

### Australian Stroke Clinical Registry

Testing and Validation of the Draft Operating Principles and Technical Standards for Australian Clinical Quality Registries

**Pilot Project Final Report** 

Version 1.1

Test and Validation of the Operating Principles and Technical Standards for Australian Clinical Quality Registries

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W. Cedillar

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(Project Manager)

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DATE

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APPROVED BY:

(Project Director)

For enquiries regarding this report please contact:

Dr Dominique Cadilhac National Stroke Research Institute

Heidelberg Repatriation Hospital Gate 10, 300 Waterdale Road Heidelberg Heights VIC 3081 T 03 9496 2888 F 03 9496 2650 <u>dcadilhac@nsri.org.au</u>

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#### ACRONYMS/ REFERENCE TERMS

AUSCR	Australian Stroke Clinical Registry
Commission	Australian Commission on Safety and Quality in Health Care
EQ5D	health-related quality of life instrument
HREC	Human Research Ethics Committee
ICD	International classification of diseases
IEC	Institutional Ethics Committee
METeOR	Metadata online registry
NEAF	National Ethics Application Form
NEHTA	National e-Health Transition Authority
NSF	National Stroke Foundation
NSRI	National Stroke Research Institute
NSW	New South Wales
OP	Operating Principle
QLD	Queensland
SNOMED-CT	Systematized Nomenclature of Medicine–Clinical Terms
SSA	Stroke Society of Australasia
TGI	The George Institute for International Health
TIA	Transient Ischaemic Attack
tPA	tissue Plasminogen Activator
VIC	Victoria
WA	Western Australia

#### **EXECUTIVE SUMMARY**

In November 2008, the Australian Stroke Clinical Registry (AuSCR) consortium were awarded a competitive tender (Australian Commission on Safety and Quality in Health Care 018/0809) to test and validate newly established national *Operating Principles and Technical Standards for Australian Clinical Quality Registries*. The purpose of these *Operating Principles and Technical Standards* are to: provide a means of improving existing clinical registers and enhancing the value of the information they provide; provide guidance for the establishment and maintenance of Australian Clinical Quality Registries aiming to measure quality of care; and suggest a best practice model to which Australian Clinical Quality Registries should adhere. There are 42 recommended principles and standards which relate to the major attributes for quality registries: organisation and governance; data collection; data elements; data security; data quality; the need to undertake risk adjustment; data custodianship; ethics and privacy; and outputs and reporting.

AuSCR was established during 2009 to provide national data on the process of care and outcome of acute stroke hospital admission. The AuSCR initiative was undertaken by a consortium of two leading academic research institutes: the National Stroke Research Institute a subsidiary organization of the Florey Neuroscience Institutes and The George Institute for International Health; and two leading non-government organisations: the National Stroke Foundation and the Stroke Society of Australasia. Together these organizations represent the broader Australian clinical and scientific community. The registry scope was that it be designed for use in public and private hospitals including children's hospitals. The aims of this report are to describe the establishment of the registry and provide evidence about the factors that have enhanced and impeded implementation to date against the recommended national *Operating Principles and Technical Standards* for clinical quality registries.

#### Summary of registry design

A prospective and continuous, multicentre, hospital register, clinical cohort design with blinded outcomes assessment at 3 months and web based data entry via a single portal was used. Acute stroke admissions were identified prospectively, whereby eligible admissions were entered in AuSCR soon after the onset of presenting clinical signs and symptoms. It was a web-based 'Level 2' register developed in line with the requirements of National e-Health Transition Authority (NEHTA) technical standards. We used an external commercial technology vendor to develop AuSCR online database. The web tool was deployed following significant user acceptance testing over several months on the 14<sup>th</sup> of July, 2009. Although established as a Level 2 registry, certain attributes have been included with the recognition that AuSCR could evolve into a 'Level 3' registry (ability to link or cross-check data with external databases or other registry systems). Therefore, currently AuSCR can be considered a 'Level 2+' registry.

#### Methods used for testing the *Operating Principles and Technical Standards*

This project was designed to provide the Commission with an opportunity to obtain a detailed understanding of how the *Operating Principles and Technical Standards* impact on the development of a new clinical registry. These were tested against the full registry lifecycle that was achievable within the twelve month period of the pilot including registry design, build, implementation and steady state operations. This included:

- Applying recommended methods to determine the minimum dataset including a multidisciplinary workshop with an independent facilitator;
- Migration of existing data into the test registry and extensive user acceptance testing prior to 'live' production;

- Implementation across multiple state jurisdictions;
- Technical development following recommended standards and implementation of a Level 2 registry, with testing of both paper-based data collection and direct entry of data into a web-based collection tool; and
- Establishment of policies and procedures as recommended;

A novel aspect of our pilot project was to include formative program evaluation using mixed methods as part of a feedback (*action research*) loop. This was to ensure strengths and limitations for each aspect would be captured. This evaluation evidence was used to make improvements to AuSCR, as well as supporting the recommendations our project has made to the Commission.

#### Main Findings

Since the 15<sup>th</sup> of June until the 15<sup>th</sup> of October *204 patients have been entered in AuSCR online* from *four active pilot hospitals.* Feedback from sites is that the web-tool is simple to use and that the user manuals, data dictionary and training are appropriate. However, sites desire easier ways of entering data already in hospital systems and adhering to the opt-out consent protocol is problematic when cases are missed during their inpatient admission.

Our main recommendations to the Commission following testing of the *Operating Principles and Technical Standards are:* 

- New registries should be encouraged 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. A sufficient pilot phase during the establishment of a new registry should be emphasised, especially where a particular patient group may be managed by a range of clinicians. Also, new registries should be encouraged to trial different methods of follow-up data collection to ensure the most reliable method for achieving complete follow-up in an efficient way is used.
- In the development of the policies there were very little pre-existing examples available in the public domain to assist a new registry. It would have been beneficial if suggested guidelines or generic policies were made available. It would also be helpful if a list of recommended policies had been provided.
- To reduce the *burden and cost of data collection*, ensure *outcomes are properly ascertained* and achieve *complete collection from the entire eligible population* requires data linkage capability. A collective process and lobbying should be made across a number of registries to ensure hospital patient administration systems can be used effectively. Resources should be leveraged from State and Territory health services, as this will be the most efficient method for achieving these Operating Principles for conditions that are: high frequency; not always confined to discrete medical units within hospitals; and require identifying information to be able to collect outcome data from patients in the community after separation from hospital. Registry projects need to find ways of incorporating data linkage in their budgets where hospital/ health department resources to invest in such activities are limited or unclear. In addition, NEHTA should provide a guidance paper on using the identifiers in future/new registries, including coding recommendations.
- A national system for accrediting and nominating e-health technology developers may assist new registries to efficiently comply with the *Technical Standards*. This could be a role for the Commission.

#### Conclusions

AuSCR (<u>www.auscr.com.au</u>) has been successfully established to provide national data on the process of care and outcomes for stroke. A lasting legacy of having been involved in this pilot project with the Australian Commission on Safety and Quality in Health Care is an important new national quality of care initiative for stroke. Very few registries have published information on whether they have used formal program evaluation methods to establish successful registries. We believe that this AuSCR project and the methods used to establish this registry make an important contribution to this field.

#### 1. INTRODUCTION

In November 2008, the Australian Stroke Clinical Registry (AuSCR) consortium was awarded a competitive tender (Australian Commission on Safety and Quality in Health Care 018/0809). This project was one of six pilot projects funded to test and validate newly established national *Operating Principles and Technical Standards for Australian Clinical Quality Registries*<sup>1</sup>. The AuSCR project was the only new registry selected for this important initiative.

The purpose of the national *Operating Principles and Technical Standards* are to: provide a means of improving existing clinical registers and enhancing the value of the information they provide; provide guidance for the establishment and maintenance of Australian Clinical Quality Registries aiming to measure quality of care; and suggest a best practice model to which Australian Clinical Quality Registries should adhere <sup>1</sup>. There are 42 recommended principles and standards which relate to the major attributes for quality registries: organisation and governance; data collection; data elements; data security; data quality; the need to undertake risk adjustment; data custodianship; ethics and privacy; and outputs and reporting<sup>1</sup>.

The AuSCR testing phase covered an 11 month period, which included data collection over four months. The rapid progress made by the AuSCR consortium demonstrates the quality, experience and commitment to meeting the short timeframes of the pilot testing phase. Clinical acceptance, the establishment of good governance structures and role delineation has ensured timely decisions and rapid progress. This pilot testing phase has seen the development and smooth roll-out of the database with associated data collection procedures for hospitals and policies to support daily activities. Establishment of a new registry provided the ideal opportunity to test the different aspects of the *Operating Principles and Technical Standards*.

In this final report, the AuSCR Management Committee are able to outline the challenges faced and report on experience through the development of the database; establishment of policies and procedures; submission of ethics applications in different States; initial training and implementation at various hospitals; establishment of methods for patient follow-up and use of formative evaluation to improve AuSCR in its *establishment phase* (anticipated to be *18 to 24 months*). The establishment phase for AuSCR will extend beyond the period for reporting our experience in adhering to the *Operating Principles and Technical Standards*. However, the majority of principles and standards were tested or partially tested to provide sufficient feedback to the Australian Commission on Safety and Quality in Health Care (referred to in this report as the Commission).

In this report, our findings are provided under each *Operating Principle and Technical Standard* based on the checklist provided on page 126 by the Commission<sup>1</sup>. A detailed summary Table of our findings and recommendations is also provided (section 3.12). In this way, we clearly articulate the relevant issues we have found, specific to testing the *Operating Principles and Technical Standards*. A brief overview of the AuSCR initiative is provided in section 1.1.1 to 1.1.2. Further details are provided in the relevant sections, as appropriate, for providing context for our comments and recommendations to the Commission.

#### 1.1. Summary of the Australian Stroke Clinical Registry (AuSCR)

#### 1.1.1. Objective

The overall goal of establishing the AuSCR initiative is to provide reliable and representative data that can be used to improve the quality of stroke care, nationally. The primary aim is to provide a mechanism to routinely and prospectively monitor acute stroke care in hospitals. Fundamental to this primary aim is the registration of all eligible stroke cases admitted to the participating hospitals. In this way selection bias is kept to a minimum. A second aim of the AuSCR initiative is to provide a database that will enable future stroke research in large numbers of people, or in those with certain characteristics, which might otherwise have not been possible. The establishment of the AuSCR initiative as a 'new registry' provides invaluable lessons about the feasibility and utility of the *Operating Principles and Technical Standards*<sup>1</sup> established for Australian Clinical Quality Registries.

#### 1.1.2. The Registry

The AuSCR initiative is a national stroke registry currently piloted in three States of Australia (Queensland [QLD], Victoria [VIC] and Western Australia [WA]). It is a web-based 'Level 2' register developed in line with the requirements of National e-Health Transition Authority (NEHTA) technical standards. An external commercial technology vendor was used to develop the AuSCR online tool (www.auscr.com.au). The tool was deployed from the developer to the data custodian on the 14<sup>th</sup> of July 2009 after significant user acceptance testing over several months. Although established as a Level 2 registry, certain attributes have been included with the recognition that the AuSCR online tool can evolve into a 'Level 3' registry. Therefore, currently the AuSCR online tool can be considered a 'Level 2+' registry. The AuSCR online tool has various access levels managed by the data custodian at The George Institute for International Health (**TGI**). For example, hospital staff cannot access follow-up data, and staff at the National Stroke Foundation (**NSF**) who are undertaking the follow-up assessments cannot access hospital data about particular patients.

Participation in the registry using the opt-out consent model has been accepted with ethics committee approvals received in four States (New South Wales [NSW], VIC, QLD and WA). With these approvals we were able to commence data collection at the end of June in four hospitals, two in Perth, WA, one in Brisbane, QLD and one in Melbourne, VIC. We are awaiting Site Specific (NEAF) approvals for a further four hospitals in NSW (Royal Prince Alfred Hospital, John Hunter Hospital, Armidale Hospital, and Tamworth Hospital). Participating hospitals benefit from access to their own data via a simple-to-use export function, as well as 'live' pre-specified reports that include summary descriptive statistics. For some hospitals, this has been an opportunity to have a stroke database for the first time.

A *minimum dataset* of variables, including personal and clinical information, processes of care and outcomes at time of separation is collected on each eligible patient, using the web-based tool and/or a paper-based form. The initial collection is done during the hospital stay and at discharge. The training package for hospitals includes: a data dictionary; an overview PowerPoint presentation; a user training manual with training exercises; the 'opt-out' consent form, protocol and patient information sheet; and data collection forms. This training package is designed to ensure a systematic approach to data collection is achieved that is also compliant with ethical requirements. After three months, and prior to six months after the date of stroke onset, all registered cases known to be alive at the time of hospital separation are contacted for a single follow-up questionnaire; this is by either telephone interview or postal questionnaire. In order to assess the most reliable and cost-efficient manner of undertaking centralised follow-up of large numbers of patients, the pilot phase has been organised to allow the follow-up of registered patients to be undertaken in a randomised manner, to either telephone interview or mail-out questionnaire. Staff at **NSF** are part of a centralised telephone follow-up service for the AuSCR initiative. Patients randomised to a postal questionnaire are contacted by the AuSCR office staff located at **TGI**. The follow-up process is coordinated at the AuSCR office. All staff doing follow-up are provided with follow-up training to ensure consistency of the follow-up procedures. In addition, a *Telephone Follow-up Manual* including a *Telephone Interview Script* is provided to ensure consistency between telephone calls. The *AuSCR Office Follow-up Manual* includes all follow-up procedures for postal and telephone follow-up and is provided to the AuSCR office staff. All follow-up data, irrespective of mode of collection, are entered in the AuSCR online tool on dedicated "Follow-up" screens.

During the pilot phase, the AuSCR Management Committee developed policies and procedures to ensure national scalability of the AuSCR project, identified the strengths, limitations and effectiveness of their application for the registry and adopted various methods of evaluation. In addition, data quality checks are embedded in routine data collection and there were quality assurance activities and a data management policy to ensure timeliness, accuracy and completeness of the data collected prior to reporting

The Management Committee has also adopted a formative evaluation process. The formative evaluation process is being used to provide evidence for improvements to AuSCR during its establishment phase. The formative evaluation includes mixed methods including semi-structured interviews and surveys, quantitative data collection reviews and audit to examine the outcomes of the establishment phase within a feedback loop. This includes the set-up process, the online tool, training tools, and effectiveness of policies, procedures and protocols.

Since the 15<sup>th</sup> of June until the 15<sup>th</sup> of October *204 patients have been entered in AuSCR online* from *four active pilot hospitals* (Table 1). The number of patients registered per month to the end of September is provided in Figure 1. An average of 50 cases per month is being submitted from these four pilot sites. Consistent with other representative stroke populations, the current sample of patients includes 54% who are male and 60% who are Australian-born (Table 2). The mean age of patients is 67.5 years (median 71 years and inter-quartile range 58 to 79 years). For the 193 patients where stroke type has been recorded, 72% are ischaemic strokes, 16% intracerebral haemorrhage, 9% TIA and 3% were undetermined. Figure 2 provides these stroke subtypes according to various age groups.

The follow-up of cases commenced on the  $21^{st}$  of September with allocation to receive a telephone and postal follow-up randomised on a weekly basis as the cases become eligible (>3 months post-stroke). To date, a total of 44 cases have been randomised for follow-up. Of the 21 mail cases and 22 telephone cases, we have completed a total of 14 cases, 11 of which were by telephone. At this stage it is not possible to determine the most appropriate manner of future data collection.

Further details about AuSCR are provided in the relevant results sections of this report.

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 1 Number of patients entered by hospital in AuSCR between 15 June and 15 October, 2009.



Figure 1 Patients entered in AuSCR online between 15 June and 15 October, 2009



Figure 2

Table 2	Characteristics	of	patients	include	d in	AuSCR
I GOIC -	Character istics	•••	patients	menuae		1 Ius Cit

	All Pilot Hospitals	
	n	%
Males	110	53.9
Females	91	44.6
Patient able to walk independently on admission	71	34.8
Australian born	122	59.8
Previous stroke	52	25.5

### 2. METHODOLOGY FOR TESTING THE OPERATING PRINCIPLES AND TECHNICAL STANDARDS

This project was designed to provide the Commission with an opportunity to obtain a detailed understanding of how the *Operating Principles and Technical Standards* impact the:

- development of a new clinical registry, spanning all aspects of the development and implementation process (from governance establishment, dataset selection, ethics, clinical uptake and operation)
- recommended methods to determine the minimum dataset including a multi-disciplinary workshop with an independent facilitator
- suggested migration of existing data into the test registry and extensive user acceptance testing prior to 'live' production
- implementation across multiple state jurisdictions
- technical development following recommended standards and implementation of a Level 2 registry, with testing of both paper-based data collection and direct entry of data into a web-based collection tool
- establishment of policies and procedures as recommended.

To achieve the above objectives the AuSCR Management Committee worked closely with consortium partner organisations, in particular the NSF, State clinical networks, and existing stroke data collection tools to ensure consistency and acceptability of the AuSCR dataset. Refer to Appendix A for an outline of the stakeholders engaged in the establishment of AuSCR and the main responsibilities of the partner organisations.

An overview of the methodology adopted in the pilot phase is outlined below. The Management Committee acknowledges that the ongoing formative evaluation process will lead to further refinement and improvement of AuSCR beyond the life of this pilot project for the Commission.

#### 2.1. Hospital selection

A non-probability sampling method was chosen to select the pilot hospital sites, whereby the AuSCR Management Committee selected a sample of sites from those who expressed an interest or were nominated to participate by their state clinical network. Expressions of interest were sent out to hospitals nominated by their state clinical networks in December 2008. Responses were overwhelming, with 22 hospitals of the nominated 26 hospitals choosing to participate (85%). Purposive selection of hospitals ensured representation from most States, as well as urban and rural hospitals, to provide scope for assessing facilitators of and barriers to data collection. Participating hospitals were also chosen based on the presence of an opinion leader to champion stroke, a commitment to joining the AuSCR initiative, and their ability to obtain ethics approval within the necessary timeline.

Hospitals selected and able to participate in the AuSCR pilot project were:

- Austin Hospital (VIC)
- Sir Charles Gardiner Hospital (WA)

- Swan Distract Hospital (WA)
- Royal Brisbane and Women's Hospital (QLD)

#### 2.2. Opt-out Consent Model

To overcome potential sampling biases, the opt-out consent model was used. That is, data are collected following provision of information to the potential subject but without requiring written consent. The AuSCR Management Committee developed a consent protocol in line with the *Operating Principles and Technical Standard*. The consent process requires that eligible registry participants must be:

- Provided with information describing the purpose and procedures of the clinical quality assurance registry;
- Informed that their participation or otherwise has no bearing on their clinical care;
- Offered simple means to obtain additional information; and
- Offered simple means to request that their personal identifying information is removed from the registry.

This protocol overcomes the common problems associated with low participation but also caters for those who are actively opposed to participating. Ethical clearance has been sought such that data may be stored without time limit, notwithstanding which ongoing ethical clearance is required.

#### 2.3. Data Variable Selection

A typical clinical quality registry must include variables for patient identification and also demography, clinical, risk adjustment, process of care and health outcome variables. To reduce the burden on staff associated with the collection, the AuSCR dataset included identification, demographic and some clinical information that is commonly collected at hospitals.

