Protocol and pilot data for establishing the Australian Stroke Clinical Registry

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Background **Disease registries assist with clinical practice improvement. The Australian Stroke Clinical Registry aims to provide national, prospective, systematic data on processes and outcomes for stroke. We describe the methods of establishment and initial experience of operation.**

Methods **Australian Stroke Clinical Registry conforms to new national operating principles and technical standards for clinical quality registers. Features include: online data capture from acute public and private hospital sites; opt-out consent; expert consensus agreed core minimum dataset with standard definitions; outcomes assessed at 3 months post-stroke; formal governance oversight; and formative evaluations for improvements.**

Results **Qualitative feedback from sites indicates that the web-tool is simple to use and the user manuals, data dictionary, and training are appropriate. However, sites desire automated data-entry methods for routine demography variables and the opt-out consent protocol has sometimes been problematic. Data from 204 patients (median age 71 years, 54% males, 60% Australian) were collected from four pilot hospitals from June to October 2009 (mean, 50 cases per month) including ischaemic stroke (in 72%), intracerebral haemorrhage (16%), transient ischaemic attack (9%), and undetermined (3%), with only one case opting out.**

Conclusion **Australian Stroke Clinical Registry has been well established, but further refinements and broad roll-out are required before realising its potential of improving patient care through clinician feedback and allowance of local, national, and international comparative data.**

Key words: health outcome, quality assessment, registries, stroke

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Introduction

In Australia, stroke is the second leading cause of death and largest cause of adult disability (1, 2). A substantial evidence-base now exists for treatments to improve survival and reduce disability following stroke, including well-coordinated multi-disciplinary stroke care units (SCUs) (3–5). Significant reduction in the burden of stroke could be achieved if these interventions were widely applied in clinical practice (6). Currently in Australia, though, SCUs exist in only 64 of the 237 public hospitals that admit patients with stroke (7). However, there are no reliable data about the coverage of important interventions and their potential impact on health outcomes, although they are likely to be widely variable and inconsistently applied as in other countries. Disease registries have been shown to improve the quality of care and health outcomes, planning of services, and development of health-care policy (8–15). Therefore, an initiative arose to establish an Australian national clinical stroke registry when funding opportunities became available in 2008.

The Australian Stroke Clinical Registry (AuSCR) is a collaborative national effort to monitor, promote, and

improve the quality of acute stroke care. It is led by a consortium of two leading academic research institutes: the National Stroke Research Institute, a subsidiary organisation of the Florey Neuroscience Institutes, and The George Institute for International Health (TGI) of The University of Sydney; and two leading nongovernment organisations, the National Stroke Foundation (NSF) and the Stroke Society of Australasia (SSA). Sanctioning for AuSCR occurred through the recently established Australian Stroke Coalition (ASC), a network of clinicians and professional associations (http://www.strokefoundation.com.au/asc).

In November 2008, the registry consortium won a competitive tender [Australian Commission on Safety and Quality in Health Care (ACSQHC) 018/0809] to be one of six pilot projects to test and validate newly established national operating principles and technical standards for Australian Clinical Quality Registries (16). The purpose of these operating principles and technical standards are to: provide a means of improving existing clinical registers and enhance the value of the data; provide guidance for the establishment and maintenance of Australian Clinical Quality Registries for measuring quality of care; and suggest a best practice model to which Australian Clinical Quality Registries should adhere. There are 42 recommended principles that relate to the major attributes for clinical quality registries (16). Awarding of the stroke registry project, coupled with an unrestricted educational grant from an industry sponsor, provided a unique opportunity to develop and pilot AuSCR in a meaningful way. Participation in the ACSQHC project also included an external assessment that provided a source of regular independent feedback throughout the first 12 months of the project.

Australian Stroke Clinical Registry was established during 2009 to provide national data on the process of care and outcomes for patients admitted to hospital with acute stroke or transient ischaemic attack (TIA). Patients with TIA were included because, in Australia, there are few data about the quality of care provided to patients with TIA admitted to hospital (about 77% of cases presenting to hospital are admitted) (17) and management recommendations are similar to those for stroke (i.e. admission to a stroke unit, discharge on antihypertensive agents, etc.) (3). The registry was designed for use in both public and private hospitals, and to be capable of storing data on both adults and children. This paper describes the process of establishment and operating procedures of AuSCR, and the factors that enhanced and impeded implementation to date.

