utilised.

The *Monash School of Public Health and Preventive Medicine* has extensive experience in the establishment and maintenance of clinical registries, and currently manages approximately 30 registries.¹⁹ The *Monash Registry Special Interest Group (SIG)*¹⁹:

- Provides an informal forum in which people affiliated with clinical registries can discuss issues relating to any aspect of registry operation.
- Facilitates discussions on a variety of issues including, but not limited to, governance, management, information technology, ethics, funding, and models for improvement.
- Provides an opportunity for registry custodians, epidemiologists, project managers, database managers and statisticians to present work they are doing or ask for input from other people working with registries.

- Builds relationships and fosters a collegial and collaborative approach to work in this area.

The *South Australian Health and Medical Research Institute (SAHMRI) Registry Centre* was established to widen their existing role in the registry space and to expand capacity and training in this area.²⁰ The SAHMRI Registry Centre currently manages approximately 11 registries, and its goals are to²⁰:

- Provide the best resources for registry building capacity.
- Lead registry science through collaborative opportunities.
- Develop strong international and industry collaborations.

Streamlining of external barriers such as ethics approval, site governance and data collection processes

Ethical and data governance burdens and constraints have been identified as a principal barrier to the development of CQRs in Australia.²¹ The mechanism of obtaining ethics approval and governance for registries can differ greatly between states and even between individual hospitals. A thorough review is needed of the way registries obtain ethical and governance approval. As CQRs are primarily quality improvement activities, it seems illogical that they need to obtain ethical approval from many different hospital ethics committees. **Streamlining of the ethical and governance framework for CQRs is needed in order to maximise their operational efficiency, and this should be addressed at a national level.**

Poor interoperability between clinical information systems leading to unnecessary duplication of data entry remains a hurdle for registry development in Australia.²¹ Additional work is required to extract data from hospital information systems and integrate data items required by CQRs in hospital clinical information systems. Ideally this should include electronic data capture at point of care capability. This will improve the efficiency of CQRs, enable systematic collection of data on all patients and reduce the need for manual data collection, which is costly in terms of human resources and increases opportunity for human error.

In Australia, there is *reluctance on the part of some healthcare providers and organisations to provide data to registries*.²¹ In Denmark, reporting to relevant registries is mandatory for hospitals.¹⁸ While in both Denmark¹⁸ and Sweden²², registry funding includes financial levers such as incentive payments to healthcare providers, to facilitate participation in CQRs.

Therefore, **federal and state governments should mandate under national healthcare standards, that Australian hospitals are required to contribute data to approved national CQRs as a requirement of their hospital accreditation.** In addition, the **sustainable CQR funding model** (discussed in Question 4) **should address the need for financial support for healthcare providers participating in national CQRs.**

3. The potential value of national CQR data is maximised (p28-30)

- **What key actions would facilitate the creation of an environment that supports access to tailored CQR information for consumers, health care providers and funders?**
- **What key actions would facilitate national CQR data linkage, interoperability and integration with Australia's health information systems and infrastructure?**
- **What key actions would facilitate the use of CQR data for:**
 - **Clinical care improvements via benchmarking?**
 - **Quality and safety monitoring?**
 - **Clinical trials and research purposes?**
- **What other key actions would maximise the potential value of CQR data?**

Facilitate the creation of an environment that supports access to tailored CQR information for consumers, health care providers and funders

Transparent reporting of quality data can inform consumers, healthcare providers and funders about the effectiveness and efficiency of healthcare at a national, state and local level. For example, the provision of the Executive Summary of Stroke Foundation's National Stroke Audit report is vital for consumers who participate in state or local clinical quality committees, in order for them to understand the performance of stroke services against international benchmarks and NHMRC Guidelines. This information is being used by consumers who are working with clinicians to improve the quality of services and through advocacy locally, and more broadly with decision makers and funders to redesign or change service provision where appropriate. The use of tailored reports to feedback to clinicians to inform their clinical practice is a defining feature of CQRs, because it enables them to benchmark their outcomes against evidence based guidelines.