A significant amount of work to refine process indicators that are relevant to clinicians in Australia by staff at the NSF and the NSRI had already been undertaken. In October 2008, a oneday workshop was held in Melbourne to extend this work and gain consensus acceptance in selection of the *minimum dataset* variables for AuSCR. The multi-disciplinary and nationally representative panel of experts, which included consumer representation, clinicians, government representatives and data experts reviewed and revised a list of variables for inclusion in the hospital component of the minimum dataset. The list of variable options presented was preceded by evidence from a literature review and an analytical assessment of potential variables outlined to the workshop participants. Small group and whole group discussions were then facilitated by an independent Chair. The variables that would require manual data abstraction were to be contained to no more than four variables. Fifteen variables (prognostic n=3 and process indicators n=12) formed the basis of the 'manual abstraction' set following the initial review. Five groups of eight people ranked their top four preferences. Preferences were then tallied. Five variables were agreed: prognostic variable: ability to walk on admission; process indicators: access to stroke units; use of intravenous thrombolysis if an ischemic stroke; care plan provided at discharge; and discharged on an antihypertensive agent. It was agreed that the variables

"discharged on an antihypertensive agent" and "care plan provided at discharge" were to be trialed in the establishment phase of AuSCR to determine which one would be most feasible, valid and useful.

In AuSCR it was agreed that health outcomes would be measured after 3 months (less than 6 months) (refer section3.1.5). In addition to objective measures such as survival status and readmission, the Management Committee elected to use standardised measures of health status developed by the EuroQoL group (http://www.euroqol.org/). The EQ5D (EuroOoL) measures the health-related quality of life dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EuroQoL has been validated for use in stroke<sup>2</sup> and has been used in many projects and in other stroke registries<sup>3-6</sup> permitting international comparisons of health outcomes. Further, the EQ5D has been shown to be valid and reliable when used over the telephone, when mailed out, and when the responder is a family member providing a proxy rating.

For patients under the age of 18 years, we are using the PedsQL<sup>7</sup>. The decision to use this QoL instrument was based on a review by experts on our Steering Committee representing paediatric stroke. The PedsQL Measurement Model uses a developmentally appropriate approach to measure health-related quality of life in children and adolescents with acute and chronic health conditions<sup>8</sup>. Since the adult scale, the EQ5D, also measures health-related quality of life, PedsQL provides the project with the greatest ability to match variables across the continuum of stroke care. Using the PedsQL was also deemed to be important to ensure that outcomes are properly ascertained; that is, it is also a brief tool (less than 4 minutes to complete), has different versions for different paediatric age-groups (i.e. developmentally appropriate), and is responsive to change over time. Very little is known about the outcomes of stroke in children and how the quality of care affects outcomes in paediatric stroke, and inclusion of the PedsQL will provide unique and important information.

Further details are provided in section 3.1.2 and 3.1.5.

#### 2.4. Data Collection Model

We nominated to offer various models for data collection and capture in AuSCR to assess which method ensures that data can be obtained in a standardised manner and minimises time demands and the burden of data collection:

- **Paper-based data collection**: paper forms may be used by sites to collect data abstracted from the participant's medical record. The paper-based form should be stored in the medical record, and can be completed at any time from admission to discharge. The paper-based form has been developed with in-built instructions to provide a prompt at the time of data collection. Hospitals can choose to enter the data directly or send the form to the AuSCR Office via a secure fax number for AuSCR Office staff to finalise the data entry. "AuSCR entered" stickers are also available to hospitals to clearly mark cases that have been entered.
- **Online data entry**: using the web-based AuSCR online tool, hospital staff directly enter data from the medical record into the database. Hospital staff have developed their own internal procedures to capture admitted stroke cases. AuSCR staff work with each site to

ensure complete case ascertainment and variable collection. Processes currently used or being considered by sites to support case ascertainment include:

- An AuSCR sticker is placed on the medical record of eligible participants at admission, and the ward clerk notifies the stroke liaison nurse or study coordinator of an eligible admission.
- A folder of admitted cases is kept on the stroke and/or neurology wards to notify the stroke liaison nurse or study coordinator (much like a log-sheet of eligible admissions). This strategy grew out of existing processes that were already in place, as many hospitals already have a study folder on the wards. Thus inclusion of an AuSCR log-sheet into this file was a simple step.
- $\circ$  Use of the AuSCR data import template or web-service for identifying information.

#### 2.5. Follow-up Process

Because it was unclear which would be the best method of obtaining follow-up data, during the establishment phase for AuSCR we randomise patients to one of two follow-up protocols. Outcomes are evaluated at approximately three months post-stroke using either telephone or mail methods. In addition to objective outcomes, including subsequent stroke, hospital readmission and death, subjective outcomes including self-reported function and health-related quality of life are collected. Function and health-related quality of life is collected using the EuroQoL-5D (EQ5D); the EQ5D tool was chosen as a simple, standardised and internationally validated tool, data from which will also permit international comparisons to the Swedish stroke register, Riks-Stroke

The follow-up is coordinated at the AuSCR office at TGI with in-kind assistance from the NSF, who conduct the telephone follow-up calls.

Automated randomization (1:1 telephone versus postal) is in-built in the AuSCR online tool, and a list is generated at the AuSCR Office by the Follow-up Coordinator. This person has Project Administrator access to the AuSCR system. When generating follow-up lists, a follow-up status of 'in progress' is assigned once an attempt to contact the patient has been made, but some or all follow-up data are missing (refer Table 3).

Regular lists are generated for the following groups of patients who:

- 1. had their first stroke three or more months previously, and
- 2. were not noted to have died on separation from hospital following their stroke.

#### 2.5.1. Procedure for Mail Follow-Up

Both '*new*' and '*in progress*' lists of patients to be followed up by mail are generated (Table 3). The Follow-up Coordinator is responsible for all mail follow-up. The AuSCR online tool is used to generate patient mailing labels, and the date of each follow-up mail out attempt is recorded for each patient on the system. Each follow-up mail out package is sent with a cover letter, postal follow-up form and reply paid envelope.

Contact method	Follow-up status
mail	new
mail	in progress
telephone	new
telephone	in progress

The AuSCR mail follow-up procedure is based on a modified Dillman's protocol for mailed surveys<sup>9</sup>. This includes the following steps:

- 1. All patients on the 'new' list for follow-up by mail are mailed a postal follow-up package;
- 2. If the questionnaire is not returned within two weeks, another postal follow-up package is sent; and
- 3. If after a four week period the questionnaire is still not returned, the patient is contacted for direct follow-up assessment by telephone using the *Procedure for Telephone Follow-up* outlined below.

In accordance with Dillman's protocol, all letters are personalised, signed by the investigators using a ballpoint pen, and include a pre-addressed postage-paid envelope for returning the follow-up questionnaire.

Patients will appear on the '*in progress*' list to be followed up once by telephone after two unsuccessful attempts at follow-up by mail have been made.

The Follow-up Coordinator is responsible for ensuring that all returned postal follow-up forms are entered into the AuSCR database.

*Mail that is returned to sender:* If a follow-up package is returned to the AuSCR office, a second mail-out will be sent to the alternate contact, provided that this person does not reside at the same address as the patient.

#### 2.5.2. Procedure for Telephone Follow-Up

For patients randomised to the telephone follow-up protocol these are conducted by trained call centre staff from the NSF. The Follow-up Coordinator from the AuSCR Office (TGI) provides '*new*' and '*in progress*' lists of patients to be followed up by telephone. NSF staff use the patient's record on the AuSCR database to obtain the appropriate contact telephone number(s). Two comprehensive attempts to contact the patient are made 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. When the patient cannot be contacted directly, this includes attempting to contact the nominated primary and secondary next-of-kin and general practitioner. The date of each follow-up telephone attempt should be recorded for each patient.

Patients will appear on the '*in progress*' list to be followed up by telephone after two unsuccessful attempts at follow-up by mail have been made. One comprehensive telephone attempt to contact the patient (within and out of hours) should be made for these patients. If unsuccessful, the patient will be deemed lost to follow-up if survival status cannot be verified. NSF call centre staff enter the information directly in to the database during the telephone interview, or alternatively they use a paper version of the *Telephone Follow-up Form* to conduct the interview and then enter the information into the database immediately after the interview. All paper-based forms should be kept as a source document for audit purposes. Every six months these forms are posted to the AuSCR Office for verification purposes and long-term archiving.

After two unsuccessful attempts at telephone contact are made, the patient is followed up once by mail. If the contact number is disconnected, NSF staff use other contact telephone numbers recorded on the database to locate the patient.

#### **2.6.** Evaluation

During the pilot testing project and the ongoing establishment phase of AuSCR, a formative evaluation is being carried out to enable identification of registry attributes that are successful, as well as those aspects that did not facilitate achievement of the desired outcomes. The process involves an action research feedback loop (see Figure 3). Therefore, it is designed to measure the effectiveness of AuSCR policies and procedures and inform future planning and revision of materials prior to national implementation.

The primary purpose of formative evaluation is to provide evaluation input from the early development stages of a project in order to create a more successful program. This formative evaluation process will later be refined and aspects integrated into the steady-state implementation of AuSCR as part of the ongoing quality assurance and data management processes.

The formative evaluation is a novel aspect of this initiative and is carried out by AuSCR staff at the NSRI. The evaluation is based on testing different aspects of the *Operating Principles and Technical Standards* for Australian Clinical Quality Registries<sup>1</sup>. Very few registries have published information on whether they have used formal program evaluation methods to establish successful registries. Incorporation of formal program evaluation methods has been a strength of our project.



#### Figure 3 Summary overview of the pilot Registry project methods incorporating formative evaluation

The formative evaluation protocol for AuSCR currently includes:

- Surveys of hospital staff one week after training and one month after commencement of data collection (refer to Appendix B for the survey template and Appendices C and D for a summary of current feedback provided from three pilot sites to date);
- Structured feedback from participants at conferences who were able to "road test" AuSCR online (see Appendix E for example survey form);
- Scheduled site visits:
  - Including a random audit of 10% of medical records to review data collection procedures and adherence to data dictionary definitions. In this pilot project, three sites participated in this audit process. For each case, the auditor completed a paper-based data collection form using the hospital medical record. The auditors form was then compared to both the paper-based form completed by a hospital staff member and the data recorded in the AuSCR database. Where the medical record was unavailable or time did not permit, partial audits were conducted. Partial audits consisted of comparing the paper-based form completed by a hospital staff member to the data recorded in the AuSCR database (results are provided in section 3.6).
  - $\circ\,$  Informal and formal discussions with site staff including doctors, nurses and information technology staff
- Extensive user acceptance testing of the web-based tool during development and also in 'live' production following identification and rectification of 'bugs'.

The evaluation during the AuSCR establishment phase is designed to ensure a full assessment of:

- participation, including number of staff and hospitals that enter data, number of staff that can recall standards and definitions, feedback on ease of use, etc.
- completeness of patient ascertainment, by examining the number of cases entered against the number of cases of stroke discharges at each site during the same period and an assessment of which model of data capture (paper-based + online or direct online entry) produced better case ascertainment
- accuracy of data entry, coding and analysis
- percentage of variables within the data dictionary
- percentage of variables with coding rules
- reproducibility of automated results reports created by the data custodian (TGI) assessed by staff at the NSRI
- review of data extraction, programming and data transfer procedures, proportion of failed transmission or extractions, proportion of incomplete or aborted extractions, software programming problems identified
- evidence that data quality guidelines have been followed
- timeliness of data collection and return of missing data site reports are assessed
- review of registry fields, through assessment of whether poorly completed fields or ambiguous fields should remain in the *minimum dataset*.

All feedback and recommendations from the evaluation are documented and presented to the Management Committee to make decisions on modifications to AuSCR procedures, policies or tools.

### **3. FINDINGS FROM TESTING THE OPERATING PRINCIPLES AND TECHNICAL STANDARDS**

The following sections provide an outline of the experience in testing the *Operating Principles* and *Technical Standards*. These findings are provided against the Australian Clinical Quality Registry checklist (p126)<sup>1</sup> and are detailed below under the following categories: Attributes, Data collection, Data elements, Risk adjustment, Data security, Data quality, Governance, Custodianship, Ethics and privacy, Outputs and Resources. After each category, a summary of the challenges and recommendations are provided.

A summary Table is also provided with recommendations (section 3.12).

#### 3.1. Attributes

#### 3.1.1. *Clear and Precisely defined purpose*

### Australian Clinical Quality Registries should be developed with clear and precisely defined purpose.

We support the need for this *Operating Principle*, since without a clear definition of purpose we would not have achieved support for AuSCR from our clinical colleagues or external agents such as government, the Australian Institute of Health and Welfare and industry.

The data collected by participating sites, as well as the comparative ability of the registry process, can be used for monitoring safety and quality of care. In addition, the data can be used to provide a spine for other research studies including cost effectiveness evaluations, provide geographical and temporal measures of caseload and outcomes, and assist in the identification of new preventive opportunities for stroke.

Methods to improve the understanding of the purpose of the AuSCR initiative have included:

- Online marketing, with a summary document about AuSCR placed on the Stroke Society of Australasia and NSF websites (refer <u>http://www.strokesociety.com.au/</u> and <u>http://www.strokefoundation.com.au/images/stories/asc/auscr%20summary.pdf</u>).
- AuSCR Office has exhibited at two clinical conferences this year, allowing direct communication with clinical colleagues. AuSCR exhibits were at SmartStrokes Allied Health and Nursing Conference in Sydney 6<sup>th</sup> and 7<sup>th</sup> August and at the Asia Pacific Conference Against Stroke in Cairns 6<sup>th</sup> to 9<sup>th</sup> September.
- AuSCR held an official launch at the Asia Pacific Conference Against Stroke (8<sup>th</sup> September 2009), and released media statements.
- Presentations have also been made to state-wide clinical networks in NSW (Greater Metropolitan Clinical Taskforce Stroke Services), Victoria, and Queensland. A presentation on the establishment of the AuSCR registry was also made this year in May at the European Stroke Conference (Stockholm Sweden).
- Distribution of monthly newsletters commenced in September 2009.

#### 3.1.2. Core data collection of essential elements

# For Australian Clinical Quality Registries to provide the maximum value to the health system they should focus their core data collection on the essential elements required to serve their main purposes.

This *Operating Principle* is sound and achievable from our perspective. Nevertheless, achieving acceptance of a core *minimum dataset* does have challenges. For the AuSCR initiative, we have found that the establishment of the core data elements has been an iterative process. This began with a workshop on 30 October 2008 using a multi-disciplinary and nationally representative group of clinicians, non-government and government representatives to agree on the essential core variables that would be used to define clinical safety and quality (refer section 2.3). An independent facilitator was used for the workshop and proved highly successful given the diverse range of stakeholders participating.

After the workshop, decisions to include variables were made by the Management Committee, and where required, expert advice was sought from members of the Steering Committee. The basic principle of keeping the variables to a minimum set to limit the burden of collection and avoid scope creep was balanced against the value of adding a new variable for ensuring appropriate risk adjustment and/or understanding the factors that might confound assessments of quality of care. Further assessment of the value of each variable in the core set is needed, but cannot be undertaken until collection from the field has occurred. This is one of the issues we have in testing the *Operating Principles* on a new registry.

A summary of the core data collection variables approved by the Management and Steering Committees is provided in the *Box* below. The *minimum dataset* will ensure that the assessment of quality and safety can be addressed within the context of the clinical variables measured; enable appropriate case-mix adjustment to occur; and also provide longer term (post-hospital) outcomes that capture mortality and morbidity.

Box: <u>AuSCR minimum variable dataset</u>	Process indicators of evidence based care
Identifying information <ul> <li>date of birth*</li> <li>gender*</li> </ul>	<ul> <li>use of intravenous thrombolysis (tPA) if an ischaemic stroke</li> <li>access to a stroke unit (geographically defined ward</li> </ul>
<ul> <li>address</li> <li>telephone number</li> <li>hospital name</li> <li>contact details for next of kin (x 2) &amp; general practitioner</li> </ul>	<ul> <li>area)</li> <li>discharged on an antihypertensive agent</li> <li>care plan provided at discharge (any documentation in the medical record)</li> </ul>
<ul> <li>Clinical information for risk adjustment and measuring timeliness of care delivery:</li> <li>ICD10 codes (diagnosis, medical condition, complications and procedures)</li> <li>country of birth</li> </ul>	<ul> <li>Hospital outcomes data</li> <li>date of discharge or</li> <li>date of death</li> <li>discharge destination</li> </ul>
<ul> <li>language spoken</li> <li>aboriginal and Torres Strait Islander status</li> <li>type of stroke</li> <li>cause of stroke (known/ unknown)</li> <li>date &amp; time of stroke onset</li> <li>date &amp; time arrive emergency department</li> <li>date of admission and in-patient stroke status</li> <li>transferred from another hospital status</li> <li>ability to walk independently on admission</li> <li>first-ever (incident) event status</li> </ul>	<ul> <li>3-month Outcome data</li> <li>survivor status</li> <li>place of residence</li> <li>living alone status</li> <li>recurrent stroke event since discharge</li> <li>readmission to hospital</li> <li>quality of life (EuroQoL5D adults PedsQL children up to 18 years old)</li> </ul>
*Also used for risk adjustment	

#### 3.1.3. Systematic data collection at all contributing sites Methods used to collect data in Australian Clinical Quality Registries should be systematic, with identical approaches used at the different institutions contributing information.

The method of data collection includes the use of the web-based online tool or the paper-based form, which have identical variables to ensure systematic collection. The variable definitions and data capture are METeOR and SNOMED-CT compliant, where appropriate. For variables not defined in METeOR, alternative sources including the NSF acute clinical audit data dictionary, state government data dictionaries, the data dictionaries of the Riks-Stroke Swedish registry and the Canadian Stroke Network registry were used. To facilitate the collection of personal information the AuSCR team acquired several standard patient admission forms from the nominated potential pilot clinical sites to ensure that these data would be readily available and uniformly collected. The forms were also used to base the order of questions about personal information, as well to facilitate ease of auditing from hospital medical records.

Because AuSCR is a new registry, research into how other registries support users to achieve systematic collection of data was undertaken. The experience of members of the AuSCR Management Committee in undertaking large and high quality clinical trials was also invaluable in making decisions about processes to ensure data would be reliably collected. Procedures we have initiated to ensure systematic data collection include:

• A standardised training program provided by one person supported with a PowerPoint overview presentation and off-line training database;

- The provision of comprehensive User Manuals (hospital and follow-up);
- A detailed Data Dictionary with variable matching to existing data dictionaries and detailed help notes;
- The data-entry screens throughout the AuSCR online tool have brief explanations and tips to assist with accurate interpretation of variables and data entry format;
- Use of dropdown menus and calendars in the AuSCR online to limit data entry errors;
- Logic checks and mandatory fields so that users are forced to provide a correct answer before moving onto the next section of the register;
- An optional import data template that can be downloaded from the AuSCR online and used by hospitals to upload data and avoid manual data entry and to reduce systematic data entry errors, e.g. spelling of name, etc. This was developed to overcome the issues of variability in hospital information technology systems. Presently, we are also developing a web-service as another option for hospital staff that would like to upload data from their patient administrative systems into the AuSCR online tool.
- Email support (<u>admin@auscr.com.au</u>); and
- Telephone support during business hours.