Method

The AuSCR protocol was developed in accordance with the national operating principles and technical standards for clinical quality registries (16). In brief, these require a registry to have an appropriate governance structure and operation policies for data access and security, publications, and effective communication to allow results to be understood. Furthermore, registry data are required to be: kept minimal and not a burden to obtain; epidemiologically sound and reproducible; available on all eligible cases and collected from all eligible settings; and that results are reported routinely and include risk (case-mix)-adjusted outcome analyses. The recommended technical standards and architecture depend on the various levels of data capture (Levels 1–4) created and on how a registry system operates and communicates with external data sources (e.g. single portal with one-way transmission vs. two-way transmission, etc.). These levels enable individuals and agencies responsible for clinical registries to easily navigate the Australian architecture and standards developed by the National e-Health Transition Authority (16). Furthermore, the technical standards cover identity management, secure access controls, secure messaging, use of standard terminologies and data specifications (e.g. compliant with national and international electronic health data dictionaries and standards), and the need for data storage and transmission features that comply with all relevant legislation and guidelines (16).

Summary of the AuSCR registry design

A prospective and continuous, multisite, acute hospital care, web-based data entry register system is used. Centralised outcome assessment is undertaken 3 months after patients are discharged or transferred from their initial hospital. Acute stroke admissions are identified by responsible clinicians. Eligible cases are entered in a customised web-tool as soon as possible after presentation, with data entry via paper or web-tool format. An external commercial technology vendor was used to develop the AuSCR online web-tool within the required pilot project timelines and deployed on 14 July 2009 after significant user acceptance testing. Although established as a Level 2 registry, certain attributes were included to allow AuSCR to evolve into a 'Level 3' registry (thus ensuring the ability to link or cross-check data with external databases or other registry systems). Such identifiers include name, date of birth, and the patient's Medicare number (the mandatory government national insurance health scheme) and allow the tracking of individuals accessing the public health-care system in Australia.

Governance

Figure 1 outlines the AuSCR governance structure which includes nationally representative Steering and Management Committees (16) (members outlined in the Appendix S1), each with explicit terms of reference. The Steering Committee was established in December 2008 and has representatives from each state in Australia, and includes clinicians, health informatics, epidemiologists, consumers, the President of the SSA, the director of the pilot project, and Chair of the Management Committee. The Management Committee was established before the commencement of data collection and includes representatives of the consortium partnership, all of whom have clinical backgrounds in medicine, nursing, or allied health and three hold positions on the Executive Committee of the SSA. The Management Committee is

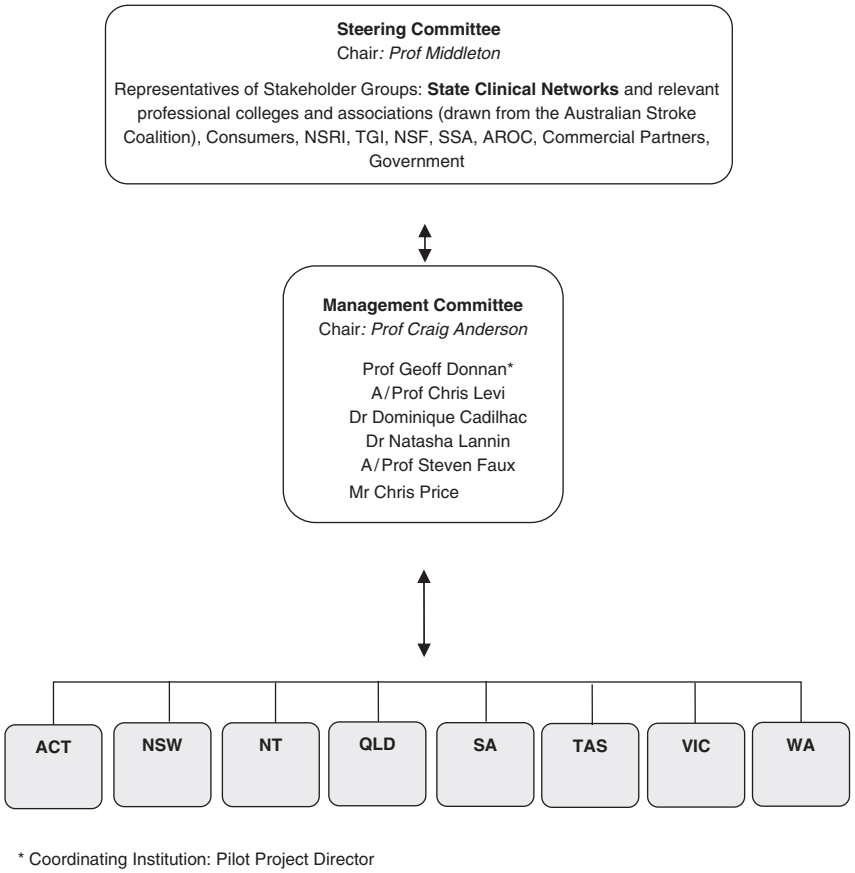

Fig. 1 Governance structure for the Australian Stroke Clinical Registry.

responsible for the day-to-day operation of AuSCR with oversight from the Steering Committee. Together the governance committees have established numerous policies to support the operations of the registry and ensure transparency (supporting information Table S1).