Increasingly, funders are seeking information that will enable them to measure the value and benefits of healthcare services, in order to inform funding decisions. The timely and appropriate provision of tailored CQR information can facilitate an environment of support for the collection of data by clinicians, and its use for quality improvement and the funding of services, based on the health outcomes these services achieve for patients.

Facilitate national CQR data linkage, interoperability and integration with Australia's health information systems and infrastructure

Linked data can be used to answer important research questions, improve the quality of care received by patients and ultimately patient outcomes, and help guide policy. Importantly, while a number of Australian states provide data linkage services to researchers, the linkage of cross-jurisdictional datasets remains under-utilised.

Between 86 percent and 96 percent of patients who suffer a stroke are admitted to hospital, and many of these patients are likely to have a history of comorbidities and risk factors which have been recorded prior to their admission for stroke. In addition, subsequent hospitalisations due to

complications or conditions that may or may not be related to a patient's stroke are also common. Therefore, the linking of stroke patient data is likely to reveal valuable information about stroke treatment and care. In Australia, within-state stroke data linkage projects have provided important insights into stroke care and health service delivery.

A 2016 study described the challenges associated with obtaining state and nationally held data for linkage to the AuSCR.²³ This study concluded the administrative load of obtaining linked data was burdensome, and highlighted the **urgent need for continued streamlining of processes, greater collaboration between jurisdictions, and increased infrastructure and funding support from governments.**

While using linked data avoids the time and cost burden of gathering additional and often duplicate data, the process involved in accessing these datasets can be slow and time consuming. This is due largely to the number of ethics committees that are required to approve data linkage proposals, and the fact that proposals need to be cleared by jurisdiction-based data custodians, all operating under different legislative regimes. **Therefore, there is a clear need for a national, streamlined ethics application and approval process.**

One of the main concerns with data linkage is the protection of individuals' privacy, and there is a need to address the legislative barriers to data access. **As such, there would be benefits in harmonising Commonwealth and State and Territory legislation in relation to privacy.** While the consideration of privacy standards is very important, it should be noted that well-established linkage protocols that are able to preserve individual privacy already exist in Australia.

It is important **government continues to fund initiatives such as the Population Health Research Network (PHRN)**²⁴, which is developing and testing leading-edge technology to ensure the safe and secure linking of data collections whilst working to protect peoples' identity and privacy. One such example is the Secure Unified Research Environment (SURE) system, a remote-access data research laboratory developed by the Sax Institute as part of the PHRN, that enables structured access for researchers to secure and sensitive datasets held on separate secure servers.²⁵

In addition to concerns regarding privacy, there are several other factors that continue to be barriers to data linkage in Australia:

- Government attitudes and legislation that assume the community would be opposed to greater sharing and use of personal data for research.

The use of registries to monitor healthcare quality and safety is in fact supported by patients.²⁶ Evidence indicates that as long as appropriate measures are taken to ensure data security and confidentiality, the majority of patients acknowledge the value of registries and the necessity to collect identifying data, and accept the requirement for registries to operate under opt-out consent with scope for linkage to other datasets.²⁶

- Internal agency and government culture and policies that have developed over time, that place unnecessary and burdensome restrictions on the release of data.
- Lack of funding for, and failure to prioritise, the development of advanced data systems and infrastructure.

An **investment by jurisdictions in hospital infrastructure to support CQR data collection** as part of routine clinical care is needed.

In our submission to the Medical Research Future Fund (MRFF) 2018-2020 Priorities consultation, Stroke Foundation identified 'Data linkage capabilities and support' as the most important unaddressed gap in knowledge, capacity and effort across the healthcare system and research pipeline, that needed to be addressed in the 2018–2020 MRFF Priorities. **As such, we supported a MRFF call for applications for research focused on 'Data linkage capabilities and support'.**

In Sweden, where there is 100 percent electronic health record (EHR) use in primary care, hospitals and psychiatry, the integration of NQRs with the EHR system has contributed to their effectiveness. Approximately 90 percent of Australians now have a My Health Record (MHR) and a framework is in place to guide the secondary use of MHR data, including linking to registry data. **Achieving MHR-registry interoperability** will become increasingly important as adoption of the MHR by health professionals and patients grows.