Training at four hospital sites was completed. Evaluation of the usefulness of the training program and tools was obtained from participants, with feedback collected on the training day and one-week following the training (refer section 2.6 and Appendices B to D). Feedback and evaluation following each training session are used to improve the format, delivery and content of the training. It also revealed needed improvements and changes to the online web-tool. For example, the need for alphanumeric fields for medical record numbers in WA. Dovetailing user training while database development was being finalised has meant important changes could be implemented immediately. It is intended that training will continue to be an iterative process, with feedback being integrated into the procedures to improve data collection during the AuSCR establishment phase.

Due to the database development being finalised at the same time as data collection for the initial sites, the collection of data commenced using the paper-based forms. Sites use various methods for data collection now based on preference which includes direct data entry with or without the use of the paper-based forms. The use of paper-based forms and direct data entry together allow the verification of data from the forms as a source document.

The reliability of data by testing participant knowledge about variable definitions and conducting a 10% random audit of medical records was carried out in September and October in three pilot sites (results are outlined in section 3.6). The outcome of these audits provide evidence about the reliability of particular variables, case ascertainment and will also be used to determine the size of routine audits when the AuSCR online tool reaches a steady-state operational phase.

#### 3.1.4. Epidemiologically sound data

## Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible.

The AuSCR *minimum dataset* variables are widely accepted in clinical practice. As outlined in section 3.1.3, we use nationally (or as appropriate internationally) accepted standard definitions to ensure that the data are epidemiologically sound so they can be reliably measured and collected. Moreover, to maximse the use of data and permit the future possibility for data linkage, we have ensured that the variables are compliant with METeOR and SNOMED-CT where possible.

Notably, several of our variables are not part of the METeOR National Health Dictionary or SNOMED-CT, and we have also found inconsistencies between these two systems. This has implications when trying to follow the *Operating Principles and Technical Standards*. There are also inconsistencies between the States and METeOR data dictionaries for health, and at times, these conflicts have had the potential to significantly impact on the validity of our data. For instance, in researching the administrative data routinely collected by pilot sites, we noted that some States do not collect indigenous data as per the METeOR standard, but rather only capture indigenous, yes/no. In this instance, and despite the available METeOR standard for Indigenous origin, we have made every effort to align the database with both dictionaries to produce a standard which will ensure compliance with available standards and dictionaries, and minimise missing data (see box below):

- 1 Aboriginal but not Torres Strait Islander origin
- 2 Torres Strait Islander but not Aboriginal origin
- 3 Both Aboriginal and Torres Strait Islander origin
- 4 Neither Aboriginal nor Torres Strait Islander origin
- 8 Indigenous (not further defined)
- 9 Missing/Not stated/inadequately described

Maximum character length: 1

#### 3.1.5. Outcomes properly ascertained

### Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.

The *Operating Principles* cover consideration of the most appropriate timing for outcome measurement; ensuring the greatest possible proportion of cases have outcome data; and practicalities of outcome data collection including cost, burden for patients; and loss to follow-up. The outcomes collected in AuSCR are summarised in Table 4.

Follow-up of cases commenced on 21<sup>st</sup> September by telephone and mail methods (refer section 2.5). As AuSCR is a new registry, we are presently unable to fully report our experience with several of these principles. However, this *Operating Principle* is appropriate and useful. In AuSCR the inclusion of a 3-month outcome assessment will ensure outcomes are properly ascertained, providing routine data previously unavailable in Australia.

Table 4

Registry	Outcomes
AuSCR	Survival In-hospital mortality 3-6 months quality of life/function/pain/anxiety Living arrangements

The AuSCR online tool has the capability to collect multiple episodes of acute care for the individual patient, discharge destination and mortality. Health outcome variables are ascertained within the AuSCR online tool at time of acute hospital discharge and more comprehensively at 3 to 6 months after an index stroke admission to a participating hospital. The 3 month time point is used in most stroke research studies as this is when the neurological condition should have stabilised and the person is most likely to be in the community setting<sup>10</sup>. Data from the Swedish Stroke Registry (Riks-Stroke) has also provided evidence that level of functional disability at 3 months is strongly correlated with longer term outcomes<sup>11</sup>. The 3-month outcome represents a time when a full assessment of the system of care for acute stroke and TIA can be made with consideration of outcomes that capture both mortality and morbidity.

Registered cases are only followed-up once in a 3-month period, with timing of follow-up based on their first episode of care. Multiple episode tracking within and between hospitals has been established within the AuSCR database to facilitate this process and ensure cases are not followed up more than once. Presently, we do not have the resources to undertake comprehensive follow-up of cases for multiple episodes of stroke that occur within the same 12-month period. However, the AuSCR database collects details about new stroke events and outcomes at time of discharge in these cases. Should funding become available, there is the future option of moving towards follow-up of subsequent episodes.

Follow-up User Manual and a telephone interview scripts for follow-up have been developed and are currently being trialled by NSF staff and the AuSCR Office staff. Training has been conducted, with training exercises developed to ensure consistency of training. Ascertainment of outcomes from data collected during a telephone interview has the potential to result in inconsistencies between interviews and be a burden on the responder. To minimise the risk of these potential issues, we are using interview scripts and interviewers experienced in conducting brief evaluations over the telephone with people who have had a stroke.

#### 3.1.6. Burden and cost of collection considered

# In determining the time to outcome assessment, Australian Clinical Quality Registries must consider the burden and cost of data collection together with the likelihood of loss to follow-up

The AuSCR consortium partners have taken into account the burden and cost of data collection. Ongoing collection of data and national scalability of the project would be difficult to maintain *unless* we collect only a limited number of variables.

AuSCR Office and the NSF staff are trained to systematically collect the outcome data and enter it into the AuSCR online tool follow-up screens using telephone follow-up or mail follow-up methods. *The most reliable* (high ascertainment and complete data) *and costeffective method for patient follow-up determined in the pilot phase will be used for the AuSCR initiative in the longer-term.* 

If contact cannot be made with a patient registered in the AuSCR online tool and survivor status is not established, then once a year we will make an application to the National Death Index to determine survivor status.

Since 21 September 2009, a total of 44 cases were randomised over three weeks for follow-up. Of the 21 mail cases and 22 telephone cases, we were able to complete a total of 14 cases, 11 of which were by telephone. This represents near 30% (n=14) of follow-up at three months conducted to date. At this stage it is not possible to determine the most appropriate manner of future data collection. However, these initial data emphasise that new registries should be encouraged to trial different methods of follow-up data collection to ensure the most reliable method for achieving complete follow-up in an efficient way is used.

#### 3.1.7. Complete collection from entire eligible population

### Australian Clinical Quality Registries must ensure that complete registry data are collected from the eligible population

One of the main purposes of establishing the AuSCR initiative is to determine outcomes of care from the highest possible proportion of patients. This requires that all eligible patients within a participating hospital are included in the register to ensure results are not biased. To ensure the data are not subject to the problem of selection bias we have implemented the following:

- The Participating Hospital Agreement clearly outlining the expectations and responsibilities of the participating hospital and the AuSCR office, including the ability for AuSCR staff to conduct site visits and audits to verify case eligibility and completeness of case ascertainment. Participating sites must sign the Participation Agreement before commencement. No hospital is allowed to participate unless they are prepared to input data on all eligible patients.
- Ethics applications are for the approval of an opt-out consent model for case ascertainment, which means that all cases admitted to the participating hospitals will be given a patient information sheet and entered unless advised otherwise by the patient or next of kin; and
- A quality assurance and data management process is put in place. This includes examining the number of cases entered into the registry at the pilot sites and the cases of stroke discharges during the pilot phase using administrative system reports of ICD-10 codes, for the same period.
- If contact cannot be made with a patient registered and survivor status is not established at follow-up, then on an annual basis we will make an application to the National Death Index to determine survivor status of all those patients who were lost to follow-up to minimise incomplete information on vital status.

In addition, planned regular audits of data and cross-verification of data from patient administrative systems at participating sites are conducted. At this stage, we are unable to provide feedback on the success of these strategies in meeting this *Operating Principle* (see also section 3.1.6). Evidence gathered as part of the formative evaluation has indicated that, currently, hospitals have focussed on collecting data from their own ward rather than for all stroke patients admitted to their hospital. This is mainly due to resource limitations. In one pilot site this is a particular problem since only about 60% of patients are being entered in AuSCR. Methods to routinely, efficiently and systematically capture missed patients using technology solutions are being investigated. An import data function has been developed for hospitals to use to upload data into the AuSCR online tool. We have also invested in the development of a web-service for uploading routine variables to reduce data entry time and systematic data entry errors. To date none of these technology solutions have been tested in the field, but progress to achieving this is being made. One of the main limitations at this stage is resources available to hospitals to integrate or use these solutions. A 'missed patient' letter was also identified as being needed and has been developed.

#### 3.1.8. Summary of Challenges and Recommendation for Attributes

- A multi-disciplinary workshop with an independent facilitator proved highly successful for deciding the core data elements to be collected for hospital care.
- Ensuring the variables can be aligned with international, prospective stroke registry and other existing data bases was important for the future of the registry. However, obtaining a definition for some of the core elements that are not exactly the same was a challenge.
- Adopting the mandate for a minimum dataset of variables assisted in the prevention of "scope creep" and "ease of burden on collection" for all parties involved.
- Dovetailing user training during the pilot phase while database development was being finalised has meant important changes could be implemented immediately.
- New registries should be encouraged to undertake a formative evaluation process to refine and inform their variable choices and data dictionary definitions and help-notes during their establishment phase.
- Although METeOR is considered the authoritative repository for data standards there is minimal common stroke related definitions. Presently, we are undertaking a mapping exercise of these issues and have also made contact with NEHTA about developing domain specific subsets of SNOMED-CT in our field of stroke.
- METeOR being the strategic repository for other data standards, do not have consistent matches with SNOMED CT.
- Although the many of the AuSCR minimum dataset variables are accepted for use in clinical practice, each state has adjusted the data standards and definitions from METeOR to suit their needs creating inconsistencies. This poses a challenge when trying to build a national register.
- Use of a telephone script has allowed for consistency in method of follow-up data collection and has reduced the potential for interviewer bias.

- New registries should be encouraged to trial different methods of follow-up data collection to ensure the most reliable method for achieving complete follow-up in an efficient way is used.
- The naming of the respective principles are not the same as in the check list or the summary within the section. For example, complete collection from entire eligible population in the check list is called Selection bias in the body of the document. This may create confusion.

#### **3.2.** Data Collection

#### 3.2.1. No impact on provision of care and not a burden or cost to consumers

### The collection of data for an Australian Clinical Quality Registry must not impact on the provision of health care and should not be a burden or incur a cost to consumers.

Data collection in the AuSCR online tool does not impact on the primary purpose of the health care visit since all variables are routinely documented within the current health care system. Variables have been carefully selected and methods for non-manual data entry are being assessed to minimise the burden and resources needed to collect the data in the AuSCR online tool (refer section 3.1.6).

In terms of reducing the burden and costs to patients, we have established a free-call (1800) number listed in the patient information sheet to allow patients to contact the AuSCR office to opt-out at anytime at no cost to them. Patient and relatives will also be given the opportunity to opt-out at follow-up contact. We have also been mindful to contain follow-up interviews to no longer than 20 minutes by minimising the outcome variables collected and using a telephone interview script. Because this is a new registry we are unsure whether patients will be more responsive to telephone interview or postal questionnaires, therefore we are trialling both options to make recommendations at the completion of the pilot phase (refer section 3.1.6).

#### 3.2.2. Data collection as close as possible to point of care

### Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors

This is a sensible *Operating Principle*, but one that is difficult to arbitrarily prescribe an ideal method for given the different hospital environments in which stroke care is provided, including the skills of staff. The AuSCR initiative has been designed to capture data on acute stroke care during and shortly after the hospital admission. Staff at each pilot site are provided with general instructions about the importance of capturing the data as near as possible to the time of care provision. It is recognised that some data are unavailable until several weeks after a patient is discharged (e.g. discharge ICD10 coding). Therefore, each hospital may use a different method. Options for online data entry and/or paper base data collection are provided for hospital staff to develop the best method for capturing data given their local circumstances. For example, at one site the data will be completed online during the weekly multi-disciplinary team meeting, with discharge ICD10 coding captured in batches several weeks

later. Other sites have nominated to use the paper-based form and then enter data online at a later stage when the ICD10 discharge code is available.

Methods for assessing the best approaches to data collection will be incorporated as part of a planned internal evaluation of the AuSCR pilot phase. Experience from the pilot sites and their perceived 'ideal' methods for capturing data in the AuSCR online tool will be reviewed. This will provide enormous value for implementation of the AuSCR online tool across more hospitals in the future.

The most reliable method for capturing patient hospital data determined in the pilot phase will be recommended to sites participating in the longer-term.

#### 3.2.3. Uniformly and easily accessible from data source Data should be uniformly and easily accessible from the primary data source.

At this stage, not all the AuSCR variables can be obtained from patient administrative systems in hospitals. Therefore, data capture will be from the primary source, which is the patient medical record. To ensure the AuSCR variables on personal information are routinely collected in hospitals and easily accessible, the AuSCR team acquired patient admission forms from several hospitals and pilot sites to ascertain they were uniformly collected and adjusted the order of the questions in the online tool for ease of use. The exercise also revealed some data was not routinely collected in hospitals patient administrative systems and not easily located in the medical records. Strategies adopted to manage these variations are allowing for some of these data variables to remain non-mandatory, providing an unknown or not applicable option, and providing examples of possible source documents in the data dictionary of each variable. The AuSCR hospital user manual details every variable and data collection methods with step-by-step instructions for all hospital users. In addition, the online tool includes mainly dropdown menu options with limited free text fields, as well as brief explanations and tips to assist with data entry. We also provide a comprehensive data dictionary (see section 3.2.5) and have planned audits and surveys to assess user knowledge of variable definitions and the reliability of data collection.

#### 3.2.4. Standard definitions, terminologies and specifications used

Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registers and other databases (if approved by relevant ethics committees, etc.)

The AuSCR variables have been carefully matched to METeOR standards, SNOMED-CT where applicable. Reference to other data dictionaries have been made to highlight consistency, standardisation of definitions and terminology and maximise linkage to other registers in the future. They include the following:

- Data Dictionary NSF national stroke audit 2009,
- Riks-Stroke Swedish registry,
- Registry of the Canadian Stroke Network,

- Victoria Hospital in the Home (HITH) *minimum dataset*
- Queensland Health Data Dictionary
- Paul Coverdell Stroke Registry in the United States of America.

In cases where there is a variance between METeOR standards and other available definitions, the METeOR standard has been used. The corresponding *data element* component, *METeOR identifier number, registration status* and *data codes* are included in the AuSCR data dictionary as appropriate. Adherence to NEHTA standards for data formats have been used, where available, in the development of the database for future linkage to other data sources. The Individual Health Identifier (IHI) has also been built into the AuSCR online tool, however its functionality will not be released until the IHI becomes active nationally (currently anticipated to be 2011).

#### 3.2.5. Data dictionaries used

# Australian Clinical Quality Registries must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. They need to publish eligibility criteria, metadata, data dictionaries, etc.

The AuSCR data dictionary outlines standard definitions and variable codes to ensure data quality and integrity for use by all people involved in the collection, processing and analysis of the AuSCR data. The data dictionary has version control, whereby a version number is issued on the document, so that when routine updates are made versions in use can easily be replaced without confusion. A "help notes" and "further information" section is also included under each variable to provide further clarification and guidelines.

The data dictionary will be readily accessible on the front page of the AuSCR web site (currently under construction) for all users and other interested parties. Currently hard copies are given to all pilot sites at training.

Each page in the data dictionary has a consistent look and feel and contains some or all of the fields listed on the example given in Table 5.

Common Name	Lists any alternative common names for the data item i.e. Person Birth Date may be known as Date of Birth
Definition	Gives a brief explanation of the data item
Main Source of Standard	Shows the derivation of the data item' definition i.e. METeOR catalogue
Format	The format of the data item i.e. (dd/mm/yyyy)
Recording Guidance	This section will give recording guidance for clinicians working in participating AuSCR hospitals
Codes and Values	This section shows any codes and values, where applicable
Further Information	Shows any further information on the data item, including context, rationale and references to key documents as appropriate.

#### Table 5 General format of data dictionary

#### 3.2.6. Use existing data sources where possible

### To avoid duplicating data capture, Australian Clinical Quality Registries use data from existing data sources, including administrative data, where they are of a satisfactory quality

In the development of the data base other existing data sources already collecting clinical stroke data have been recognised and taken into consideration. The AuSCR team worked closely with the NSF and NSW Stroke Services to ensure that the AuSCR online tool would conform to these organisations' respective data audit projects to limit duplication of data capture. Alignment with these sources also includes using common definitions (see section 3.1.4)

Data items in the AuSCR online tool are obtained directly from the patient's medical record and we acknowledge that ancillary patient administrative data systems are already in place in participating hospitals that include several variables recorded in the AuSCR online tool. The AuSCR online tool provides import capability from an Excel-formatted template which is simple and easy to use. The testing of this feature has included migration of data from two different datasets (NSF National Acute Clinical Audit 2007 and the NSW Health Stroke Audit datasets). One of the benefits of undertaking this process was to also enable the testing of many other functionality features in the AuSCR online tool.

A separate web-service for importing data is also being developed by our technology vendor. AuSCR staff will start by working with one or two participating hospitals to test this interface initially. This will assist in clarifying potential issues and identifying barriers, as well as the strengths of this feature, before making it fully available to the other participating hospitals.

#### 3.2.7. Use record linkage where possible

## Australian Clinical Quality Registries should have the capacity to enhance their value through linkage to other disease and procedure registers or other databases

The AuSCR online tool is a standalone web-service developed as a Level 2 registry. However, a range of patient identifiers (e.g. name, Medicare record number, date of birth, medical record number) are collected and may be used for probabilistic matching of cases. Where possible, variables are designed to be formatted according to national standards to enable data linkage in the future (refer section 3.2.4). We have also been assured by our technology vendor that AuSCR online tool will be capable of HL7 messaging as a standard for clinical communication to enable future development to a Level 3 register.

#### 3.2.8. Summary of Challenges and Recommendation for Data Collection

- Most sites nominate one person who is responsible to collect registry information. This may impact on data collection or not be sustainable when staff are sick, go on leave or change jobs.
- Every hospital has their own admission form and may use different patient administration systems which can provide a challenge for collecting basic demographic and uniform data for a national registry.
- Flexibility in when to collect some variables could be emphasised. Some variables which are fixed e.g. ICD10 codes can be collected at routine intervals (i.e. every 6 months) if this is a way of reducing the burden of collection for clinicians and they are not required for conducting follow-up assessments.
- Obtaining standard definitions to enable future data linkage to other registries was a challenge. The Operating Principles could identify that the administrative data collected differs across health jurisdictions and hospitals, and that hospital administrative data processes may not be METeOR compliant.
- A guide on the core items appropriate for a register's data dictionary such as demography and variables essential for data linkage, as well as documenting the reference to METeOR codes used and possibly some basic mandatory fields that are kept consistent across registries would be helpful for new projects, as well as providing improvements for existing data dictionaries.
- Linkages to other registries or databases were not able to tested in the pilot project due to time constraints. Negotiations with hospitals and health departments are continuing.

#### **3.3. Data Elements**

The data elements were summarised earlier in section 3.1.2 and in the *Box*. Further details are provided below.