Establishment of the minimum dataset

The minimum dataset was established using a multifaceted approach, which included a systematic review of the scientific literature on stroke quality of care indicators coupled with a face-to-face consensus workshop held in October 2008. During the workshop, a multidisciplinary panel of 40 experts agreed on the national minimum dataset through a scientifically rigorous, open, and consensus-based process that was facilitated by an independent chairman. The expert panel was national in its representation and included clinicians, consumers, researchers, educators, health-care organisations, representatives from government and the Australian Institute of Health and Welfare, and experts from other disease registries. Evidence for >30 variables was presented (e.g. proportion of missing data, interrater reliability, information on whether they were collected across different Australian jurisdictions, level of scientific evidence, generalisability for the stroke population, etc.). The variables initially considered included nonroutinely captured stroke severity variables to improve case-mix adjustment required for outcomes analyses, as well as clinical indicators developed to capture compliance with the National Acute Clinical Guidelines (3). These data were obtained from the NSF audit 2007 (18, 19).

The Management Committee, with expert advice from the Steering Committee, made the final decision about which variables identified at the workshop would be included. The basic principle was to keep manually abstracted variables to a minimum (e.g. less than five quality clinical indicators and one prognostic variable), to limit the burden of collection and avoid scope creep. We also required appropriate variables for risk adjustment and/or other factors that potentially confound quality of care. Importantly we ensured that the AuSCR variables were consistent with the biennial NSF acute services clinical audit, so that both activities were complementary: AuSCR with a prospective collection of core dataset in large numbers of patients, while the NSF audit captures retrospective cross-sectional data (including vascular risk factors, stroke severity, processes of clinical care, and outcomes at time of hospital discharge) in a smaller subset of patients (e.g. 40 per site). As AuSCR can be used to identify eligible patients for the NSF audit, hospital staffs only need to provide data on the additional variables.

The operating principles recommend that health outcomes be properly ascertained at the most appropriate time point in

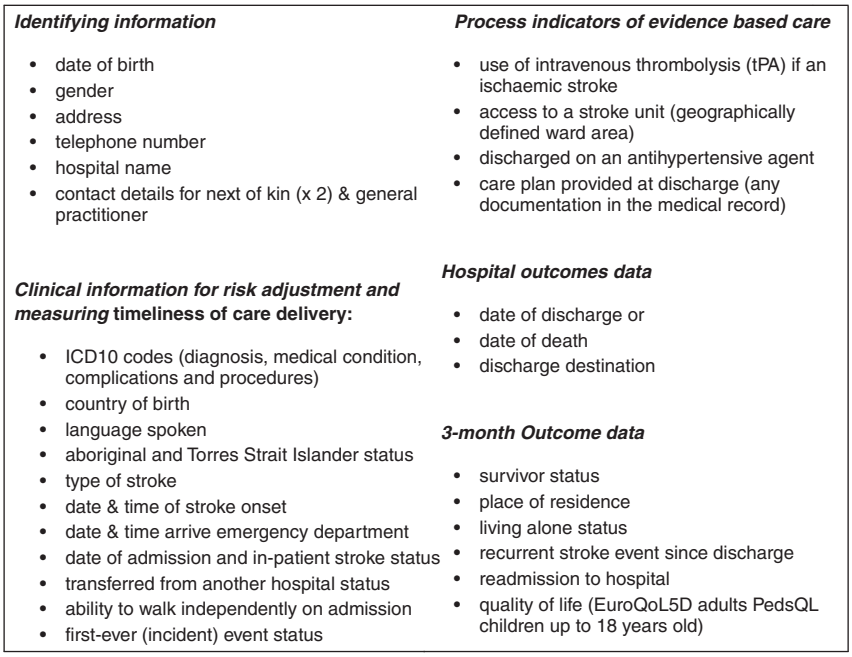

Fig. 2 Australian Stroke Clinical Registry minimum variable dataset.