Facilitate use of CQR data for clinical care improvements via benchmarking

A number of opportunities have been identified for Australian CQRs to facilitate the use of registry data by making it more **accessible and understandable**¹⁸.

In order to make CQR data more **accessible**, Australian Governments should require registries to¹⁸:

- Share data more widely, by extending reporting to all relevant clinicians, hospital boards and management teams, funders and accreditors, as CQR data can be difficult to access for some stakeholders.
- Ensure data is provided to clinicians and other key stakeholders in a more timely fashion.

In order to make CQR data more **understandable**, Australian Governments should require registries to¹⁸:

- Ensure data is presented as clearly as possible, so clinical teams can see how they are performing compared with their peers, and how they can improve.
- Ensure data is accompanied by analysis and presentation that assists understanding. Visual data aids can enhance the transparency of reporting, and should be used more consistently.
- Report data in a way that is meaningful for stakeholders.
- Make data easier to manipulate for quality improvement purposes.
- Assist hospitals and health teams to better understand the data and apply the lessons learnt.

In Sweden, NQRs use **a variety of strategies to ensure that accessible, up-to-date and understandable data is available for all stakeholders, and that quality improvement work is supported**. Many of these strategies are also employed by Australian CQRs⁹:

- Registry reports are presented at national, regional and/or local meetings with involved professions. These meetings focus on learning from results and improvements over the past year, as well as identifying areas in need of improvement or more research. Regional/local meetings are designed either for managers responsible for the care produced by clinical units, or for specialists engaged in the care of patients with registry specific diagnoses.

- Online access to up-to-date, processed reports is provided to clinical users, enabling clinical units to follow their quality performance, at any given moment, in relation to set goals.
- Aggregated data is provided in registry annual reports where clinical units can compare their results nationally and, in some cases, internationally.
- Registry based research results are presented at national and international scientific meetings.
- Regular visits are made by regional registry representatives to all participating clinical units in a particular region to discuss results and registry issues, and support quality improvement work.
- Questionnaires are sent to participating clinical units asking them how registry results are used.
- Clinical units in need of improving their performance are invited to participate in an improvement project set up by the registry management team, or are offered support to set up and pursue their own improvement projects.
- Consultation services are provided for physicians in need of discussing a clinical problem with a colleague.

In Australia, **Stroke Foundation's StrokeLink + Program** has been an integral part of the Queensland Stroke Quality Improvement Program (QSQIP) since 2009, and has been supported by Queensland Health since 2012. This program includes a single outreach visit to each hospital, during which quality improvement workshops are facilitated by a trained Stroke Foundation employee. Interpretation of local audit and AuSCR data against national benchmarks helps clinicians identify barriers, and using local consensus processes, an agreed local action plan to improve care is developed.

Since the introduction of the StrokeLink + Program, significant improvements have been made in the quality of stroke care in Queensland, including increases in the proportion of patients²⁷:

- receiving stroke unit care (2009: 58 percent, 2017: 78 percent)
- receiving thrombolysis treatment (if ischaemic stroke) (2009: 7 percent, 2017: 10 percent)
- being discharged to the community with a care plan (2012: 49 percent, 2017: 65 percent)
- being discharged with secondary prevention medications (antiplatelets or antithrombotics if ischaemic stroke) (2009: 65 percent, 2017: 83 percent).

This program has demonstrated how registry data can be used to drive quality and safety improvements in patient care, and is a best-practice exemplar for other states. A similar program, delivered in collaboration with the AuSCR, is currently underway in Tasmania with support from the Tasmanian Department of Health.