#### 3.3.1. Collect individually identifiable patient information

### Australian Clinical Quality Registries should collect individually identifiable patient or subject information

In the design of the AuSCR online tool socio-demographic and contact details are collected on each individual case. A unique patient identifier is automatically created for each entry made in AuSCR that is linked to their first name, surname, hospital medical record number, Medicare number and date of birth. In addition unique identifiers for each episode are also created allowing the ability to track and monitor each the individual journey. This provides the ability to perform probabilistic duplicate entry methods and track transfers from another hospital.

Hospital Identifiers are also created automatically when a hospital is registered to participate and all hospital users' and patients' for that hospital is linked only to that identifier.

Variables collected include first name, surname, address, hospital medical record number, Medicare number, date of birth, general practitioner and next-of-kin details. These variables are all routinely recorded in the hospital inpatient administrative system.

The identifiable data are collected for the AuSCR initiative to:

- Enable outcome information to be collected, at three months follow-up;
- Enable linkage to other administrative other databases within the hospitals;
- Track people through multiple episodes of care and sometimes across multiple institutions;
- Facilitate data quality checks to be undertaken, e.g. by comparing registry data with information held in medical records; and
- Enable a single person record to cross-check for duplicates.

The various hospitals data collection of personal information are non- mandatory, which poses difficulty in obtaining some information such as Medicare numbers, Next of kin and GP contacts, to assist in contacting the patient for follow-up. The titles used for some of the personal information are also not consistent but similar (such as sex and gender). The use of the data dictionary has been helpful is defining the title for consistency.

For compliance with the Privacy Act (1988) the AuSCR online tool access is passwordprotected with the hospital users linked only to the specific hospital they work in, via the hospital identifier. The AuSCR online tool design therefore has the capacity to produce identifiable, deidentifiable and re-identifiable data with security and password protection. This facility will be useful for future linkages with other databases.

#### 3.3.2. Collect process of care information

#### Where patterns or processes of care have an established link to outcomes and process measures are simple, reliable and reproducible, they should be considered for collection by Australian Clinical Quality Registries

In meeting the purpose of the AuSCR initiative to improve quality of care, the collection of best practice principles to best measure compliance was discussed and agreed upon at the *minimum dataset* workshop in Oct 2008 and approved by the Management Committee.

The AuSCR initiative also has to collect data that is reliable and reproducible and that also have established links to outcome.

The variables selected to assess the quality of in-patient hospital care for stroke patients include:

- Date and time of admission;
- Date and time of stroke onset;
- Use of intravenous thrombolysis (tPA) if an ischaemic stroke;
- Access to a stroke unit;
- Discharged on an antihypertensive agent;
- Care plan provided at discharge;
- Transfer from another hospital;
- In-patient stroke;
- Previous stroke; and
- Discharge destination

Analysis of these variables will provide useful information to examine the reasons for differences in outcomes.

#### 3.3.3. Collect objective outcome information

## Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools.

It is not possible to measure the outcome of "quality of life" using an objective measure. In the AuSCR follow-up questionnaire the outcome measure on quality of life uses a standardised and validated tool: the EuroQOL (adults) or PedsQL (children).

Other outcome information collected are objective, such as death and place of residence. (refer **Box** section 3.1.2). At the commencement of each telephone follow-up a cognitive and language screen is used to assess the respondent's recovery and ability to proceed with the follow-up questions.
The telephone follow-up questions will be asked by an independent person from the NSF. The advantage of this approach is that the *trained call centre staff are blinded to the hospital data and other data in the AuSCR online tool related to the type and severity of stroke* (refer section 3.1.6).

To ensure staff conducting the telephone interviews do not influence the respondent's answers a telephone script and training is provided.

#### 3.3.4. Summary of Challenges and Recommendation for Data Elements

- Some hospitals do not document health data such as Medicare number and ICD codes in medical records because these are not needed on the wards. This can pose some difficulty for persons entering data and a procedure to obtain and/or verify the information for completeness of data collection is required.
- Mobile numbers are becoming the main contact number instead of telephone landlines. Personal information on hospital admission forms should include the capacity to collect mobile numbers.
- The definitions of some variables were not available in METeOR, although they are considered to be 'best practice' by peak professional bodies. Guidance and approaches to assist groups in deciding which processes measures should be collected may include direct evidence between process and outcome but also be based on other considerations such as the perspective of consumers.
- Maintaining the consistency of the questions and remaining objective at follow-up interviews with the different scenarios and abilities of post-stroke patients, reveal the need to have well-trained staff and supports such as telephone interview scripts.

### 3.4. Risk Adjustments

### 3.4.1. Collect objective, reliable co-variates for risk adjustment

# Australian Clinical Quality Registries should collect objective, reliable co-variates for risk adjustment to enable factors outside the control of clinicians to be taken into account by using appropriate statistical adjustments.

The AuSCR initiative collects objective and reliable covariates for risk adjusting outcomes. This ensures that factors outside the control of clinicians can be taken into account with the use of appropriate statistical methods. Co-variates chosen are epidemiological sound variables, including first or recurrent stroke, age, gender, ethnicity and main pathological type of stroke (i.e. haemorrhage or ischaemic stroke, or TIA) (see **Box** section 3.1.2).

The AuSCR covariate collected on severity of stroke (ability to walk on admission) has shown to be either not recorded systematically in clinical records or not able to be easily extracted. Therefore, as an alternative the AuSCR online tool also includes the use of individual risk strata, such as first or recurrent stroke, age, gender, ethnicity, type of stroke.

#### 3.4.2. Summary of Challenges and Recommendation for Risk Adjustment

- Trialling variables for risk adjustment as part of a pilot project could result in hospitals accepting it as an indication for inclusion in the future. Appropriate variable selection and communication methods are needed.
- Training should focus on ensuring data collection of risk adjustment variables, in addition to the more often understood clinical outcome variables.

#### 3.5. Data Security

In recognising the need for transparency about data security for the AuSCR online tool, a Data Security policy has been developed. Details about how we have addressed the *Operating Principles and Technical Standards* re data security are outlined below.

#### 3.5.1. Secure access controls and securing messaging

# To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems

The external technology vendor who built the AuSCR online tool has taken all precautions to mitigate data security risks. The database has been built to clearly defined specifications and requirements to meet the standards for the protection of electronic health information as defined by NEHTA, the National Health and Medical Research Council, and the Australian Research Council and Universities Australia. Specifically, the following has been put in place:

- Secure data housing. Staff employed by TGI, the AuSCR data custodian, have configured the firewall so that the access to the application server is restricted. The AuSCR web site which will be accessible to the general public is housed on a separate server, for extra security and access control. The servers are held under strict security and limited access, within a locked room which is located behind a swipe-card enabled door access with security personnel aware of all access into the building;
- Secure access controls to ensure that only authorised people have access to the database. Access to identifiable information and encrypted password access codes are only provided to two levels of users within the AuSCR data management centre. The AuSCR database is password-protected at an individual level, thus ensuring that an audit trail exists to ensure that data cannot be altered or exported without authority. Follow-up data entry also occurs by users unable to access hospital-level data. Thus, different aspects of the database are locked to various users and users only have access rights relevant to their role;
- All web-based data is transmitted in a secure manner. The AuSCR online tool uses the highest secure internet connection (Secure Sockets Layer), available in Australia, to protect against the loss, misuse, and alteration of any information received from participating hospitals. Secure Sockets Layer is used for all pages of the database. The JBoss/Apache security layer enforces various security measures such as Secure Sockets Layer encryption. The user roles are maintained by the application and govern

the authorisation of the exposed functionality. Passwords for user accounts are MD5encrypted by the applications and stored as such in the database.

• Data transmitted via the postal or fax system will be addressed to the AuSCR Project Officer (employee) who will take responsibility for ensuring the arrival and appropriate storage of the data. This paper information will be stored in a locked filing cabinet at TGI. The instruction on the AuSCR paper-based forms and the hospital user manuals, include the sending of the forms to a secure fax number, designated for confidential faxes only. This is housed within the office of the Director of the Department, responsible for the AuSCR initiative.

# 3.5.2. Data collection, storage and transmission complies with all relevant legislation and guidelines

### The collection, storage and transmission of clinical registry data must be in line with relevant legislation and guidelines

The AuSCR processes and procedures (as outlined previously) ensure compliance with NEHTA, the National Health and Medical Research Council, and the Australian Research Council and Universities Australia policies and guidelines. In addition, ethics committee approvals from hospitals in four States (NSW, WA, QLD and VIC) have been obtained to collect personally identifiable data from patients. Therefore, we have developed the AuSCR data collection, storage and transmission procedures to meet privacy legislations in all States and territories of Australia, including: NSW Privacy and Personal Information Protection Act (1998); NSW Health Records and Information Privacy Act (2002); Vic Information Privacy Act (2000), Vic Health Records Act (2001); NT Information Act (2002); and Tasmanian Personal Information Protection Act (2004).

We required that the technology vendor adhered to the standards outlined for development of the AuSCR online tool as a Level 2 clinical registry. To ensure this, extensive and rigorous user acceptance testing had to be implemented. User acceptance testing was completed by members of the Management Committee, several members of the Steering Committee and staff at the NSRI and TGI (both familiar and unfamiliar with the AuSCR initiative). To manage the communication between the technology vendor and AuSCR representatives an *'issues register'* was maintained during user acceptance testing.

Working with an external technology vendor who was not entirely familiar with the *Operating Standards and Technical Standards*, and the health care setting meant that the following steps and difficulties were identified:

- Constantly re-specifying and checking compliance;
- Time consuming exercise;
- Changes incurred additional costs and delayed the release of the web-tool; and
- Several face to face meetings and teleconferences were required to ensure we were all working towards the same objectives.

The technology vendor was also requested to provide detailed Technical Specifications and a User Manual. This was to ensure that AuSCR staff could clearly understand, use and assess

the system that had been developed to detailed specifications that had been outlined in the contract with the technology vendor.

At times, compliance with METeOR definitions and variable standards was a challenge for the technology vendor, as well as for AuSCR staff. As outlined in section 3.1.4, there was not always a direct match between the AuSCR variables and available METeOR elements. At times an incorrect METeOR element was chosen by the developer because (a) the information within each element was broad, or (b) there were several possible options available (e.g. health versus community, with different codes), or (c) a link to another website to provide the variable codes (e.g. codes for language spoken). Thus, choosing the most appropriate variable format for each registry variable has not always been as straight forward as possible. Table 6 provides an example of variables in the AuSCR online tool where METeOR standards were used.

METeOR codes used in AuSCR (as at 15 June 2009)			
Attribute	Туре	Code	
Gandar	Male	1	
Genuer	Female	2	
	Business	1	
Address Type	Home	3	
	Other	g	
Rhono Number Type	Home	F	
Filone Number Type	Mobile	N	
	Aboriginal but not Torres Strait		
	Islander origin	1	
	Torres Strait Islander but not		
Aboriginal or Torres Strait Islander	Aboriginal origin	2	
Aboriginal of Torres strait Islander	Both Aboriginal and Torres Strait		
	Islander origin	3	
	Neither Aboriginal nor Torres		
	Strait Islander origin	4	
	Yes	1	
ØVes / No / Not Applicable / Upknown Apswers	No	2	
eres / No / Not Applicable / Olknown Allswers	Not Applicable	3	
	Unknown	g	
	Alley	Ally	
	Arcade	Arc	
	Avenue	Ave	
	Boulevard	Bvd	
	Bypass	Вура	
	Circuit	Cct	
	Close	C	
	Corner	Crn	
	Court	C	
	Crescent	Cres	
	Cul-de-sac	Cds	
	Drive	Di	
	Esplanade	Esp	
In Street Type	Green	Grn	
	Grove	Gi	
	Highway	Hwy	
	Junction	Jno	
	Lane	Lane	
	Link	Link	
	Mews	Mews	
	Parade	Pde	
	Place	P	
	Ridge	Rdge	
	Road	Rc	
	Square	Sc	
	Street	St	
	Terrace	Tce	
	1269.0 Standard Australian Classif	ication of Countries	
Country of Birth	(SACC) Second Edition		
	Cat.no. 1267.0 Australian Standard Classification of		
Language spoken	Languages (ASCL)		
cangaage spoken	cangadges (ASCE)		

Table 6 Example of several variables where METeOR standards were used

In addition, we found that METeOR guidelines were not always aligned with the *Operating Principles* for a clinical quality registry. That is, they do not always *consider the burden and cost of collection*. One such example of a pragmatic decision employed in the development of the registry database is in the case of compliance with the date accuracy element of METeOR. The AuSCR online tool requests entry of a number of dates and times, including date and time of stroke, date and time of presentation to the Emergency Department, date of admission to hospital, and date of discharge/death (separation). To comply with METeOR elements, each date and time would require a coding of accurate/estimated/unknown for each element of each variable. The pragmatic decision was made that elements of each time date could be assumed to be correct, that is, month and year. Thus, a single estimator for date antry for clinicians.

SNOMED-CT has been reviewed both by the technology developer, but also by the project managers to ensure that wherever available consistent terminology has been used. With the future intention of benchmarking with international prospective registry projects, matching the AuSCR variables to SNOMED-CT in addition to METeOR content is considered important by the Management Committee. In reviewing the SNOMED-CT National Release, it is clear that matching the clinical terminology between the AuSCR variables and SNOMED-CT is, while possible, time consuming to locate the match, and inconsistent in where matches are available.

### 3.5.3. Policies Comply with Part B: Technical Standards – Standards map

#### Institutional policy principles set out in Part B: Technical standards should be met.

Table 7 outlines the NEHTA recommended standards applicable to the implementation and operation of a Level 2 Registry, and provides commentary on how the AuSCR online tool is being developed to address each of these.

In addition the data custodian has in-house IT policies that were adapted to comply with the Technical Standards. Policies are developed related to the *Operating Principles and Technical Standards* include:

- Data Security (ratified)
- Data Access
- Data Custodian
- Intellectual Property

Relevant standards NEHTA Recommended Standard		Level 2 Registry	Australian Stroke Clinical Registry Alignment	Note(s)
Interoperability Framework (eg. Architecture)	Interoperability Framework	Optional	The framework was based on a short-term architecture solution	Interoperability based on NEHTA requirements have been built in for a IHI and HPI but are not operational. We have developed short term architecture recognising the need for it to be flexible enough to support evolution of interfaces in the future (see further detail below)
	Unified Modelling Language v2.0	Not required	UML 2.0v was used for application architecture	UML was used in the application solution architecture.
	TOGAF	Optional	N/A	TOGAF is an Enterprise Architecture framework and was not required for this simple application architecture.
	Information Technology – Open Distributed Processing	Optional	N/A	The application is not distributed
Clinical Communications	Terminology	Required	Complies	Used METeOR standards and NEHTA standards (which includes SNOMED-CT). Applied ISO/IEC 11404 for language-independent datatypes.
	Data Specifications	Required	Complies	Used METeOR
	HL7 Messages	Not required	N/A	The integration is provided via Web Services. Capable in a future release. The data schema is current and would only need to build an extra interface for HL7 messaging
	Datatypes	Required	Complies	Java complies with the ISO/IEC 11404 international standard
Unique Healthcare Identification	Health Care Provider Identification	Required	N/A	Hospitals are identified by name and there is an automatically assigned Hospital ID which is unique in the system. METeOR identifier 269973 is not used but may be applied in a future release. Provision for use of unique individual health organisation identifiers as envisaged by NEHTA have also been created in the web-tool
	Health Care Client Identification	Optional	First Name, Last Name, Medicare Number and Date of Birth	These four pieces of information are used to identify a patient. Hospital medical record number is also captured. All patients have a unique patient record ID and person record ID assigned in the system. Provision for use of unique individual health identifiers as envisaged by NEHTA have also been created in the web-tool
ldentity Management	Authentication Assessment Methodology	Optional	N/A	Simple authentication and application user management was used. No Authentication Assessment Methodology was required.
	Framework for Analysing, Planning and Implementing Identity Management	Optional	N/A	Users are managed within the application therefore no framework was required for the IM. But a framework would be used in the future if the application becomes part of a distributed system. Only small changes would be required to make use of a national identify management system.
	Identity Management Resource Set	Optional	N/A	See above comment
	AGAF	Optional	N/A	
	ACSI 33	Optional	N/A	
	Security Techniques	Optional	complies	Built to adhere to standard AS/NZS ISO/IEC 27001:2006 Information technology - Security techniques - Information security management systems - Requirements HTTPS SSL, Password encryption MD5 Data custodian has secured a SSL certificate for 12mths.
	OASIS eXtensible Access Control Markup Language (XACML) TC	Optional	N/A	Not used
	OASIS Security Services (SAML)	Optional	N/A	Not used
Secure Messaging	Web Services	Not required	Yes	A web-service developed in Jboss using a client programming model for J2EE for uploading data into AuSCR has been developed and conforms with the standards that NEHTA supports.
	XML	Recommen ded	N/A	

#### Table 7 NEHTA standards map and alignment with the AuSCR online tool

#### Table 7 continued

Supply Chain	Supply Chain	Required	N/A	Product information is not held in the registry.
Relevant standards	NEHTA Recommended Standard	Level 2 Registry	Australian Stroke Clinical Registry Alignment	Note(s)
Engagement & Adoption	Understanding Standards	Optional	Consulted HB 107-1998 and used where appropriate	Technology vendor has provided a Technical Notes document and User Manual to ensure purchasers of AuSCR are aware of the standards used
	CGOI and Communication Technology	Optional	Consulted AS 8015- 2005 and used where appropriate	Technology vendor has provided a Technical Notes document and User Manual to ensure purchasers of AuSCR to ensure effective use of the ICT created. IT governance is included in the Registry Governance structures.

### 3.5.4. Summary of Challenges and Recommendation for Data Security

- The ability to ensure security for the registry was compliant with the *Operating Principles* and *Technical Standards* would not have been possible without a well-resourced and experienced IT department located within the data custodian, who were also able to support and advise the AuSCR Management Committee.
- Working with a technology vendor who, although having previously completed large scale projects, were not entirely familiar with the *Operating Principles and Technical Standards*, and the health care setting, provided a challenging task.
- Compliance with METeOR definitions and variable standards was a challenge for the technology vendor, as well as for AuSCR staff, due to not always having a direct match or hospital data collection not adhering to the same standards.
- METeOR guidelines were not always aligned with the *Operating Principles and Technical Standards*
- We suggest a national system for accrediting and nominating e-health technology developers which may assist new registries to efficiently comply with the technical standards. This would also reduce duplication of effort and minimise costs. This could be a role for a national organisation like the Commission or NETHA.
- The development of the AuSCR online tool using a commercial company had its advantage in that development and subsequent changes to features and function could occur in an expedient manner. However, a downside was some limitations in the transfer of corporate knowledge and a reluctance to provide a detailed technical handover to our IT department staff.
- Cooperation and early involvement of the data custodian IT department (TGI IT) also assisted in the AuSCR team's understanding and ensuring compliance with the *Technical Standards*.

#### 3.6. Data Quality

To date three of the four pilot sites have been involved in data quality audit processes (refer section 2.6). Our experience is that quality control can be resource intensive, but is essential in the early phase of new sites coming on board and in the establishment phase of a registry. A summary of pilot site audit results are provided below. This information is currently being used to refine the data dictionary, and Hospital User Manual, as well as the paper-based and web-tool:

#### First Name

• The issue of how to record preferred first name was raised during the audits. This is of importance/relevance when contacting the patient for follow-up.