the greatest possible proportion of cases. However, the practicalities of collecting such data must take account of cost, burden for patients, and potential loss to follow-up (16). Three months was chosen as the most appropriate time to assess recovery outcomes as it is widely acknowledged that neurological function is near stable and patients are most likely to be residing in the community by then (20). Moreover, the Swedish Stroke Registry has shown that level of function at 3 months is strongly correlated with longer-term outcomes (21). For adults, the EQ5D, which was developed by the EuroQoL group (http://www.euroqol.org/) to measure the health-related quality-of-life (HRQoL) dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, is used in AuSCR. As the EQ5D is a valid and reliable measure in patients with stroke (22) when administered by direct or telephone interview, or as a self- or proxy-completed mail out, and is common to other stroke registries (11, 23–25), there is the opportunity for future international comparisons of health outcomes. For children <18 years of age, we chose to use the PedsQL (26) as the HRQoL instrument recommended by the relevant experts on the various committees as it uses a developmental approach to measuring HRQoL in children and adolescents with acute and chronic health conditions (27). Because there is limited information on the quality of care and outcomes in paediatric stroke, the inclusion of the PedsQL will provide unique and important data. Other outcomes collected at 3 months include the patient's current residence and living arrangements, and presence or absence of a recurrent stroke or rehospitalisation.

Figure 2 provides a summary of the core AuSCR data collection variables. In total, there are 197 variables with 157 considered technical (e.g. patient and family contact information at baseline and 3 months, identification numbers, and other administrative variables), 15 pertain to patient background characteristics (e.g. date of birth, previous stroke), 10 on clinical processes (e.g. time of admission), and 18 variables on outcomes. The definitions and criteria for the variables collected in hospitals can be found in the data dictionary (http://www.auscr.com.au).

Selection of hospitals

In Australia, the great majority of patients with acute stroke is generally undertaken in public hospitals funded by state governments' departments of health, rather than in private hospitals. To ensure a representative sample of hospitals, the AuSCR consortium approached the state clinical networks via the ASC who nominated 22 eligible hospitals. The eligibility criteria for hospitals to be included in the pilot phase of AuSCR included sites that were representative of Australia's health-care system and geography (i.e. public and private hospitals located in rural and urban areas); had an opinion leader to champion stroke; showed a commitment to joining the pilot project and entering all eligible cases; and had an ability to submit an ethics application within the required timeline (February 2009). From the 22 eligible sites a selection of six hospitals were included as part of the pilot phase.

Patient eligibility

All acute stroke or TIA admissions to participating hospitals are to be identified for inclusion using a prospective design. Clinicians were asked to identify eligible patients and subse-

quently to enter their data using International Classification of Diseases (ICD-10) codes. Eligible ICD-10 codes are: I63, cerebral infarction (I63.0, I63.1, I63.2, I63.3, I63.4, I63.5, I63.6, I63.8, I63.9); I64, stroke, not specified as haemorrhage or infarction; I61, intracerebral haemorrhage (I61.0–I61.9); I62, other nontraumatic intracerebral haemorrhage (I62.0, I62.1, I62.9); or G45 codes for TIA. Regular reviews of ICD-10 discharge codes are obtained from hospital patient administrative systems to verify case ascertainment and identify potentially missed patients in participating hospitals.

Consent

Clinicians who provide data to the AuSCR must seek approval from their Institutional Ethics Committee before commencing any data collection. Waiver of consent was not used because patients are contacted at 3 months by a third party. As the conventional, written informed consent process has been shown to severely limit the number of patients included in a registry (16), we sought approval to use an 'opt-out' consent protocol. The opt-out consent protocol requires patients to be provided with information on the purpose of the registry, how the information is collected, and an explanation of the simple, cost-free avenues available to them should they wish to have their information excluded (free-call telephone number or postage-paid). This method is consistent with the ethics approach recommended by the ACSQHC (16) for clinical quality registries and is used by several registries in Australia. To date, AuSCR has obtained ethics approval for use of the 'opt-out' consent protocol in both public and private hospitals, and in the states of New South Wales, Queensland, Victoria and Western Australia.

Hospital participation

Once hospitals have obtained the approval from their ethics committee, relevant staff are trained in the AuSCR process and database. A data dictionary, overview PowerPoint presentation, user training manual, and consent protocol, make up the training package that is provided to all participating hospitals to ensure a systematic approach to data collection. Each hospital nominates whether a paper- and/or web-based method is the best approach for collecting data, based on local circumstances and resources. As required, the AuSCR office can receive paper-based forms from sites via a secure fax to enter data in the web-tool. A participant agreement form is signed by the lead investigator at each site to commit to providing data on all eligible patients with stroke admitted to that hospital.