Facilitate use of CQR data for clinical trials and research

CQRs can assist in case identification for prospective and retrospective studies and clinical trials. Enrollment and follow-up of patients in randomised trials can be complex and expensive, and many randomised trials never reach their targeted number of participants.²⁸ In registry-based randomised trials, investigators are able to leverage clinical information already collected for the registry to identify potential participants, enrol patients relatively quickly, and obtain accurate follow-up with

minimal effort.²⁸ These trials are comparatively inexpensive to run, and as such investigators are able to enrol large numbers of patients.²⁸

Despite these and other benefits, CQR data remains under-utilised for research purposes in Australia, highlighting the need to **raise awareness within the research community about the availability of, and benefits of using, CQR data** for clinical trials and research. In addition, while **CQRs such as the AuSCR** have clear and well-established processes in place for accessing registry data, they **lack the flexible tools researchers need to make the most of this data**.

In Sweden, NQRs provide support for researchers to access and use registry data for research purposes, and processes for accessing registry data are well-developed.⁹ Research questions are often raised within the registry itself and handled by one or two researchers in the steering committee, or are advertised and presented at various user meetings as suggestions for scientific studies.⁹

Importantly however, there has been a low level of interest among researchers in using Swedish quality registries for research purposes, and NQRs have long been a largely untapped resource.⁹ Improving methodological competence among registry researchers, particularly the use of epidemiologic methods, has been identified as a critical strategy for increasing the value of NQRs within research.²⁹ The **limited availability of epidemiological and biostatistical skills** has also been identified as a principal barrier to the development of CQRs in Australia.²¹

The MRFF has funded a number of research projects with a clinical registry component under the 'Clinical Trial Activity (previously known as the Lifting Clinical Trials and Registries Capacity)' MRFF initiative. In our submission to the MRFF 2018-2020 Priorities consultation, Stroke Foundation identified CQRs as the most important MRFF priority, and emphasised **the need for continued funding of research that utilises CQRs to drive improvements in quality of care**.

4. National, prioritised CQRs are sustainably funded (p31-32)

- What key components should be included in a sustainable CQR funding model for national, prioritised CQRs?
- What key actions would facilitate a:
 - co-ordinated, prioritised approach to the funding of CQRs?
 - sustainable funding model for national, prioritised CQRs?
- What key criteria should be used to finalise a list of national, prioritised CQRs?
 - For background information on this question, refer to the Australian Commission on Safety and Quality in Health Care's, '[Prioritised list of clinical domains for clinical quality registry development](#)', which includes prioritisation criteria and a prioritised list of clinical domains.
 - Click on the link below to access the prioritisation document: <https://www.safetyandquality.gov.au/wp-content/uploads/2016/12/Prioritised-list-of-clinical-domains-for-clinical-quality-registry-development-Final-report-Nov-2016.pdf>

A sustainable CQR funding model for national, prioritised CQRs

Establishing a new CQR requires a significant and long-term investment; however, an evaluation of its health and economic impact can only be undertaken once it achieves a sustainable operation, which can take considerable time.

A 2016 evaluation of Australian CQRs demonstrated that these registries have a number of important benefits, including greater survival for patients and improvements in quality of life after treatment.² In addition, they represent value for money, returning between two dollars and seven dollars for every one dollar invested.² Despite this, CQRs continue to be under-funded in Australia.

Registries are frequently viewed as 'infrastructure', and face challenges attracting competitive research grants from funding bodies such as the National Health and Medical Research Council (NHMRC). A fundamental shift is needed to recognise registries as essential tools that monitor quality and appropriateness of care, drive continuous improvements in patient outcomes and ultimately deliver value to the health system.³⁰

As a consequence of their use of identifiable patient datasets and an opt-out consent model, CQRs usually bear significant ethical as well as research governance establishment costs during the first few years of operation. Australia has developed a number of successful clinical registries which have benefitted from sustained funding; however, for many Australian CQRs, securing ongoing funding is a year-by-year proposition.³¹

Therefore, **there is a clear need for a sustainable funding model for national, prioritised CQRs**, as part of a coordinated national registry program, **which should include a minimum 5-year funding term** for organisations contracted to develop and operate CQRs. This has obvious efficiencies, and will significantly reduce the amount of time registry teams are required to spend in order to secure funding for CQRs.