#### Medicare Number

- In one hospital, Medicare numbers were not available in the medical record and therefore not entered in the database.
- The issue of how to fill in the Medicare number for overseas patients was raised.

#### Telephone Numbers

• In several instances home and mobile numbers were available but not recorded, particularly for emergency and alternate contacts.

#### Addresses

- In several instances addresses were not recorded in the database even though they were recorded on the paper-based form. This highlighted a problem with people not clicking the *Add* button in the database after typing in the address details.
- If the patient address is not entered this has a flow-on effect for emergency/alternate contact addresses that are the same as the patient's as no address details are transferred when *same as patient* is selected in the address section.

#### Date of arrival at Emergency Department

• In one instance the date of arrival to the emergency department of another hospital was entered rather than the current hospital emergency department.

### Time of arrival at Emergency Department

• There were some differences found between times recorded in the medical record and that recorded on the paper-based form and in the database

### Date of Stroke Onset

• There were a few instances where the date of stroke onset and accuracy were incorrectly recorded.

#### Time of Stroke Onset

• There were a few instances where the time of stroke onset was incorrectly recorded and several instances where time accuracies were incorrectly recorded.

### Cause of Stroke

• There were several instances where the cause of stroke was incorrectly recorded as 'known' or 'unknown' or left blank.

#### **Discharge** Information

- There were a few instances where date of discharge was incorrectly recorded. This was sometimes due to a patient being transferred to rehabilitation and confusion regarding when the discharge from acute occurred.
- There were several instances in one hospital where discharge information was found in the medical record but that information had not been added to the database. This highlights a need to ensure processes are in place within hospitals to add this information when available.
- Evidence of a care plan some issues were identified regarding how to complete this for nursing home patients.
- The issue of how to capture a type change to nursing home was raised particularly in relation to making patient follow-up easier.

### **Other Issues Identified**

Other issues identified during the audit included:

- Some emergency, alternate and GP contacts found in medical records but not entered in the database;
- No ability to add a third telephone (work) number for emergency and alternate contacts in the database;
- How to complete the GP section if there is no GP because the person is new to the country;
- No facility to add a second doctor's name in the database;
- No ability to add a fax number for GP contacts in the AuSCR database. In most instances a GP mobile number is not available. Therefore, the fax number could replace the mobile number by modifying the paper-based form and web-tool;
- Not enough space on the paper-based data collection form to record the name of the medical practice and the street address for GPs;
- In one hospital it was identified that the paper-based form would be easier to complete if the GP details were all on the one page rather than across two pages;
- During the audit, the auditor identified issues with identifying outliers in some hospitals;

- In some instances the *form completed by* section on the paper-based form was not completed; and
- In one of the audited cases, the same episode was entered twice for the same patient.

#### 3.6.1. Reports percentage of eligible patients recruited Australian Clinical Quality Registries should report as a quality measure the percentage of eligible patients recruited to the registry

As part of the quality assurance and data management processes, a comparison of patient registrations entered by hospital staff into the AuSCR online tool will be compared to patient administrative system reports for the same period using ICD-10 codes. These quality control processes have been put in place to monitor completeness of patient registration (refer section 3.1.7).

### 3.6.2. Data quality control plan used

# Australian Clinical Quality Registries should have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected

A quality assurance and data management processes policy has been drafted for the pilot phase. The quality assurance and data management processes are used to assess, maintain and improve the quality of data provided by hospitals. This will compliment and extend the many in-built logic checks of the AuSCR online tool. The quality assurance and data management processes will incorporate assessment of participation; completeness of patient ascertainment; accuracy of data provided to the registry; accuracy of data entry; coding and analysis; timeliness of data collection; and review of registry fields. In the pilot phase, the quality assurance and data management processes will be sent back to hospitals for verification prior to locking episodes. This information in the pilot phase will be used to improve the future phases. In addition, there will be a review of data extraction, programming and data transfer procedures including:

- Proportion of failed transmission or extractions
- Proportion of incomplete or aborted extractions
- Software programming problems identified
- Verifying that in-built data logic checks work correctly by performing a manual assessment on a subset of data and conducting cross verification

### 3.6.3. Data checks/audits routinely performed

Australian Clinical Quality Registry data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible.

This *Operating Principle* is essential. We have undertaken the following to ensure data checks and audits are routinely performed.

The pilot phase includes an internal evaluation to ensure processes result in accurate and complete data capture. Regular audit checks are incorporated into the quality plan to be performed by AuSCR staff using a random 10% case selection at the pilot sites (refer section 3.1.3). The audit data will be used to assess the amount of audit that may be required in future phases as part of an on-going quality assessment plan.

The AuSCR initiative will have a one-off formative evaluation during the pilot phase in order to have input at this early stage of development of the project to create a more successful program. It will be a comprehensive review within the first year of participating hospitals using the AuSCR online tool.

#### 3.6.4. Data management processes used

### Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks

Built-in logic checks and variable limits have been created to prevent inaccurate data being entered. Furthermore, in-built functions to identify duplicate entries have also been developed and the ability to merge multiple patient records has been established.

Additional quality checks will be run manually on a regular basis, which includes the development of quality assurance reports. These reports include verification of hospital data, missing data, outliers, merged records, follow-up data and opt-out consent requests received. These quality assurance reports are to be run as "programmed script files", that once developed, can be re-run at routine intervals as per the *Quality Assurance and Data Management processes* policy. Ongoing liaison between the AuSCR data management team and participating hospitals will be an integral part of maintaining high quality data.

Any missing data identified in these reports will be verified with hospital sites by the **Project Coordinator** to enable acquisition of the missing data within a set time period. The Project Coordinator will be responsible for liaising with hospitals about data discrepancies and will ensure the correct data are applied into the AuSCR online tool before locking episodes or merging patient records. All changes made by the Project Coordinator are to be logged in the AuSCR data administration file (database/Excel spreadsheet).

The **Project Managers** will oversee the QA processes and will respond to queries in relation to the QA processes. They are responsible for communicating QA issues to the Management and Steering Committees, and will resolves issues arising from such processes.

**Prof Craig Anderson**, Director, Neurological & Mental Health Division at The George Institute for International Health (TGI) and Chair of the AuSCR Management Committee, is ultimately responsible for the data management processes including documentation; audit trails; approved changes to the register or data tables; routine quality assurance practices and reporting; in-house statistical analyses of group data for annual reports; and data backup procedures undertaken while TGI is the data custodian.

Where important contact information and outcome data are missing, alternate sources for obtaining this information will be investigated. For example, establishing potential data linkages; use of web-services to import data from hospital patient administrative systems; or applications to the National Death Index. We have investigated the cost of data linkage re applications to the National Death Index. It has been estimated that it may cost a \$1000 per linkage. Therefore, we will only apply for these data once a year to reduce operational costs. This highlights an example of where quality control can prove costly and decisions about acceptable levels of missing data need to be made where resource limitations exist. As a new registry, AuSCR staff plans to find out what levels of missing data are acceptable in other similar registries to inform the extent of quality assurance and data management processes and plan for future operational costs.

### 3.6.5. Reports produced to specific timetable

# Australian Clinical Quality Registry reports should be produced according to a strict timeline and should be appropriately funded to enable this to occur

We have been able to meet this operating principle by investing in inbuilt "live" pre-specified reports downloadable from the AuSCR online tool, that are readily available to participating hospitals showing their own data with national comparisons. There is also a downloadable "raw" data export for ad hoc reporting and analyses of their own data. The data in these reports have not been verified or checked by the AuSCR office and are for internal hospital use only. The AuSCR office will provide a detailed annual report with verified data that is case mix-adjusted.

These "live" pre-specified reports include:

- Patient episode totals
- Patient Characteristics
- Age group profiles
- Summary age data
- Discharge destination
- Summary discharge data
- Length of stay
- Processes of hospital care
- Stroke type by gender
- Stroke type by age
- Patients per month.

### 3.6.6. Summary of Challenges and Recommendation for Data Quality

- Quality control can be resource intensive, but is essential in the early phase of new sites coming on board and in the establishment phase of a registry
- New registries should be encouraged to use a formative evaluation process to refine and inform their data quality verification and support methods during their initial 12 months of operation.

### **3.7.** Governance

The overall governance of the AuSCR initiative was well-organised, well-documented, efficiently managed with clearly defined roles and responsibilities, and met the goals and purpose of the register.

The mix of expertise within the stroke community and the collaboration of the consortium partners provided the support and environment to achieve the setting up of formal structures, identifying initial important policies and areas of risk at early stages.

### 3.7.1. Formal governance structures

# Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry

It is essential to have clear accountability and ensure transparency for governance in a register, in particular where it contains private and personal identifying information. In supporting the importance of this *Operating Principle*, a structure that included a separate Management Committee and Steering Committee was established for AuSCR. The roles of the two committees were clearly defined under the terms of reference for each committee. These committees represent the breadth stakeholders required for AuSCR to be successful and acceptable.

The **Management Committee** comprised seven members with representatives from the consortium partnership. This included two members from the National Stroke Research Institute (NSRI), two members from The George Institute for International Health (TGI), one member from the NSF (NSF) and two clinical specialists.

The Management Committee members between them had experience in data management, analysis, quality assurance, stroke research, rehabilitation and acute care applicable to setting up and maintaining a registry. All members of the Management Committee had clinical backgrounds in either medicine, nursing or allied health. The composition was chosen to ensure credibility and acceptance of the AuSCR initiative, because stroke is a disease requiring multi-disciplinary clinical management. Within the Management Committee, three members also held a position on the executive committee of the Stroke Society of Australia. The full Management Committee membership is shown in Appendix A.

The Management Committee was responsible for the day-to-day management of the project with oversight from the Steering Committee. Terms of reference, which adhered to the objectives of the project and the *Operating Principles*, were approved by the Steering Committee.

The Management Committee met by teleconference fortnightly. The frequency of the meetings was necessary to achieve the timelines of the pilot phase. Commitment of the members was evident in that a quorum (n=4, 50%) was achieved in 98% of the meetings.

A face-to-face meeting was held in Melbourne in June. The full Management Committee attended together with the Chair of the Steering Committee. The aim of this meeting was to review activities at this mid-point of the project and to discuss future planning and sustainability of the register. Meeting minutes were taken for all the Management Committee meetings with outstanding business carried forward to the next meeting. Minutes were provided to the Chair of the Steering Committee, included in monthly project reports to the Commission, and circulated to members of the Management Committee.

In review, the Management Committee has achieved and complied with the operating principles in the following areas:

- Administration of the register, management of budgets and staffing;
- Development of the online web-tool;
- Ensured data collection in the initial pilot hospitals was undertaken maintaining quality and effective processes;
- Dealt with issues in a timely manner;
- Reported and liaised with the Steering Committee to ensure issues were addressed and expertise of the members were utilised appropriately; and
- Provided timely reports and liaised with the funders.

There are some areas of the *Operating Principles* pertaining to governance that have not been fully tested because the registry has only been in operation for eleven (11) months, and data collection occurred at only four (4) sites. The *Operating Principles* not yet tested are:

- Setting up, coordinating and supporting the function of the task groups; and
- Undertaking a financial audit of the registry and providing it to the Steering Committee.

Four **specific task** groups have been identified by the Management Committee as necessary to support the Registry. The task groups include i) Research, ii) Clinical, Practice, User Feedback and Improvement, iii) Health Information and Policy, and iv) Complaints. To date, only one of these groups, the Research, Clinical Practice task group has been established.

Terms of reference for the Research task group have been drafted, however, there has not yet been a need to call a meeting. The Research task group is an independent group of members who are not currently involved in the AuSCR initiative. This prevents any conflict of interest when reviewing requests to access AuSCR data for research and/or publications. Plans are underway to establish the remaining three task groups after the pilot phase As outlined in the Quality of Care policies (section 3.7.2) various policies have been developed to support these future task groups. An important policy that has been developed to support governance and transparency, as well as to improve registry processes, is the *Complaints policy* which includes the *Complaint Action form*. As stated above, a Complaints task group will be established in the future.

The **Steering Committee** was established in December 2008 and had full membership since February 2009. The Steering Committee operates under a terms of reference developed in line with the objectives of the register and the *Operating Principles*, which have been approved by the members.

The *Operating Principles* recommend that membership of the Steering Committee should comprise:

- 1. Senior clinicians in a leadership role with the relevant speciality group;
- 2. Representation for the funding body and /or appropriate jurisdiction;
- 3. Senior staff from the Management Committee;
- 4. Community or consumer representatives;
- 5. Any group involved in providing care in the subject area; and
- 6. The major national professional organisations must be party to the clinical registry.

The current 19 members on the Steering Committee represent more than the above six categories, with some members relevant to more than one category of representation, due to their involvement in various state and national, health and stroke networks. The numbers in each category of representation are as follows:

- 1. Senior clinicians in a leadership role in the stroke area, (n=8);
- 2. Representation for the funding body and stroke network across Australia, (n=7);
- 3. The chair of the Management Committee and the Director of AuSCR, (n=2);
- 4. Consumer representative, (n=1);
- 5. Clinicians and allied health groups involved in providing care for stroke patients, (n=10);
- 6. Major national professional organisations including the consortium partners and other registries, (n=4); and
- 7. Health statistics and data management areas, (n=2).

The Chair of the Steering Committee is Professor Sandy Middleton, who is a senior, distinguished and independent clinician and researcher in the area of stroke. The full Steering Committee membership is shown in Appendix A.

The Steering Committee met four times through the year by teleconference and the final meeting for the pilot project was a face-to-face meeting in September (Table 8). This occurred in conjunction with the Stroke Society of Australasia's Annual Scientific Meeting in Cairns. Provisions to call additional meetings as required were in place but this was not necessary.

Date of meeting	Mode of meeting
11 December 2008	Teleconference
11 February 2009	Teleconference
22 April 2009	Teleconference
10 June 2009	Teleconference
8 September 2009	Face to Face

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Table 8	Steering	Committee	Meeting	Dates	and M	nde
I abic 0	Steering	committee	meeting	Daits	anu m	Juc

During the pilot project phase the Steering Committee members were committed in their involvement, and there were no meetings where a quorum (n=10, 50%) was not met.

Also in progressing matters, within the very tight time frame of the pilot phase, the members of the Steering Committee at the initial meeting agreed that for minor urgent matters the Chair of the Steering Committee was authorised to make decisions on behalf of the Steering Committee at her discretion.

In providing oversight to the Management Committee there were close and regular liaisons with the Chair of the Steering Committee, including provision of all Management Committee minutes.

Minutes were taken of all Steering Committee meetings and all issues identified were forwarded to the Management Committee for action. At the end of each meeting the Steering Committee identified any risk to timely completion of the project. These risks were documented and fed back to the Management Committee for action.

In review, the Steering Committee achieved compliance in the following areas:

- Provided oversight on the activities of the registry through the Management Committee;
- Reviewed the objectives of the register and the effectiveness of meeting the time lines;
- Provided feedback on policies to support the establishment of the register, including matters related to quality of care, data quality, data security, data access communication to consumers, publications of data and data management;
- Provided feedback and advice from the expertise within the membership to the management, organisation, development, processes and improvement of the register;
- Provided advice on the collection and interpretation of the data; and
- Provided advice on communication strategies and planning for sustainability in the future including funding opportunities.

Due to the short project timeline there are certain operating principles that the Steering Committee has not yet been able to test. However, the Steering Committee has put in place policies and working groups to address the following areas:

- Review and advise on outputs of the registry;
- Review and provide comments on reports published;
- Review all research and data requests; and
- Review and advise on publications arising from the register.

### 3.7.2. Quality of care policies developed

Australian Clinical Quality Registries must establish policies to manage a range of contingencies arising from the analysis of data from the registry, which includes formal plan ratified by the Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately.

The AuSCR Steering and Management Committees have identified the importance of timely feedback processes where data collected from individual sites may provide evidence of poor performance. Where results of individual sites are inconsistent with national standards or at least two standard deviations from the mean pooled estimate appropriate notification to the hospital and a review of data will be instigated. We cover these issues in the separate policies.

The following policies have been ratified by the Steering Committee:

- Data Security
- Complaints.

The following have been developed and currently being finalised for ratification by the Steering Committee:

- Quality Assurance and Data Management Processes
- Data Access
- Intellectual Property
- Consumer and Community Advisory Statement
- Publication
- Outlier Communication Plan.

The following policy is currently under review by the Management Committee.

• Data Custodian.

#### 3.7.3. Summary of Challenges and Recommendation for Governance

Challenges and recommendations for Steering and Management Committees include:

- Being a national register, finding the balance between including all appropriate stakeholders and maintaining a workable Steering Committee has been a challenge.
- The definition of *"representation from an appropriate jurisdiction"* was unclear. The Management and Steering Committee interpreted this to mean representation by state stroke clinical networks which are part of State government health departments.
- There were certain items under the specific roles of the Committees that were not able to be tested during the pilot phase as outlined above.
- The inclusion of funders in the Steering Committee membership could be a conflict of interest. If funders choose to be on the Steering Committee, they should be included as observers only. This was the approach adopted for AuSCR. We envisage that this is

different from having members such as clinical state networks or government bodies with a mandate for ensuring safety and quality in health care. Clear rules about decision-making when there are potential vested interested, e.g. from industry partners including private hospitals or health insurance agencies need to be agreed from the outset.

Challenges and recommendations regarding quality of care policies include:

- In the development of the policies there were very little pre-existing examples available in the public domain to assist a new registry. It would have been beneficial if suggested guidelines or generic policies were made available. It would also be helpful if a list of recommended policies had been provided.
- The heading "Addressing Quality of Care" in the *Operating Principles* is confusing, as it relates to the need to have policies, clinical governance and escalation processes which relate to quality of care within a project. It does not relate to recommendations for improvement of practices in hospitals. An improved description or use of a different heading would be clearer. For example, re-label "Reporting and feedback process requirements for local variations found in quality of care"

### **3.8.** Custodianship

### 3.8.1. *Custodianship explicitly declared*

### Custodianship of clinical register data needs to be made explicit in Contracts and/or Funding Agreements

The custodianship of the AuSCR data has been established formally with TGI for a period of three years. TGI is one of the consortium partners of the AuSCR initiative and a collaborative agreement has been signed between all the partners. Ethical clearance for the data custodianship has been approved till 2011.

Change of custodianship will require (a) Approval by the Steering Committee; and (b) Application to seek an amendment to the relevant ethics committees prior to a change in custodianship.

The criteria for the AuSCR data custodian is clearly outlined in the Data Custodian policy that is currently in review with the Management Committee.

The data custodian while having custodianship is also responsible for other IT applications related to the security and maintenance of the server, all related software applications for AuSCR online tool and help desk support.

Currently TGI IT provide support to all the operations of the AuSCR online tool including:

- The AuSCR generic email;
- The AuSCR web domain; and
- The maintenance of the Secure Socket Layer (SSL) within the AuSCR server.

### 3.8.2. Data access and reporting polices available

# Data access and reporting policies for Australian Clinical Quality Registries should be made available to persons wishing to use register data.

A policy development timetable was created and presented to the Steering Committee for approval to ensure no policies were omitted and to maintain transparency of the AuSCR processes and timelines. This timetable is also used to schedule the ratification of policies during the AuSCR pilot phase.