Patient follow-up

All registered cases not known to have died in hospital, or after discharge where hospital staff know and modify the survival status, are followed up 3 months after the date of stroke onset. As we were unclear as to the most efficient method of obtaining follow-up data for AuSCR, we nominated to randomise patients to alternative follow-up methods, either by telephone interview or postal questionnaire, during the pilot phase. The method allows patients to be randomly assigned to a follow-up approach on a one-to-one basis. Telephone interviews are undertaken by specially trained NSF staff using a scripted interview guide and data dictionary, while the postal questionnaires are sent from the AuSCR office located at TGI. The AuSCR postal follow-up procedure is based on a modified Dillman's protocol for mailed surveys (28), whereby up to two attempts to contact a patient via mail are made and, if after a 4-week period the questionnaire is still not returned, the patient is contacted for direct follow-up assessment by telephone using our procedures for telephone follow-up. The telephone follow-up procedure may include up to two comprehensive attempts to contact the patient on separate days (within and out of hours) for patients assigned to telephone follow-up. A comprehensive telephone attempt is defined as using all contact sources recorded in the register at each attempt. After two unsuccessful attempts at telephone contact, the patient is followed up once by mail. All follow-up data, irrespective of mode of collection, are entered in the AuSCR web-tool. Staff entering follow-up data are blind to the hospital data to avoid interviewer bias.

Data security

The Australian Stroke Clinical Registry online web-tool has various access levels managed by the data custodian at TGI. For example, hospital staff can only view and modify their own data, and cannot access follow-up data, while NSF staff cannot access hospital data about patients. In addition, data security and access policies have been established and ratified by the Steering Committee to protect against potential breaches of privacy, as well as to ensure appropriate ethical integrity and scientific merit of proposals using AuSCR data (supporting information Table S1).

Data quality

Data quality is assessed monthly whereby data exports are conducted and missing data reports sent to hospitals. The online web-tool has built-in logic checks and variable limits to prevent inaccurate data being entered. Mandatory fields have also been created to reduce missing data because incomplete fields prevent progress to the next section of the web-tool. Furthermore, in-built functions within the database will identify duplicate entries and multiple patient records may be merged if necessary (e.g. if a patient has a recurrent stroke). Full coverage of patients is desired and an annual assessment against hospital ICD10 stroke discharge codes has been incorporated as part of the 'Quality Assurance and Data Management Processes' policy (supporting information Table S1).

Formative evaluation

The AuSCR protocol includes use of formative programme evaluation methods. The first year of AuSCR (2009) was

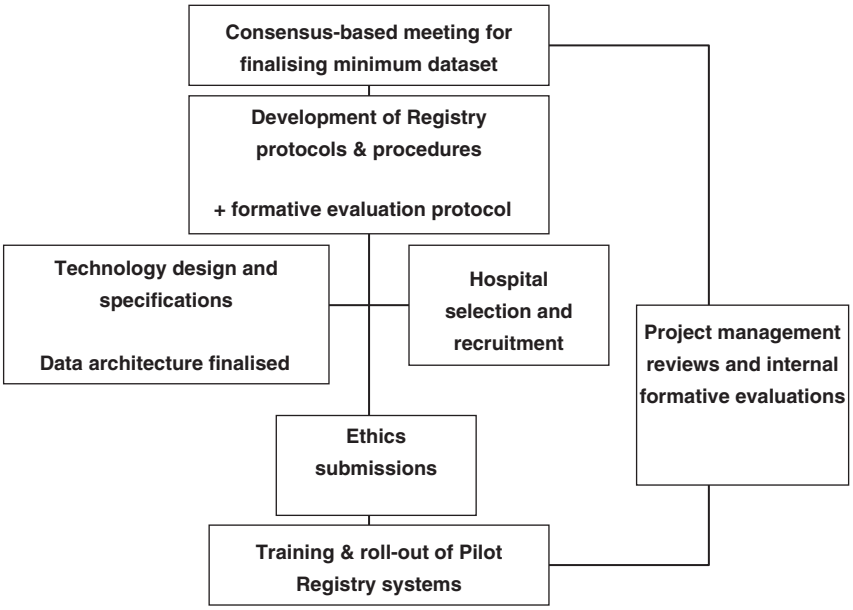

Fig. 3 Overview pilot project methods incorporating formative evaluation.

deemed the pilot (establishment) phase. During this time we evaluated training and support documents, data capture and quality and reporting methods and policies with the purpose of identifying the strengths, limitations, and effectiveness of the registry. During the early development stages the results were then fed back so that revision of registry materials, structure, and procedures could occur, thereby ensuring maximum utility and participation of clinicians (Fig. 3). Failure to engage in user-informed evaluation of such tools can have negative consequences for future implementation, related both to poor usability or clinical utility and to suboptimal stakeholder sanction (29). Few registries have published information on whether such formal programme evaluation methods are used. Some aspects of the formative evaluation will be integrated into the steady-state implementation of AuSCR as part of the ongoing quality assurance and data management processes (e.g. medical record audits).