Sources of funding for national, prioritised CQRs

Currently, funding for CQRs in Australia comes from a variety of sources including the federal and state governments, NHMRC, MRFF, research organisations, non-government organisations, professional medical societies, industry (health insurers or pharmaceutical or device manufacturers), or a consortium of these groups. As the main funders of health services in this country, Australian governments will be the key beneficiaries of a rise in registry activity, and the resultant improvements in healthcare quality and patient outcomes.

With regard to CQR prioritisation and funding within a coordinated national registry program, it would be optimal if a shared model, involving the federal and state governments working in partnership, was used.

Governments across Australia have invested in a number of registries with a jurisdictional focus. The Victorian Government in particular, has invested in a significant number of CQRs, and is currently providing direct or indirect funding to 20 CQRs.³² One of the key areas of work for a national registry program will be to **reduce duplication of effort by consolidating those state and territory-based registries that are collecting the same data.**

From the perspective of organisations contracted to develop and operate registries, the key benefit of a nationally coordinated approach is that they only have to deal with a single entity with regard to the application process, contract negotiations, and ongoing reporting, regardless of the number of funders a particular CQR has.

While it is anticipated that a significant proportion of funding for national, prioritised CQRs will come from public sources, **it is critical the CQR funding model is able to identify multiple sustainable public and private sources for support of registry operations.**

Prioritising the establishment of new national CQRs and evaluating existing national CQRs

A key element of a sustainable CQR funding model will be **clear and robust decision-making processes for evaluating existing national CQRs and prioritising the establishment of new national CQRs.**

While there is no publicly available, exhaustive list of Australian CQRs currently in operation, a 2017 analysis undertaken by the Grattan Institute identified 37 CQRs in Australia, only a small number of which have national coverage.¹⁸ As outlined in our response to Question 2, a survey of Australian registries revealed numerous gaps in coverage, auditing and data collection, and the registries had highly variable reporting procedures.¹⁵ In fact, high quality registries only address a small proportion of the health burden in Australia.³⁰

In 2016, the ACSQHC published a national prioritised list of clinical domains for CQR development.³ This document prioritised clinical domains for potential development of national CQRs based on specific threshold criteria (relating to feasibility and evidence base) and prioritisation criteria (relating to burden of disease and financial burden). Prioritised clinical areas were those where investment in CQRs was likely to yield the greatest savings to the health system.³ Importantly, some have argued for further domains to be prioritised, including those related to long-standing existing registries that have been integral to ongoing service improvement.³¹

Therefore, within a national registry program, funding support should be targeted at CQRs that:

- are high quality, and comply with appropriate technical and operating principles

- address key gaps in registry coverage
- target clinical areas of high burden and high variance where they can add the greatest value to the health system.

For the funding of **new national CQRs**, greater weighting should be given to those registries that **address high priority clinical domains** as outlined by the ACSQHC, as well as **address key gaps in registry coverage**. For established CQRs that have achieved sustainable operation, in addition to addressing high priority clinical domains, their **eligibility for ongoing funding should be contingent on their ability to attain the highest national CQR accreditation level, requiring achievement of all national CQR standards** (see our response to Question 2). Other factors such as registry size and complexity may also influence eligibility for ongoing funding.