Several AuSCR policies have been developed and tabled at the Steering Committee meeting on 8 September 2009. Feedback from Steering Committee members have been received and are now being collated for ratification. These polices include the two policies relevant to this principle, i.e. the Data Access Policy and the Publication Policy.

#### 3.8.3. Third party access only via Steering Committee and IEC approval

#### Third parties wishing to access data and publish findings must seek approval from the Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data or contact with patients is sought

Third parties wishing to access AuSCR data and publish findings must seek approval from the Steering Committee and obtain relevant Institutional Ethics Committee (IEC) approval where identified or re-identifiable data or contact with patients is sought.

To facilitate this, the Steering Committee approved the establishment of a Research Task group to review all applications for third party access and providing detailed scientific review to the Steering Committee. Criteria for the Research Task group to use in assessing request for third party access has been developed (refer section 3.9.4).

The Research Task group comprise of members from with specific interest and expertise in epidemiology and clinical datasets in stroke and are not members of the AuSCR Management Committee or Steering Committee. This is an independent group of members to prevent any conflict of interest.

Terms of Reference for the Research Task group have been drafted and sent to the group for review and acceptance. The need for a meeting of the group has not been required as yet.

#### 3.8.4. Summary of Challenges and Recommendation for Custodianship

- The early involvement of the data custodian, provided assurance that they were able to accommodate the requirements of the register.
- Handover procedures and requirements could be developed to ensure proper and sufficient information is provided to the data custodian to operate and support the system.
- In the development of the AuSCR policies, it was apparent that there were very few preexisting policies available in the public domain, for registries. It could have reduced duplication of effort if the Commission coordinated the sharing of policy development amongst the projects testing the *Operating Principles*.

• This *Operating Principle* for third party access was not able to be tested in this pilot project, but a policy has been established to cover this principle.

### **3.9.** Ethics and Privacy

#### 3.9.1. Institutional Ethics Committee IEC approval gained

### Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry

IEC approval for the first stage of the AuSCR pilot phase consisting of four sites has been received. Our approach to use an opt-out consent model is consistent with the ethics approach recommended for the registries to avoid "cherry picking" cases for entry <sup>1</sup>. In presenting this model of consent in ethics applications, the timelines for our project were adjusted to accommodate a potentially longer period of debate by Human Research Ethics Committees (HREC). Even so, it took eight months to receive full ethical approval from NSW, longer than anticipated in the project timeline. To date no site specific approvals have been granted for NSW. The second stage of the pilot phase for IEC approvals are in progress, with submissions pending approvals.

IEC Approvals have been obtained from:

- NSW Population and Health Service HREC as a Lead Committee for nine NSW hospitals in June 2009.
- QLD Royal Brisbane and Women's Hospital HREC in May 2009, with Site Specific Application approval in June 2009.
- WA Sir Charles Gairdner Hospital HREC, which also simultaneously reviewed the application of Swan District Hospital, accepted the submission as a Low Risk application and approved with Site Specific Application for both the hospitals in March 2009.
- VIC Austin Health HREC with Site Specific Application in June 2009.

Ethics approvals received from all of the above committees have been granted for three years, with the exception of WA which was approved for five years.

Following approval *Amendment 1*, comprising revision of formats for the Project Protocol and reference list, Acute Data Collection Form and Follow-up Forms, Opt-Out Consent Protocol (version number added) and new *Patient contact letter post discharge* (for patients who missed receiving the "patient information sheet" while in hospital i.e. a 'missed patient' letter) was submitted to the following:

- NSW Population and Health Service HREC with approval received 17/09/2009
- QLD Royal Brisbane and Women's Hospital HREC with approval received 21/09/2009
- WA Sir Charles Gairdner Hospital HREC, with approval pending.

In VIC Austin Health Amendment 1 was submitted on 15/10/2009.

In the second stage of the pilot phase for IEC approvals submissions for the following are in progress:

- NSW Site Specific Application for Royal Prince Alfred Hospital has been submitted
- NSW Site Specific Application for three hospitals in the Hunter New England Area Health Service (John Hunter Hospital, Armidale Rural Referral Hospital and Tamworth Rural Referral Hospital) have been submitted.
- QLD –a full ethics committee application for Greenslopes Private Hospital is in progress.
- Preparations are in progress for submission at Royal North Shore Hospital, Wagga Wagga Base Hospital, and Shoalhaven Hospital.

The AuSCR team has worked hard to gain IEC approvals from the various States and hospitals. Only one IEC accepted a Low Risk application and granted approval.

A system that will ultimately allow the recognition by all jurisdictions of a review by any Human Research Ethics Committees (HREC) in any jurisdiction, is long overdue. The NHMRC's current review of the NEAF system within the Harmonisation of Multi-centre Ethical Review (HoMER) project should in the future allow for a nationally harmonised system of scientific and ethical review process involving multi-centred health research. The AuSCR team is currently assisting NHMRC with their HoMER project providing feedback on the disjointed NEAF process across the various state jurisdictions.

Some issues encountered include:

- Ethics committees in the various States have different requirements and have requested different changes to the main ethics documents (e.g. patient information sheets), and are reviewing the application at different levels in different States.
- Delays in ethics approvals are causing delays in our ability to commence data collection and hospital site testing of the online tool.
- Regular contact with the various HRECs, requesting a face-to-face interview were made but not accepted.
- Ethics requirements of individual States and hospitals have been a challenge, in particular with the requirements to use different forms, different attachments, and a necessity for each hospital to have a unique patient information sheet. This meant the need to track the different variation of one document.

The AuSCR team's strategy to overcome the various issues of IEC applications across the nations, is preparing ethics package templates for the different States with all appropriate documents and application information to ensure some consistency where possible. The goal of ethics packages is to allow site-directed ethics applications, with support from the AuSCR office for the second stage pilot phase applications.

### 3.9.2. Personnel familiar with and abide by relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian code for Responsible Conduct of Research

# Registry personnel should be familiar with and abide by the requirements set out in relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research

This is an important operating principle and is reinforced when quality disease registries, which collect personal identifying information, must be approved by IECs. This operating principle is also upheld when a registry is being managed by academic research institutes who have organisational policies consistent with these national statements.

The AuSCR staff are familiar with, and will at all times abide by the National Statement on Ethical Conduct in Human Research, the Australian Code for Responsible Conduct of Research, and the relevant privacy legislations in each Australian state and territory (refer section 3.5.2). Evidence of compliance with these national policies is reflected in the policies and procedures established for AuSCR.

The AuSCR staff, because they are not employed by the participating hospitals, have also been required to sign a covenant of confidentiality as required by hospital Ethics Committees (e.g. in WA).

# 3.9.3. Participants or the next of kin made aware of the collection of registered data and given the option to not participate

#### Participants or their next of kin should be made aware of the collection of register data. They should be provided with information about the Australian Clinical Quality Registry, the purpose to which their data will be put and provided with the option to not participate. This should be at no cost to the registry participant

The AuSCR pilot phase has put in place several strategies to test this operating principle. An information sheet for patient and relatives has been developed and approved by ethics committees in NSW, Queensland, Victoria and Western Australia. The information sheet is provided to all patients and/or their next of kin by the admitting clinician as soon as possible after admission to the ward. The clinician will also explain and clarify any questions to the patient and/or their next of kin, including that they maintain the option to not participate.

A freecall 1800 number and a generic email address has been set up for patients and relatives to contact the AuSCR office to seek further information or to request that some or all of their identifiable information is removed from the registry at any time. The AuSCR opt-out protocol, approved with the ethics applications in each state, is explained to hospital users at the training sessions and is detailed in the Hospital User Manual. The opt-out consent protocol clearly outlines that the information sheet will be given to all participants. Should any patient be missed (e.g. in the case of inpatient strokes which may not have come to the attention of the stroke service at a hospital) and have not received the patient information sheet, a "missed patient letter" has been developed for use by participating hospitals to send with the patient information sheet.

The opt-out protocol also outlines that patients have the choice of removing some or all of their data from the AuSCR online tool (Figure 4). The opt-out request options of all the AuSCR variables are detailed in the AuSCR online tool opt-out screen and in a paper base form for use by hospital and AuSCR office. When a request is made while the patient is still an inpatient at the hospital, the paper-based opt-out form is used and faxed by hospital staff to the AuSCR office (using the secure fax line) with a copy filed in the patient's medical record. Hospital staff can also enter the opt-out request information directly into the AuSCR online tool.

The opt-out process in the AuSCR online tool requires a two stage process, the first stage involves requesting removal of data items, and the second involves verification by the Project Administrator or Super-user that the opt-out request is accurate. In this way, there is a clear audit trail that also minimises the risk of deleting variables that were not requested to be removed by the patient. The AuSCR Project Administrator or Super-user verifies these variables against the paper-based request faxed from the hospital before opting out these data.

At follow-up the patient is given an opportunity to opt-out. The telephone follow-up script includes giving the option for patient to opt-out before proceeding with the interview. In postal follow-up the patient information sheet is included with the postal questionnaire to remind them of the option to opt-out.

Currently, with over 200 cases entered there has been no request for opt-out from hospitals, patients or next of kin.

Select All	Do not con	tact for follow-up		
First Name	Last Name	Date of Birth	Medicare No	Title
Gender	Phone Number	Mobile Number	Aboriginal/Torres St. Islander	Country of Birth
Language Spoken	Interpreter Needed	-		
Address/Mailing	Address/Address Type	Address/Street	Address/Suburb	Address/State
Address/Postcode	Address/Country	-		
Contacts/First Name	Contacts/Last Name	Contacts/Phone Number	Contacts/Mobile	Contacts/Relationship
Contacts/Address Type	Contacts/Address	Contacts/Suburb	Contacts/State	Contacts/Postcode
Contacts/Country	-			
Date of arrival to emergency department	Time of arrival to emergency department	Onset of stroke date	Onset of stroke	Date of admission to hospital
Was the patient transferred from another hospital?	Did this stroke occur while the patient was in hospital?	Was the patient able to walk independently on admission?	Is there documented evidence of a previous stroke?	Was the patient treated in a Stroke Unit at any time during their stay?
Type of stroke	Did the patient receive Intravenous Thrombolysis?	Cause of stroke		_
ICD10 code -	ICD10 code -	ICD10 code -	ICD10 code -	
Diagnosis	Medical Condition	Complications	Procedures	F
Date of discharge	Date of discharge	Discharge destination/mode	Discharge on Antihypertensive agent	Is there evidence that a care plan outlining post discharge care

Figure 4 Screenshot for Opt-out request options within the AuSCR online tool for hospital users

### 3.9.4. IEC approval sought for projects using register's data

# Where projects are undertaken using register data, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity

AuSCR is a new registry therefore this aspect of the *Operating Principles* has not been fully tested. The AuSCR governance committees view this as an important operating principle which has been addressed in several ways.

A *Data Access* policy is being established which clearly outlines that data will not be relinquished to a third party without IEC approval for the specified project. It is anticipated that AuSCR data will be used as part of ongoing quality assurance activities within participating hospitals, and has been explicitly stated in the IEC applications and information sheets submitted to date. For all other projects which seek to use AuSCR data, a separate IEC approval will be sought for any further research projects. An independent and multi-disciplinary research sub-committee has been established (AuSCR Research Task Group) and has its own 'Terms of Reference'. Members of this committee have been drawn from different Australian States. The aim of this committee is to ensure appropriate use of the AuSCR data for high quality research projects and ensure the protection of privileged personal data located on the registry.

The **Research Task Group** will be responsible for reviewing all applications to use AuSCR data against the following 10 criteria:

#### Criteria used to assess request for AuSCR data:

- 1. Appropriate background and rationale for project
- 2. Appropriate study design
- 3. Feasible timelines
- 4. Appropriate level of statistical support
- 5. Appropriate funding
- 6. Study conforms to the original consent statement
- 7. Clear level of protection of personal information
- 8. Ethics approval granted
- 9. Clear reporting process of results
- 10. Overall recommendation for data release, including any recommendations to the applicants

#### 3.9.5. Summary of Challenges and Recommendation for Ethics & Privacy

- Inconsistent requirements across States, Area Health Departments and hospitals for IEC applications provided a challenge in the desire to have consistent documents for a national registry. For example, the patient information sheet had to be tailored to each individual hospital's requirements.
- Promotion and training for IECs is needed across the nation to ensure better understanding for registry applications in the future. The possibility of developing a separate section for clinical quality registries in the application form might be one solution.

- The ability to ensure that the patient information sheet is given to all eligible patients in the hospital has been a challenge. Until AuSCR is part of the hospital data system and the patient information sheet is part of the admission package, there will be instances when patients could be missed if admitted over the weekend, study coordinators or liaison nurses are on leave, or patients that may not have come to the attention of the stroke service team while in hospital.
- The principle regarding IEC approval sought for projects using registry data has not been fully tested due to the infancy of the AuSCR initiative.

### 3.10. Outputs

The *Operating Principles* for timely reporting are being tested using several approaches in the AuSCR online tool. Details of what we have put in place to ensure timely reporting of quality of care and health outcomes, as well as benchmarking are outlined below.

### 3.10.1. Quality of care assessed

# Data from Australian Clinical Quality Registries should be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.

In the AuSCR online tool, we have created inbuilt "live" pre-specified reports (refer section 3.6.5). These reports are readily available to participating hospitals providing their own data with national comparisons. In addition, hospitals can export all their own "raw" data for ad hoc reporting and analyses. This allows participating hospitals to use their own data for internal reporting and assessment of quality of care.

The AuSCR office will also provide a detailed annual report with verified outcome data that is case mix-adjusted to participating hospitals. Prior to finalization of the annual report, hospitals which appear to have poor performance will be followed up as per the **Outlier Communication** policy to allow the opportunity to review the factors which may have contributed to being an outlier or exception (e.g. if definitions for data collection have not been understood, etc).

### 3.10.2. No delay in reporting risk – adjustment outcome measures

# Australian Clinical Quality Registries must report without delay on risk-adjusted outcome analyses to institutions and clinicians

More comprehensive statistics will be used in annual reports whereby outcomes will be adjusted for case mix using multi-level statistical models. Descriptive statistics will be used to detail baseline characteristics. Group differences in factors such as gender and stroke type will be tested using Chi Square, Fisher's exact, and non-parametric tests as appropriate. Factors associated with survival during the first 3 months after stroke will be investigated using standard survival analysis methods as appropriate. Details of the statistical analysis plans are outlined in the *Quality Assurance and Data Management processes* policy. A more

comprehensive description will be provided by the appointed Data Manager (epidemiologist) as sufficient data become available in order to develop the annual report.

### 3.10.3. Formal peer review process prior to publication

# Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings

The AuSCR consortium supports this operating principle and are putting in place polices to adhere to this principle. A *Publication* policy outlining authorship guidelines and clarifying the process of peer review of AuSCR data has been drafted (unavailable for submission with this report). It is the intention of the AuSCR governance committees to ensure that, prior to release of information, data are assessed by a number of clinicians specialising in the area being reported. It will be the responsibility of the Steering Committee to monitor this process, using the relevant task groups for guidance.

The AuSCR consortium expects that researchers who have been granted access to Registry data will, to the best of their ability, ensure that their research results are placed in the public domain. The minimum requirement for authorship should accord with the principles outlined in the "Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication", established by the International Committee of Medical Journal Editors (ICMJE, <u>www.icmje.org</u>).

#### 3.10.4. Local database manager can perform adhoc analyses

# Local clinical register database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care.

Staff at both TGI and the NSRI can perform ad hoc analyses. This includes checking the reproducibility of automated results reports available in the AuSCR online tool to ensure these are accurate. A *Data Manager* and *IT Database Officer* at TGI will undertake these important processes during the pilot phase. Role designation has been outlined in the *Quality Assurance and Data Management processes* policy. In brief, the *Data Manager* will be responsible for running reports and performing statistical analyses using de-identified aggregated data. These processes will also be used to identify data issues and verify data. These processes are in addition to the routine reports undertaken by the *IT Data Officer*. All data analyses and reviews are to be performed on exported data and saved as separate files by the Data Manager. Any changes to data are to be logged in a separate *AuSCR data administration file* (e.g. database/Excel spreadsheet). Where approved data corrections are needed to the original AuSCR data tables, these are to be checked by the Data Manager following a data export.

### 3.10.5. Annual report publicly available

# Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings

Data collection commenced in June 2009. Because this is a new registry and many processes need to be established in a systematic way, the annual report format has not currently been developed. The Steering Committee has approved the annual report on a calendar year. This means data will be closed off at the end of the each year with an annual report published in June the following year.

Recognising the importance of this operating principle, the AuSCR consortium intends to make the annual report available to participating hospitals and to the public in June 2010. This will also be made available on partner organisation websites.

# 3.10.6. Documented procedures for reporting on quality of care, including addressing outliers or unexplained variance

# Australian Clinical Quality Registries must have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance

The AuSCR consortium have developed several polices to ensure this operating principle can be tested. We have found that we needed to address this issue in several policies including the *Quality Assurance and Data Management processes* policy, *Publication* policy and the *Outlier Communication* policy. These policies provide guidance for documenting and reporting quality of care, addressing outliers, acceptable data analysis methodologies and variance. In principle, where results of individual sites are inconsistent with national standards, or at least two standard deviations from the mean pooled estimate, appropriate notification to the hospital and a review of data will be implemented (refer section 3.6).

### 3.10.7. Summary of Challenges and Recommendation for Outputs

- The use of a Research Task Group to review proposed research projects will minimise any conflicts of interest and provide an avenue for an unbiased academic review.
- The *Operating Principles* may provide examples of compliant policies governing clinical quality registries to provide new registries with a basis from which to develop their own.

#### 3.11. Resources

# 3.11.1. Appropriate and sustainable funding for collection, quality control and reporting

### Australian Clinical Quality Registries should be appropriately funded to allow data collection, reporting and the institution of strong quality control procedures

In terms of testing this operating principle, it is unclear which formal and longer-term funding strategies are available to clinical quality registries. It appears that registries are funded in a

variety of ways and government support for registries is often inconsistent and negotiated on a one-by-one basis. AuSCR is a new registry that is still in the pilot phase, and so determining the scope of future operational costs and ongoing resources that will be needed is important. In our experience, new registries need sufficient start-up funding to allow the registry to reach steady-state operations and provide evidence of 'value' regarding relevance, impact and performance. If assessed too early, funding estimates may be inaccurate and the value of the registry may be compromised and not immediately recognisable. Therefore, a realistic start-up phase of 24 months is probably necessary. In particular, a sufficient lead time is required if achievement of the *Operating Principles and Technical Standards* for Australian Quality Clinical Registries are to be fully implemented and to also make the registry attractive as a 'good buy' to potential funders that will have competing priorities.

To date, the AuSCR consortium partners have addressed resourcing using a multi-focal approach while we remain in an immature phase. We are seeking to secure long-term funding beyond the pilot phase to cover on-going operational costs to make the registry sustainable. The business plan and applications for future funds is occurring in conjunction with this pilot phase to ensure the effort and momentum gathered in establishing the AuSCR initiative has been worthwhile. 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. Without the in-kind support of the NSF, follow-up telephone calls at 3 months would not be able to be funded within the current operating budget.

Long term sustainability of this initiative remains insecure, and of great concern to both the Steering and Management Committees. To this end, the Management committee, in consultation with the Steering Committee Chair, is currently seeking avenues for ongoing funding beyond November 2009. Such avenues include commercial and non-commercial sponsorship, competitive grants, and development awards.