Both quantitative and qualitative methods of evaluation are used involving survey, remote observation, semistructured interviews, electronic feedback, and medical record audit. Within 1 week of AuSCR hospital training, feedback is obtained including an open-ended discussion about the AuSCR web-tool, hospital user guide, data dictionary, and the registry in general. These interviews are followed by a 10% random audit of medical records conducted by the AuSCR staff after the first 50 patients are entered in the registry. Users are also invited to discuss any issues related to case registration, data entry processes, access to data, and style of online reports, to aid in improving the AuSCR. Engagement in the process of evaluation at an early phase of registry development has been found to lead to high levels of stakeholder ownership and widespread implementation (29). Participation in feedback questionnaires and other evaluation processes is voluntary and all data used have been aggregated and de-identified.

In the first year of AuSCR, three sites had sufficient numbers of cases to participate in an audit. For each case, the auditor completed a paper-based data collection form using the hospital medical record. The auditor's form was then compared with both the paper-based form completed by a hospital staff member and the data recorded in the AuSCR database, to allow an assessment of the completeness and accuracy of data. Finally, the data management processes developed by AuSCR office staff are also assessed and revised as needed, and this is facilitated by weekly team meetings and fortnightly Management Committee meetings.

Results

Formal AuSCR operational activities began in November 2008. For the period 15 June to 15 October 2009, 204 patients were entered in the database from four active pilot hospitals (Table 1), and 125 cases completed 3-month follow-up assessments (only two failed to provide quality of life responses) after follow-up commenced in September 2009. An average of 50 cases per month was submitted from these four pilot sites. Consistent with other representative stroke populations, the current sample of patients comprises 54% males and 60% Australian-born (Table 2), whose mean age was 67·5 years (median 71 years; interquartile range 58–79 years). For the 193 patients with a recorded stroke subtype, 72% were ischaemic stroke, 16% intracerebral haemorrhage, 9% TIA, and 3% undetermined.

Table 3 provides data about processes of hospital care to highlight the dynamic nature of collecting prospective registry

Table 1 Number of patients entered by hospital in the Australian Stroke Clinical Registry between 15 June and 15 October 2009

Pilot hospital	Patients	Episodes	Patients with multiple episodes
1	15	15	0
2	88	90	2
3	67	67	0
4	30	32	2
Total	200	204	4

Table 2 Characteristics of patients included in the Australian Stroke Clinical Registry

All pilot hospitals	*n*	%
Males	110	53·9
Patient able to walk independently on admission	71	34·8
Australian born	122	59·8
Previous stroke	52	25·5

All data are 100% complete.

Table 3 Processes of hospital care

Processes of hospital care	*n*	%	Unknown/ missing (%)
Patients treated in a stroke unit at anytime during stay	166	81·4	5·9
If an ischaemic stroke, patients receiving intravenous thrombolysis (tPA)	9	4·4	1·0
Patient transferred from another hospital	35	17·2	1·5
Strokes that occurred while the patients were in hospital	19	9·3	0
Evidence of care plan on discharge*	23	11·3	32·8
Discharged on antihypertensive agent*	97	47·5	32·8

*The prospective nature of this registry means that not all data were known for these variables at the time they were downloaded. These figures are provided to illustrate the issues in collecting data using these methods.

data whereby the discharge variables have a large proportion (about a third) of missing or unknown values. In contrast, all mandatory variables for the patient background characteristics and processes of care variables are 100% complete. However, some nonmandatory fields have incomplete data (e.g. ICD10 discharge diagnosis 42% incomplete, Medicare number 29% incomplete, patient contact telephone number 18% missing). Processes to obtain incomplete or missing data occur monthly with hospital staff and as part of the 3-month follow-up where patient and emergency contact details are verified. As the ICD10 coding data may not be available for up to 3 months after the patient has been discharged, these data will be collected biennially from patient administrative systems to avoid increasing the workload for clinical staff using the AuSCR.

Critical success factors for establishment of this registry within this short-time frame include: (a) having broad clinical acceptance; (b) having national peak nongovernment and government bodies supportive of the initiative; (c) the establishment of good governance structures and role delineation to ensure timely decisions and rapid progress; and (d) support from the local established registry community who were willing to share information.