References

1. Deloitte Access Economics. 2017. Stroke in Australia – No postcode untouched.
2. Australian Commission on Safety and Quality in Health Care (ACSQHC). 2016. Economic evaluation of clinical quality registries: final report. Sydney: ACSQHC.
3. 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.
4. Australian Stroke Clinical Registry (AuSCR). Available at: <https://auscr.com.au/>
5. Reuben DB, Tinetti ME. Goal-oriented patient care--an alternative health outcomes paradigm. *N Engl J Med*. 2012; 366(9):777-9.
6. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ*. 2012; 345:e6572.
7. Healthcare Quality Improvement Partnership (HQIP). Available at: <https://www.hqip.org.uk/>
8. Crandall W, Kappelman MD, Colletti RB et al. ImproveCareNow: The development of a pediatric inflammatory bowel disease improvement network. *Inflamm Bowel Dis*. 2011; 17(1):450-7.
9. Sparring V, Granström E, Andreen Sachs M et al. One size fits none - a qualitative study investigating nine national quality registries' conditions for use in quality improvement, research and interaction with patients. *BMC Health Serv Res*. 2018; 18(1):802.
10. Bloem BR, Munneke M. Revolutionising management of chronic disease: the ParkinsonNet approach. *BMJ*. 2014; 348:g1838.
11. Wolfe F, Michaud K. The National Data Bank for rheumatic diseases: a multi-registry rheumatic disease data bank. *Rheumatology (Oxford)*. 2011; 50(1):16-24.
12. Black N. Patient reported outcome measures could help transform healthcare. *BMJ*. 2013; 346:f167.
13. Prodinger B, Taylor P. Improving quality of care through patient-reported outcome measures (PROMs): expert interviews using the NHS PROMs Programme and the Swedish quality registers for knee and hip arthroplasty as examples. *BMC Health Serv Res*. 2018; 18(1):87.
14. Nelson EC, Dixon-Woods M, Batalden PB et al. Patient focused registries can improve health, care, and science. *BMJ*. 2016; 354:i3319.
15. Evans SM, Scott IA, Johnson NP et al. Development of clinical-quality registries in Australia: the way forward. *Med J Aust*. 2011; 194(7):360-3.
16. Fredriksson M, Halford C, Eldh AC et al. Are data from national quality registries used in quality improvement at Swedish hospital clinics? *Int J Qual Health Care*. 2017; 29(7):909-915.
17. Australian Commission on Safety and Quality in health Care (ACSQHC). 2008. Operating principles and technical standards for Australian clinical quality registries. Sydney: ACSQHC.
18. Duckett S, Jorm, C, Danks L. 2017. Strengthening safety statistics: how to make hospital safety data more useful. Grattan Institute.
19. Monash University Registry Special Interest Group (SIG). Available at: <https://www.monash.edu/medicine/sphpm/registries/registrysig>
20. South Australian Health and Medical Research Centre (SAHMRI) Registry Centre. Available at: <https://www.sahmriresearch.org/our-research/sahmri-registry-centre>
21. Wilcox N, McNeil JJ. Clinical quality registries have the potential to drive improvements in the appropriateness of care. *Med J Aust*. 2016; 205(10):S27-S29.
22. Levay C. Policies to foster quality improvement registries: lessons from the Swedish case. *J Intern Med*. 2016; 279(2):160-72.

23. Andrew NE, Sundararajan V, Thrift AG et al. Addressing the challenges of cross-jurisdictional data linkage between a national clinical quality registry and government-held health data. *Aust N Z J Public Health*. 2016; 40(5): 436-442.
24. Population Health Research Network (PHRN). Available at: <http://www.phrn.org.au/>
25. Sax Institute. Secure Unified Research Environment (SURE). Available at: <https://www.saxinstitute.org.au/our-work/sure/>
26. Donohue F. Patient opinions of patient registries. *Irish J Med Sci*. 2012; 181:S127.
27. Cadilhac D, Kilkenny M, Kim J. 2018. Queensland Stroke Quality Improvement Program (QSQIP) - End of Project Evaluation Report. Monash University and Florey Institute of Neuroscience and Mental Health.
28. Lauer MS, D'Agostino RB Sr. The randomized registry trial--the next disruptive technology in clinical research? *N Engl J Med*. 2013; 369(17):1579-81.
29. Adami HO, Hernán MA. Learning how to improve healthcare delivery: the Swedish Quality Registers. *J Intern Med*. 2015; 277(1):87-9.
30. Wilkins S, Best RL, Evans SM. Need for a roadmap for development of a coordinated national registry programme. *Intern Med J*. 2015; 45(11):1189-92.
31. Ahern S, Evans S, Hopper I, Zalcborg J. Towards a strategy for clinical quality registries in Australia. *Aust Health Rev*. 2018 Feb 8.
32. Victorian Agency for Health Information (VAHI) and Safer Care Victoria (SCV). Available at: <https://bettersafecare.vic.gov.au/our-work/performance-and-safety-reporting/clinical-quality-registries>