Communication with state stroke networks and government departments on the benefits and potential of the AuSCR online tool has received positive feedback.

At this stage, we can confirm that we have commitment from the Stroke Society of Australasia for \$20,000 for 2 years, in-kind support commitment from the NSF to continue telephone follow-up for 2 years, and Allergan Australia has committed \$45,000 in 2010. Rehabilitation Studies Unit has committed in-kind salary support for Project Manager Lannin for a further 12 months (2010).

### 3.11.2. Summary of Challenges and Recommendation for Resources

- A joint initiative on behalf of clinical quality registries to secure long-term funding and act as a broker for such funding is recommended. It is envisaged that this is a role that the Australian Commission on Safety and Quality in Health Care may make an important contribution to in driving such an initiative.
- New registries should be provided with guidance regarding the costs of developing a business case for resourcing based on the work currently underway as part of the current tender process by the Australian Cardiac Procedures Registry.

3.12.	Table Summary of Operating Principles and Technical Standards items testing against the new Australian Stroke Clinical
	Registry

	Checklist Items	Tested	Comments	Recommendation
1.0	ATTRIBUTES			
1.1	Clear and precisely defined purpose	Yes	This operating principle ( <b>OP</b> ) was applied for stroke and used to avoid scope creep and engage partners in the process of establishing and implementing AuSCR.	None
1.2	Core data collection of essential elements	Yes	It was important for us to keep the data collection to a minimum number of variables and achieve sufficient scope to enable patient follow-up, assessment of the quality of hospital care for specific stroke patients (i.e. ischemic strokes) and all types of stroke and allow future data linkage. Despite our best efforts to provide a strict process for keeping variables to core essential items (which we achieved) we have been disappointed by our initial naïve belief that many data elements could be easily extracted from hospital patient administrative systems. We have found that the identifying data has been creating much grumbling from the clinical coal face because, at present, manual entry is required despite us providing technology solutions. Hospitals/Health departments require resources to integrate technology solutions with external databases/registries and this process in Australia is time consuming and not clear cut.	We have found that, at present, the number of variables needed to identify patients and enable the best chance of obtaining follow-up data (i.e. up to two other potential contacts plus the GP) is the major source of clinician burden re data collection for our registry. So far, we have been unsuccessful in being able to directly obtain these data (via an import template or use of a web service) which are routinely collected by hospitals in patient administration systems. This OP could highlight more strongly this particular pitfall which can compromise the number of variables about process of care or outcome that are collected and/or participation in the registry (even in registries where differences in quality can have a major impact on quality of life or cost p26). Furthermore, to ensure the greatest utility of a registry sufficient funds to establish technology solutions are needed. This is of particular importance for high frequency conditions which are not always managed in the one location in a hospital (such as stroke) thus the burden of manual data collection at some sites can be great even when the core data items for measuring quality of care are few e.g. <7.
1.3	Systematic data collection at all contributing sites	Yes	Paper-based data collection commenced 22 June 2009 and the web-tool data entry with many in-built logic checks commenced 3 August 2009. Training programs, user manuals and data dictionaries are used.	Advice/ examples from other registries re what is acceptable in a Clinical Quality registry for missing data and the best approaches to ensure & verify systematic collection might be helpful.

	Checklist Items	Tested	Comments	Recommendation
1.4	Epidemiologically sound data	Yes	Selection of our variables included using literature review and existing data sources to assess how reliably these potential variables could be collected. Data dictionaries, training and user manuals are used to ensure standardised definitions are used. Formative evaluation processes and random audits during this pilot project have been used to assess digressions from agreed definitions. This information has been used to further educate site personnel and improve the data dictionary and/or refine the web paper- based tools. The formative evaluation has been essential to our ongoing development and improvement in our data dictionary.	This is an important OP which could provide more detail re how to assess for epidemiological soundness. A particular mention of METeOR is made, however this resource did not cover the entire scope of variables in our registry. Advice could be incorporated re other sources for deciding on whether a variable is epidemiologically sound as part of this OP. New registries should be encouraged to undertake a formative evaluation process to refine and inform their data dictionary during their initial 12 months of operation.
1.5	Outcomes properly ascertained	Yes	Follow-up user manual and telephone script based on a defined protocol for randomly assigned attempted contacts via telephone or mail and when cross-over to the alternate method should occur.	New registries should trial different methods of follow-up data collection to ensure the most reliable method for achieving complete follow-up in an efficient way is used. Use of follow-up procedures should be stardardised and where telephone interviews are conducted telephone scripts developed to limit interviewer bias.
1.6	Burden and cost of collection considered	Yes	An import function has been developed for hospitals to use to upload data into the AuSCR online tool. A web-service is being developed for uploading routine variables to reduce data entry time and systematic data entry errors.	Automated data entry is desirable, but in reality very difficult to achieve. This is a process that collective effort and investment should be made across a number of registries.
1.7	Complete collection from entire eligible population	Yes	Evidence gathered as part of the formative evaluation has indicated that, currently, hospitals have focussed on collecting data from their own ward rather than for all stroke patients admitted to their hospital. This is mainly due to resource limitations. In one pilot site this is a particular problem since only about 60% of patients are being entered in AuSCR. Methods to routinely, efficiently and systematically capture outliers using technology solutions are being investigated. A 'missed patient' letter is also needed.	A sufficient pilot phase during the establishment of a new registry should be emphasised, especially where a particular patient group may be managed by a range of clinicians. Data linkage with State and Territory health services is the most efficient method for achieving this recommendation. This is a process that collective effort and lobbying should be made across a number of registries.

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	Checklist Items	Tested	Comments	Recommendation		
2.0	DATA COLLECTION					
2.1	No impact on provision of care and not a burden or cost to consumers	Yes	Our agreed variables are routinely collected in most hospital systems. The paper-based tool is made available where online access is not easily available. Feedback obtained on the burden of data collection as part of the formative evaluation, is being used to improve data collection processes for AuSCR. Issues re the burden of collection were raised in the relevant 'attributes' section above.	We agree with this principle and solutions to avoid manual abstraction are needed. However, these automated solutions can also be costly and time consuming to bring to fruition and this also could be highlighted in this section on p30. As outlined in 1.6, it is our recommendation that collective effort and investment should be made across a number of registries to develop an IT solution for automated data collection of administrative variables		
2.2	Data collection as close as possible to point of care	Yes	Each hospital has one or two nominated registry 'champions' to promote data collection as per the procedures manual. Among our 4 active pilot sites each has taken a different approach to when they collect data. Procedures for data collection can require accessing medical records up to three different times. Methods to streamline this process and ensure all eligible cases (including outliers admitted to other parts of the hospital) have sufficient data entered before the 3 month follow-up is due is a new mandate for AuSCR. The timing of ICD10 coding is variable and we have decided that this may be collected annually or every six months using an IT report generated from each hospital which is acceptable as these data are fixed.	New registries should be encouraged to use a formative evaluation process to refine and inform their training and support methods, policies and procedures and documents during their initial 12 months of operation. Further, new registries should consider including a process for assessing different methods of capturing data so that best (evidence based) methods can be promoted to new sites as they are enrolled. Furthermore, some variables which are fixed can be collected at routine intervals if this is a way of reducing the burden of collection for clinicians and they are not required for conducting follow-up assessments.		
2.3	Uniformly and easily accessible from data source	Yes	The paper-based tool is consistent with the on-line tool and is METeOR compliant where applicable. The formative evaluation has provided evidence that in our 4 active pilot sites the majority of variables for AuSCR can be directly abstracted from the medical record. Items such as ICD10 codes and Medicare number at some hospitals have to be obtained from patient administrative databases because they are not recorded in the paper-based medical record.			

	Checklist Items	Tested	Comments	Recommendation
2.4	Use existing data sources where possible	Yes	Training encourages hospital staff to access local patient administration systems to obtain most variables. We have, however, discovered variability between government jurisdictions with respect to collection of administrative data in existing data sources, for example collection of Indigenous status, Medicare number and country of birth differs across pilot sites.	This OP should identify that the administrative data collected differs across health jurisdictions and hospitals, and that hospital administrative data processes may not be METeOR compliant, and make recommendations for the coding of missing data within registry databases
2.5	Use record linkage where possible	No	AuSCR is a Level 2 registry. However, we have developed a web-service and an import data facility (see above comments). Currently, we are investigating implications of using a web-service with several of the pilot sites IT departments. Although there is much willingness, the reality is that resources are needed for such an initiative and quotes to date per site are between \$17k to \$25K. Sufficient time allowances for such activities are also needed given competing priorities for IT services and there is a risk that momentum might be lost while waiting for a fix.	In practice, this is difficult to achieve and many registries would face the same issues. Common methods should be established for basic demographic variables and economies of scale might be achieved through a collective effort among similar registry projects (e.g. those that target acute hospitals). Registry projects need to find ways of incorporating data linkage in their budgets where hospital/ health department resources to invest in such activities are limited or unclear.
3.0	DATA ELEMENTS			
3.1	Collect individually identifiable patient or subject information	Yes	AuSCR includes identifiable information for each of the reasons outlined in the OPs (p 39). Patients are identified using first name, last name, hospital record number and Medicare number. The potential to de-identify/re-identify cases is achieved by a unique person, patient and episode ID being automatically assigned for individual patients. Each hospital also has a unique ID code. Provision for use of unique individual health identifiers and individual health organisation identifiers as envisaged by NEHTA have also been created in the web-tool.	This operating principle is essential because it maximises the utility of data collection and allows assessment of the quality of data within a registry. We recommend that NEHTA provide a guidance paper on using the identifiers in future/new registries, including coding recommendations.

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	Checklist Items	Tested	Comments	Recommendation
3.2	Collect process of care information	Yes	PoC variables capture length of stay, time between stroke onset and admission; time between arrival to ED and admission; transfers from other hospitals; in-hospital strokes; use of intravenous thrombolysis; admission to stroke units; discharge status/ destination; discharged on antihypertensive; discharge with a care plan developed with the patient and/or family.	This OP is essential in the measurement of quality of care and for the assessment of evidence-practice gaps. Guidance and approaches to assist groups in deciding which processes measures should be collected may include direct evidence between process and outcome but also be based on other considerations such as the perspective of consumers. Despite limited evidence for an association with outcome our rigorous and consensus-based approach for selecting process measures included one element for <b>provision of a care plan at discharge</b> which was driven by consumer interests. Inclusion of such a variable may be valid if it is sensible; there has been limited research; and if acceptance of the registry is compromised if patients feel things that are important to them are not being measured. Furthermore, a registry may be used to provide evidence for such process measures re: association with outcome and whether such a variable can be reliably and systematically collected. Thus, the OP for including PoC measures that are within scope of a registry could be broadened.
3.3	Collect objective outcome information	Yes	At 3-6 months we determine survivor status; readmissions; recurrent stroke events; and living arrangements/place of residence. In addition, we use standardised quality of life assessment for adults (EuroQoI5D) and children (PedsQL). The paper-based and online tools are consistent and METeOR compliant where possible. 3 mth telephone and postal follow-up commenced 21/09.	This OP may benefit from listing examples of preferred outcomes, in particular those instances were it is not possible to use objective outcomes and registries must resort to assessing outcome using an independent person and use standardised and validated tools.
4.0	RISK ADJUSTMENTS	1	1	
4.1	Collect objective, reliable co-variants for risk adjustment	Yes	Variables that can be used for risk adjustment include Age, gender, Country of Birth, ATSI status; previous stroke; ability to walk on admission.	Trialling variables for risk adjustment as part of a pilot project could result in hospitals accepting it as an indication for inclusion in the future. Appropriate variable selection and communication methods are needed. Training should focus on ensuring appropriate understanding and data collection of risk adjustment variables, in addition to the better understood and accepted clinical outcome variables.

	Checklist Items	Tested	Comments	Recommendation		
5.0	DATA SECURITY					
5.1	Secure access controls and securing messaging	Yes	SSL being used and license obtained initially for 1 year. Passwords are MD5-encrypted. The web-tool uses JBoss/Apache application. Several levels of access via password control, time out functions, inability to use back browser function and store passwords are features of the AuSCR online tool.	An "easy-to-interpret" guide to sit alongside the Technical Standards may ensure that new registries adhere to all security guidelines.		
5.2	Data collection, storage and transmission complies with all relevant legislation and guidelines	Yes	Technology vendor meets ISO quality standards. They have been contracted to develop the AuSCR online tool ensuring compliance with the NEHTA standards. The data custodian adheres to requirements for the Australian Code for Responsible Conduct of Research. The AuSCR server is kept in a locked (swipe card) protected room with restricted staff (TGI) access. The AuSCR website is partitioned separately to the AuSCR online tool. AuSCR has established an audit trail for all data entry and access through the use of signed applications to receive log- in access, signed covenants of confidentiality for all AuSCR staff, and an explicit agreement undertaken with each site.	OP may provide examples of methods for ensuring an adequate audit trail in future releases, this may include example copies of such methods for centralised access to proven methods for meeting the OP.		
5.3	Policies comply with Part B: Technical standards – standards Map	Yes	<b>Data Security</b> policy which includes Security Technical Standards and Principles, Disaster Recovery and Backup Procedures has been approved by the Steering Committee.	OP may provide examples of compliant policies governing clinical quality registries to provide new registries with a basis from which to develop their own.		
6.0	DATA QUALITY					
6.1	Reports percentage of eligible patients recruited	Yes	Have developed 'live' online reports available from the online system to assist with this aspect of data quality.	Refer 1.7		

	Checklist Items	Tested	Comments	Recommendation
6.2	Data quality control plan used	Yes	Many inbuilt logic checks have been created to prevent incorrect or invalid data being entered. Data verification and cleaning, audit checks and site visits as per the <b>Quality</b> <b>Assurance and Data Management</b> policy is in progress. Sites receive training along with user manuals and data dictionaries. Site feedback is obtained immediately following training and one month after training to improve data quality and processes. User manuals are revised as necessary.	New registries should be encouraged to use a formative evaluation process to refine and inform their data quality verification and support methods during their initial 12 months of operation.
6.3	Data checks/audits routinely performed	Yes	These procedures are incorporated as part of the Quality Assurance and Data Management policy. Formative evaluation will be conducted in the first year to will determine how much routine auditing of data will be needed. Audit visit commenced in September. Sites receive regular missing data reports and direct feedback following audits.	
6.4	Data management processes used	Yes	<b>Quality Assurance and Data Management</b> policy is pending approval. The data management including verification and cleaning process has been initiated as part of the formative evaluation and will be used as an ongoing monthly process, after the first year. Weekly 'missing data' checking processes are in place and random audits have been used as part of data management cleaning processes.	Refer 2.2 & 6.2
6.5	Reports produced to specific timetable	Yes	Have developed 'live' online reports (n=11) available from the online system. Each hospital can also directly export all their own data. Annual reporting with risk-adjusted outcomes will be undertaken based on the calendar year.	Description of recommended or usual timelines for closing databases off, cleaning and analysing data and releasing annual reports should be reported in future OP. This information is useful for new registry initiatives in planning for such reporting, and for existing registries to align with

	Checklist Items	Tested	Comments	Recommendation		
7.0	GOVERNANCE					
7.1	Formal governance structures	Yes	We used the proposed governance model of having a Steering Committee and a Management Committee. We also recognised that the governance structure would benefit from separate specialist groups and established a Research Task Group during the pilot period. Regular meetings for the Management Committee occurred fortnightly or more frequently as required. The Steering Committee had four teleconferences and one face to face meeting.	The characteristics of who should be the Chair of the Steering Committee re "independence" could be more clearly defined. In some speciality areas it is can be difficult to identify a person of such senior repute who is not collaborating on projects with members of the Management Committee or Steering Committee that has sufficient knowledge of the area to act as Chair. We nominated a Chair who did not work for NSRI or TGI, (or our funders) interpreting 'independence' this way. Recommendations for frequency of meetings should indicate that new registries will meet more frequently than the monthly schedule outlined in the OP.		
7.2	Quality of care policies	Yes	Data Security and the Complaints policy have been ratified. Quality Assurance and Data Management processes, Data Access, Outlier Communication, Intellectual Property, Publication ,Consumer and Community Advisory Statement and Data Custodian policies have been tabled for ratification by the Steering Committee.	OP may provide examples of compliant policies governing clinical quality registries to provide new registries with a basis from which to develop their own. The heading "Addressing Quality of Care" in the <i>Operating</i> <i>Principles</i> is confusing, as it relates to the need to have policies, clinical governance and escalation processes which relate to quality of care within a project. It does not relate to recommendations for improvement of practices in hospitals. An improved description or use of a different heading would be clearer.		
8.0	CUSTODIANSHIP					
8.1	Custodianship explicitly declared	Yes	The George Institute for International Health will be the data custodian for a 3 year term. Change of custodianship will be according to the <b>Data Custodianship</b> policy currently pending approval by the Management Committee.	OP may provide examples of compliant policies governing clinical quality registries to provide new registries with a basis from which to develop their own.		
8.2	Data access and reporting polices available	Yes	<b>Data Access</b> policy which include third party access are currently pending approval by the Steering Committee.			