Qualitative formative evaluation feedback from sites has been that the web-tool is simple to use and the user manuals, data dictionary and training are appropriate. However, sites desire easier ways of entering data already in hospital systems and the opt-out consent is problematic when cases are missed because of their short length of hospital stay or being an outlier from the SCU or main ward. Regarding the data collection burden, it is recognised that most of the identifying personal information is already in hospital database systems. It takes approximately 15 min to manually enter all patient data at the hospital level, whereby 10 min is needed for the personal information required to contact patients at follow-up. Despite setting up technology solutions and cooperation from hospital information technology staff to allow the importing of these data in the AuSCR, the ability to test these solutions to date has not been possible. The barriers identified include hospital software issues and human resources. As major issue identified for opt-out consent are patients who are discharged or die before receiving an information sheet, a priority for the AuSCR staff is to revise the consent process.

The 10% random audit of medical records in the first three sites to have at least 50 cases recruited revealed that changes to the data dictionary and/or web-tool were needed. For example, there were several instances where the response for 'cause of stroke' as known or unknown was inconsistent, which required more explicit criteria to be developed as to how this variable should be answered. This inconsistency was due to some hospital staff interpreting this question from a stroke mechanism perspective (e.g. large-artery atherosclerosis), while others considered epidemiological evidence such as presence of preexisting risk factors (e.g. atrial fibrillation). Another misunderstanding arose with the definition of 'discharge date' when patients were reclassified as an in-patient receiving rehabilitation in the same hospital or ward. When discharge dates were taken as 'discharge from the ward' instead of 'discharge from acute care' these hospitals would appear to have long lengths of stay for acute care compared with the national average. The interpretation of whether there was 'evidence that a care plan outlining postdischarge care in the community developed with the team and patient and/or family' has occurred was also inconsistently recorded. This was because of a lack of detail in the data dictionary, which has now been rectified.

The evaluation also revealed that hospital staff often did not have access to a patient's Medicare number. This caused problems both in creating a case record in the database and in entering the data at a later stage. Other problems included the numeric medical record number created in AuSCR being unable to accept Greek (e.g. α) numerals in those hospitals using these characters (easily corrected), and the frequent omission of the mobile telephone number for the patient's general practitioner (overcome by recording alternative contact numbers such as a primary care clinic fax number). Another problem identified was the mean length of stay provided in a 'live' downloadable length of stay report being inaccurate where the default for missing or not applicable value of 01/01/1900 was used for date of arrival at hospital. This error in the design of the report was overcome by using the date of admission instead of date of arrival, because admission date can never be coded as missing or not applicable in the AuSCR.

Discussion

We consider that effective methods have been used to establish the AuSCR. The rapid progress made by the consortium suggests the feasibility of applying these methods when appropriate resources are allocated, and the Management and Steering Committees are more experienced. The wide acceptance by clinicians and establishment of functional governance structures with clear role delineations, have all contributed to ensuring timely decisions and rapid progress. This pilot phase has seen the development and implementation of the database with associated data collection procedures for hospitals and policies to support daily activities. This was also facilitated by the support garnered from state-based stroke clinical networks and the participating hospitals. Moreover, being part of a larger project to test national operating principles and technical standards for registries provided independent feedback and broader support. The pilot hospitals benefit from participation by having access to a national stroke database with 'live' summary comparisons of the local site with all sites. This, coupled with the prospective 3-month outcome data, makes AuSCR a unique tool for stroke clinicians, hospital administrators, and researchers in Australia. Comparisons with international stroke registries will be possible because we ensured that many variables mapped to other registries, such as Riks-Stroke (Sweden) and the Canadian Stroke Network registry.

The AuSCR pilot phase involved four active sites contributing data from three different states in Australia. These hospitals have provided the AuSCR consortium with evidence to improve processes and procedures to ensure the efficient national roll-out in 2010. Since October 2009, four additional hospitals have received ethics approvals among the initial 22 sites nominated to participate during the pilot phase. Some delays have occurred because of the lack of familiarity by some institutional ethics review committees of the opt-out consent model.

The AuSCR project (http://www.auscr.com.au) has been successfully established to provide national data on the process of care and outcomes for stroke in Australia. In the future, the data will provide the capacity to investigate important uncommon clinical subgroups that are inadequately sampled in population-based stroke incidence studies (e.g. in younger age groups where nonatheromatous causes of stroke are more common, or in people who suffer a stroke while already in hospital for another reason). Therefore, AuSCR has the potential to provide value for clinicians, researchers and decision makers.

One of the strengths of AuSCR has been the ability to develop the registry on the basis of essential requirements recommended for clinical quality registries (16). This included: (a) participation of all types of hospitals (e.g. private and public, rural and metropolitan); (b) inclusion of all patients; (c) systematic collection of data with use of standard definitions; (d) collection of only core essential factors; (e) the burden of collection does not outweigh the societal benefits; (f) data are entered prospectively close to the time of discharge; and (g) health outcomes are collected when the clinical condition has stabilised. Other strengths include comprehensive written policies as we found that several more established registries did not have formal written policy documents for several aspects encouraged in the operating principles. Moreover, we are unaware of other local registries having applied formal formative evaluation methods during their establishment phase. Therefore, we feel the AuSCR initiative has made an important contribution in the area of Australian Clinical Quality Registries. We would encourage new registries to use a formative evaluation process to refine and inform their training methods, policies and procedures and documents during their initial 12 months of operation.

While there are other forms of data collection for stroke in Australia, each has its strengths and limitations. For example, routine national data collection systems for stroke are limited in being focused on mortality and ICD-coded hospital separations. These data reflect episodes of care and do not allow an easy distinction between individual patients, raising the possibility of double counting, and information on morbidity is excluded. Current national audit programmes and government data do not include longitudinal patient outcomes, with health status only available at time of hospital discharge. While population-based incidence studies are the gold standard measure of the burden of stroke, they are costly and demanding undertakings that are not nationally representative due to being logistically limited to particular well-defined geographic regions. Moreover, the data collected from incidence studies do not allow comparison of changes in health services practice and resource utilisation in a timely manner as they are fixed for the reference year in which the data are collected. While retrospective clinical audits of medical records provide useful cross-sectional data

on a limited number of patients, their specific focus on hospital care for quality assurance purposes limits their broader and longer-term extrapolation. Such limitations of using retrospective data collection on stroke are widely acknowledged (30).

Hospital-based stroke registries are an extremely useful method for longitudinal tracking of stroke severity, mortality, and processes of care. However, in practice, local registers can be difficult to maintain and may be biased when registration is incomplete. In Australia, it is estimated that only about 20% of hospitals maintain a local stroke register (31), and there is uncertainty about their data quality and comparability. The AuSCR initiative is designed to national standards and will meet the needs of the clinical community. There is also potential to link the AuSCR database with other clinical registries through the use of unique national patient identifiers that will be an important future advancement and ensure greater utility of the data. For example, if we are able to link our data with the Australian Rehabilitation Outcomes Centre database this will offer a unique opportunity to be able to track stroke-related disability and outcomes of rehabilitation care both in the inpatient and outpatient settings. Importantly, the data in the registry will allow locally driven, regional, and national approaches to developing strategic interventions where evidence-practice gaps are identified.

We recognise some limitations to our approach, including a failure, at this stage, to report on the nondata collection rate and an assessment of the follow-up data collection methods. Another issue is sustainability, as there is uncertainty as to the most appropriate long-term (e.g. government) source of funding required to support the infrastructure necessary to support clinical quality registries, such as AuSCR in Australia. It will, therefore, be important to determine the scope of future operational costs and ongoing resources for AuSCR, as the register is new and not mandated by government. Presently, we are fortunate that we have substantial in-kind support. Specifically, all data collection is on a voluntary basis, and all follow-up telephone calls are provided by trained staff employed by the NSF (commitment assured for the next 2 years). The experience from other countries with established stroke registries might be helpful to guide different strategies for obtaining sustainable funding. Lastly, continued manual data entry of all variables by clinicians is impractical and technology solutions to import data already in patient administrative systems are needed. Our current minimum dataset, therefore, will not be expanded in the near future as this will further compound this problem. We acknowledge that our minimum dataset does not include many variables to reflect comorbidity, risk factors, or stroke severity. This will limit our ability to understand factors associated with timely care provision, such as door-to-needle times for thrombolysis. Nevertheless, an advantage of this registry is that, in the future, additional data-spines can be added to answer particular research questions.

In conclusion, AuSCR is now established as the basis of providing ongoing national data on important processes of acute hospital care and outcomes for stroke. The registry initiative was designed to national standards and will meet the needs of the clinical community. Very few registries have published information on whether they have used formal programme evaluation methods to establish successful registries. We hope our experience will contribute to this field.

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Supporting Information

Additional supporting information may be found in the online version of this article:

Appendix S1. The Australian Clinical Stroke Registry 2009 Steering Committee and Management Committee membership.

Table S1. Registry policies developed to to manage a range of contingencies arising from the analysis of data from the registry and ensure transparent processes.

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