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	Checklist Items	Tested	Comments	Recommendation
8.3	Third party access only via Steering Committee and IEC approval	Yes	An independent Research Task group was established with Terms of Reference & objective assessment criteria developed. The Group reports to the Steering Committee via the Management Committee. The Group will operate in line with the <b>Data Access</b> policy (pending approval by the Steering Committee) which includes role of the Research Task group, third party access to data and IEC approvals.	OP may provide examples of compliant procedures governing the process of approval through Management and Steering Committees of the registry.
9.0	ETHICS AND PRIVA	СҮ		
9.1	IEC approval gained	Yes	<ul> <li>IEC applications submitted in NSW, QLD, VIC and WA.</li> <li>Approval obtained for :</li> <li>QLD Royal Brisbane and Women's Hospital</li> <li>WA low-risk review (2 hospitals)</li> <li>VIC Austin Health HREC</li> <li>The NSW lead HREC has provided approval. Site specific applications are in progress.</li> </ul>	Promotion and training for IEC is needed across the nation to ensure better understanding for registry applications in the future especially re use of 'opt-out' consent
9.2	Personnel familiar with and abide by relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian code for Responsible Conduct of Research	Yes	Academic institutions as collaborating partners on the establishment of the Registry ensured that all personnel were familiar with the privacy legislation, National Statement on Ethical Conduct of Research, and the Australian Code for Responsible Conduct of Research. The changing landscape for ethical review within Australia currently has resulted in variations in the ethical review and recommendations for the AuSCR project- at some sites it has undergone full review, while at others only Executive review as a low-risk project. While some States accept the NEAF, others require additional information to the NEAF, and each state has a unique NEAF form that negates the ability to use the consistent form at all sites/States and territories. Further, many HRECs undertaking the review found it difficult to apply existing standards for ethical conduct to the Registry project- in particular with respect to the issue of informed consent.	We strongly support the initiative of guidelines for ethical review of Clinical Quality Registry projects, and would go as far as to recommend that such guidelines become a National Statement ratified by the National Health and Medical Research Council. It would be helpful if there was better alignment of state legislation in this area with national privacy principles

	Checklist Items	Tested	Comments	Recommendation
9.3	Participants or the next of kin made aware of the collection of registered data and given the option to not participate	Yes	Patient Information Sheet for Opt-out consent protocol approved via IEC. A letter designed to contact <i>missed patients</i> has been submitted as an ethics amendment. Participants who do not recall receiving the information sheet at follow-up are sent another Patient Information Sheet and are also given the opportunity to opt-out at follow-up.	Guidelines for the application of opt-out consent within the hospital system would benefit participating hospital sites and ensure consistency in the approach taken by clinical quality registries.
9.4	IEC approval sought for projects using register's data	Partial	An independent Research Task group has been established with Terms of Reference and objective assessment criteria developed to assess all request for access to AuSCR data with recommendations to the Steering Committee. This is outlined in the <b>Data Access</b> policy currently pending approval by the Steering Committee. No projects have tested the policy and procedures put in place.	OP may provide examples of compliant procedures governing the process of approval through Management and Steering Committees of the registry.
10.0	OUTPUTS			
10.1	Quality of care assessed	Yes	Data collection has commenced at the four initial sites with 193 episodes recorded and 28 patients followed up as of the 12/10/2009. Hospital can use 'live reports' to obtain Quality of Care results for their patients and contrast these to the pool of patients entered in AuSCR from all sites.	This OP could highlight that for new registries more simple descriptive statistics can be provided until sufficient data have been included.
10.2	No delay in reporting risk – adjustment outcome measures	Yes	<b>Quality Assurance Data Management Processes</b> policy includes an outline of the statistical methods for case-mix adjustment. At this stage, the annual report will be used to provide timely risk adjusted outcome data. Sites are able to obtain live reports at anytime which are not risk adjusted. Sites can undertake their own analyses to investigate short-term outcomes (e.g. in hospital deaths/discharge destination) by exporting their data and analyzing it themselves.	Refer 6.5

	Checklist Items	Tested	Comments	Recommendation
10.3	Formal peer review process prior to publication	Partial	<b>Publication</b> policy currently pending approval by the Steering Committee. No projects/investigators have tested the policy and procedures put in place.	None
10.4	Local database manager can perform ad hoc analyses	Yes	The AuSCR online tool allows for the export of live data into EXCEL. The extent (scope) of data that can be downloaded depends on USER status. Individual AuSCR Hospital Administrators can download their own hospital data at anytime. However, hospital users are responsible for verifying any data download that has not been verified and cleaned by AuSCR staff. The data custodian IT staff and AuSCR epidemiologist are able to undertake adhoc analyses and run additional logic and data verification checks as outlined in the <b>Quality</b> <b>Assurance Data Management Processes</b> policy.	None
10.5	Annual report publicly available	No	Not applicable at this stage Decision made to base annual report on calendar year	Refer 6.5
10.6	Documented procedures for reporting on quality of care, including addressing outliers or unexplained variance	Yes	<b>Quality Assurance Data Management Processes</b> policy includes acceptable data analysis methodologies. Methods for assessing data, running routine data verification reports and procedures for contacting sites are outlined in these policies. An <b>Outlier Communication</b> policy was also established to address the recommendation of this OP.	Registries should be encouraged to have consistent measures to allow within country or international comparisons of quality.

	Checklist Items	Tested	Comments	Recommendation
11.0	RESOURCES			
11.1	Appropriate and sustainable funding for collection, quality control and reporting	Partial	Commitment from the Stroke Society of Australasia has been secured for \$20,000 for two years (2009/2010, 2010/2011) National Stroke Foundation is committed to providing in kind support for telephone follow-up for 2 years (until end of 2010) Allergan Australia has committed a further \$45,000 for 2010. Rehabilitation Studies Unit has committed in-kind support for Project Manager (NL) for a further 12 months (2010).	A joint initiative on behalf of clinical quality registries to secure long-term funding and act as a broker for such funding is recommended. New registries should be provided with guidance regarding the costs of developing a business case for resourcing. This could be based on the work currently underway as part of the current pilot project by the Australian Cardiac Procedures Registry group.

AuSCR: Australian Stroke Clinical Registry ; OP: Operating Principle; PoC: process of care

# 4. GENERAL COMMENTS ABOUT THE OPERATING PRINCIPLES AND TECHNICAL STANDARDS DOCUMENT

In establishing AuSCR to date, we have found the majority of the *Operating Principles and Technical Standards* to be relevant and able to be applied in practice. Because we are a new registry we have had the opportunity to test the *Operating Principles and Technical Standards* against a 'clean slate'. Nevertheless, at this stage of our project, not all principles and standards have been able to be fully tested. Important factors for our registry project have been costs associated with start-up, delays due to ethics amendments being needed and our ability to access and use NEHTA technology standards.

The largest cost we have incurred is for adhering to the *Technical Standards* in having chosen to have our online register developed by a commercial vendor. The costs are both financial, as well as resource-related with significant investment of the Project Managers' time in specifying the system requirements and coordinating and performing user acceptance testing. We are anticipating that this upfront and large investment has resulted in a system that is compliant with the *Technical Standards*, but also reflects the *Operating Principles* in providing transparency for the registry attributes. These attributes include reliable and efficient data collection that is user friendly and not a burden for hospital staff and patients; data elements that are reliable and valid for quality of care assessment in stroke; quality controls to reduce the need for audit and missing data; and is of value to clinicians in having functions to export, import and download summary reports.

Another resource intensive aspect was application to multiple ethics committees requesting an opt-out consent protocol. The system in Australia is not uniform across States which add to the burden of preparing IEC submissions for a national project. Moreover, ethics committees requested amendments to the opt-out process and patient information sheet that resulted in delays. This has also resulted in several AuSCR patient information sheets being approved, rather than a single national information sheet.

In relation to feedback on the *Operating Principles and Technical Standards* document<sup>1</sup> some general comments for ease of use have been recommended in detail. In addition, several of the principles overlap and it might improve clarity of these principles if some were combined. For example, principles related to attributes, data collection and data elements could be combined or streamlined to avoid duplication of information. In addition, security of messaging and security operational principles and *Technical Standards* could all be in one section with improved integration of these aspects. The *Operating Principles* could be improved with the provision of specific guidelines for securing opt-out models of consent for ethics applications. For example, we found the links to a good data dictionary within the document very helpful. Thus, the document could be further strengthened by having the same level of support for policies and procedures which underpin many *Operating Principles*.

With regards to the *Technical Standards*, it would be helpful if more of these were detailed rather than having to go to external documents to find information. We also found that web links to the NEHTA standards directed us to e-procurement documents which seem out of context for the aspects being referred to in that section of the document. See reference links on page 91 and 92 re Unique Healthcare Identifier; authentication, access control and secure messaging and clinical communication. Also, the standards document was not always clear where to find the information

from these web links and support from local academic departments were used to facilitate this e.g. where to access and how to use SNOMED-CT in relation to METeOR. Another problem we encountered was the NEHTA website search tool which does not allow long terms like Unique Healthcare Identifier to be inserted, as there is a character limit. This limitation made searching for key documents problematic. Therefore, more practical information about the technical standards within the document would improve use of these standards and increase efficiencies for people trying to apply the standards.

### 5. ADHERENCE TO OPERATING PRINCIPLES AND TECHNICAL STANDARDS

Overall, as a new registry, we have found that we have been able to follow and adhere to the *Operating Principles and Technical Standards*. Our main issues to date have been acceptance of the opt-out consent protocol by ethics committees and clinicians, an inability to attain a national approach to the Patient Information Sheet (with ethics committee requesting differing changes to the patient information sheet unique to each site), and working with a technology vendor unfamiliar with hospital-based health care. New issues include methods to capture all patients admitted to our participating hospitals with stroke and achieving the integration of technology solutions to reduce the burden of data collection. The majority of issues we have encountered have been overcome during this pilot project. Nevertheless, the impact of these issues created time delays for the pilot phase resulting in only partial testing of some of the *Operating Principles and Technical Standards*.

We have found that implementation of a new registry has been facilitated by having a local registry community that is very supportive and willing to share information, as well as the significant benefit from participating in the Monash Registry Special Interest Group. This has assisted the AuSCR team to apply and better understand the *Operating Principles and Technical Standards*, and seek expert advice in a timely manner from Special Interest Group colleagues. Interestingly, we also 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.

## 6. IMPLEMENTATION STATUS

This section of the report outlines the status of the current pilot phase against each operating principle and technical standard and achievement of the key milestones.

## 6.1. Detailed Task List and Status

Phase	Task	Commence	Finish	Status
Project In	itiation	03/11/08	31/12/08	
	Steering Committee Initiation	03/11/08	03/11/08	Completed
	Finalise Project Plan	03/11/08	28/11/08	Completed
	Develop Report Formats	03/11/08	31/12/08	Completed
	Recruit Project Officer	03/11/08	28/11/08	Completed
Establish	National Dataset	13/10/08	28/11/08	
	Identify / invite participants	13/10/08	24/10/08	Completed
	Review international / closed stroke datasets	13/10/08	29/10/08	Completed
	Conduct workshop	30/10/08	31/10/08	Completed
	Ratification of dataset	04/11/08	30/6/09	Completed
Developm	nent of Operational Procedures	01/12/08	31/1/09	
	Develop data collection sheet	01/12/08	31/1/09	Completed
	Develop Operations Manual	02/3/09	30/9/09	In Progress
	Develop Training Manual (pilot)	02/3/09	30/6/09	Completed
	Develop quality assurance plan and formative evaluation protocols	01/6/09	31/8/09	In Progress
Ethics Ap	provals	01/12/08	31/3/09	
	Application development	01/12/08	31/1/09	Completed
	Applications finalised for submission(s)	15/12/08	31/1/09	Completed
	First round ethics consideration	12/2/09	24/3/09	Completed
	Amendment to First round approvals	24/6/09	07/8/09	Completed
	Response(s) to Ethics Committees	23/3/09	25/5/09	Completed
	Second round ethics consideration	03/7/09	8/10/09	On Target
	First ethics approvals obtained for four sites plus NEAF in NSW	12/3/09	31/8/09	Completed
Database	& Technology Design & Build	10/12/08	02/3/09	
	Scoping, information and architecture design Sub-contractor to build	10/12/08	2/3/09	Completed
	Database & web entry tool build Sub-contractor to build	02/3/09	15/7/09	Phase 1 release completed
	Phase 1 development & testing (acute)	27/4/09	10/7/09	Completed
	Phase 2 development & testing: paeds follow- up	8/4/09	10/7/09	Completed

Phase	Task	Commence	Finish	Status
Database	& Technology Design & Build continued	10/12/08	02/3/09	
	Server and software procurement	2/4/09	30/4/09	Completed
	Formalisation of hosting agreements	30/3/09	15/4/09	Completed
	Set up and installation of server (at data custodian centre)	24/4/09	09/6/09	Completed
	Deployment to hosting server and technical handover	11/07/09	27/7/09	Completed
	Testing (technical after deployment)	22/7/09	27/7/09	Completed
	Steady state registry hosting	9/6/09	30/10/09	On-going
Data Entry Training		09/2/09	03/4/09	
	Develop training material	02/3/09	29/6/09	Completed
	Conduct training at initial sites	09/6/09	31/7/09	Completed
	Refine training	29/6/09	31/7/09	Completed
	Follow-up training	31/8/09	15/9/09	Completed
Registry (	Dperations	1/5/09	30/10/09	
	Data Dictionary	2/3/09	3/8/09	Completed
	Policy Development	9/3/09	31/8/09	Completed
	Presentation and Exhibit at Conference	3/8/09	9/9/09	Completed
	Registry launch	08/9/09	08/9/09	Completed
	Entry of first case: acute	22/6/09	22/6/09	Completed
	Entry of first case: follow- up	14/9/09	22/9/09	Completed
	Steady state registry operations	20/7/09	08/12/09	Completed
	Last new case eligible for inclusion in pilot reporting	30/9/09	30/9/09	On Target
	Test Migration of NSF 2007 stroke audit data into Registry	22/6/09	19/6/09	Completed
	3 months follow up procedure and implementation	14/9/09	31/12/09	In progress
	Formative Evaluation	20/7/09	30/10/09	In Progress
Pilot Rep	orting	28/11/08	30/10/09	
	Monthly status reports	28/11/08	30/9/09	Monthly Target
	Progress report #1	16/3/09	27/3/09	Completed
	Progress report #2	13/7/09	24/7/09	Completed
	Draft final report to Commission for comments	28/9/09	16/10/09	Completed
	Final Report preparation & submission	26/10/09	06/11/09	Completed

## 6.2. Key Milestones

Mi	lestone	Target Date	Note(s)
1	Minimum Dataset Agreed and Ratified	28 Nov 09	Management Committee ratified
2	Ethics approvals for initial sites	1 June 09	Multiple sites to be approved for inclusion by this date.
3	Data entry training commenced	18 June 09	Training scheduled for initial sites through to early July and on-going as new sites come on.
4	Database and web entry ready & first case entered	22 June 09	Located in secure data custodian centre Represents completion of technical development, and ethics processes for at least 1 hospital
5	Conferences and Registry launch	8 Sept 09	Presentation and exhibition at conference and Formal Launch at an Event and Media release
6	Up to 200 stroke cases entered	30 Sept 09	Based on 4 initial hospitals over the three months of data collection
7	Migration of past NSF 2007 stroke audit cases into Registry	22 June 09	To test impact of <i>Operating Principles</i> when past data is migrated into the AuSCR online tool
8	Formative Evaluation	20 August 09	Policies and Operational Procedures Training feedback form in use

NSRI: National Stroke Research Institute; TGI: The George Institute for International Health; NSF: National Stroke Foundation.

## 7. CONCLUDING COMMENTS

In the 11 months since the formal commencement of the AuSCR initiative much progress has been made to deliver the pilot project objectives. The main challenge for the AuSCR team has been working within short timeframes in order to maximise the testing of the *Operating Principles and Technical Standards*. This is because delays were created that were beyond the control of the AuSCR team (e.g. ethics committees and technology vendor), but in turn, demonstrate the practical issues in developing a new registry that is aligned with the *Operating Principles and Technical Standards* for a Level 2 registry. The demonstrated enthusiasm and commitment from the various State clinical networks for the establishment of the AuSCR initiative has greatly assisted the AuSCR team in meeting the timeframes for the pilot phase.

Realising the concept of the AuSCR initiative, as a new national clinical quality registry for stroke, has been well embraced by the stroke networks and the participating hospitals. This has assisted in the initial successful implementation of the AuSCR online tool in the pilot hospitals with the benefit of a stroke database, 'live' reports and national comparisons available to the hospitals as required. This coupled with the prospective three month outcome data makes AuSCR a unique tool for stroke clinicians, hospital administrators, and researchers.

The AuSCR initiative is designed to national standards and will meet the needs of the clinical community. As the *only new registry* involved in this larger project for the Commission it was ambitious because the short pilot project timeframe. In particular, since every aspect of the registry needed to be developed. Nevertheless, this Level 2 registry has provided sufficient detail about the *Operating Principles and Technical Standards* to meet the overarching objectives of the Australian Commission for Safety and Quality in Health Care. Use of the *Operating Principles and Technical Standards* document was invaluable in this process and clearly mapped out the essential requirements for establishing a registry to the highest standards. Moreover, the relevance and impact of AuSCR will be more meaningful since it has been developed to these national principles and standards, maximising the future utility of the data e.g. data linkage. A lasting legacy of the pilot project is a national registry for stroke which will provide essential data about the quality of stroke care (*Australia's second leading cause of death and largest cause of adult disability*) that has not been available before in Australia.

## 8. REFERENCES

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## 9. APPENDICES

## **APPENDIX** A

### STAKEHOLDERS ENGAGED IN THE ESTABLISHMENT OF AuSCR

The AuSCR initiative is a multi-disciplinary collaborative project undertaken by two leading academic research institutes: the National Stroke Research Institute and TGI; and two leading NGOs: the NSF and the Stroke Society of Australasia. Together, these organisations represent the broader clinical and scientific community. Significant buy-in from clinicians and professional associations has occurred via the Australian Stroke Coalition, a network of clinicians and professional associations formed to link organisations involved in supporting the development and delivery of high quality stroke services.

The Steering Committee has 19 members which represent a range of stakeholders from across Australia. Members include representatives from rehabilitation, state-based stroke clinical networks, health data management, allied health, physicians, nursing and paediatric health. A consumer representative is on the Steering Committee and regular reviews by consumers of the AuSCR documents and procedures are also initiated through the NSF. As this pilot testing phase reaches completion, consideration of the future membership for the Steering Committee was addressed as part of the face to face meeting in September, where expression of interest to remain was invited from the existing members.

Stakeholder	Service	Involvement	Nominated Delegate
NSRI & TGI	Sponsor	Financial responsibility for outcomes Administration and management	G. Donnan & C. Anderson
TGI	Information Technology (IT) Program Manager	Resolve issues Provide IT resources Data custodianship	C. Anderson
NSF	Follow-telephone call management to collect registered patient outcome data at 3 months	Employ and train staff to conduct follow-up telephone calls in line with project protocol.	C. Price
SSA and NSF	Communication	Use established networks to obtain feedback or communicate information about the AuSCR initiative to clinicians; government and nongovernment organizations.	A. Thrift and C. Price

## MAIN RESPONSIBILITIES OF THE PARTNER ORGANISATIONS

Steering Committee membership 2009					
Name	Position	Organisation	State		
Prof Sandy Middleton	AuSCR Steering Committee, Chair , Director, Nursing Research Institute	St Vincent and Mater Health Sydney	NSW		
	Director, National Centre for Clinical Outcomes Research (NaCCOR), Nursing and Midwifery, Australia ACU National	Australian catholic University Nursing Research Institute			
Prof Craig Anderson	Director, Neurological & Mental Health Division	The George Institute for International Health	NSW		
	Professor of Stroke Medicine and Clinical Neuroscience NMHBC Senior Principal Research Fellow	Affiliated with Royal Prince Alfred Hospital and The University of Sydney, Australia			
Associate Professor Julie Bernhardt	Director AVERT, Very Early Rehabilitation Research Program	National Stroke Research Institute	VIC		
Mr. Paul Bew	Research and Quality Officer Specialist Neurological Physiotherapist QLD Stroke Network CIPC	Internal Medicine Services The Prince Charles Hospital	QLD		
Prof Chris Bladin	Director, Eastern Melbourne Neurosciences Chairman, Division of Medicine Chair, DHS, Victorian Stroke Clinical Network Committee	Box Hill Hospital, (Monash University),	VIC		
Prof Geoff Donnan	Director, Florey Neuroscience Institutes Director, National Stroke Research Institute Professor of Neurology, University of Melbourge	Florey Neuroscience Institutes	VIC		
Dr David Dunbabin	Chairman, Tasmania Stroke Unit Network	Dept Geriatric Medicine Roval Hobart Hospital	TAS		
Ms Anne Gordon	Senior Occupational Therapist - Neuroscience Stroke Research Coordinator- Critical Care & Neurosciences Theme	Murdoch Children's Research Institute The Royal Children's Hospital Melbourne	VIC		
Dr. Andrew Granger	Chair, WA Stroke Network	Osborne Park Hospital Stroke Rehabilitation Unit Perth	WA		
Dr. Niall Johnson		Australian Commission on Safety and Quality in Health Care	NSW		
Dr Erin Lalor	Chief Executive Officer	National Stroke Foundation	VIC		
Dr Andrew Lee	Neurologist NHMRC - NICS Fellow Neurologist	Flinders Comprehensive Stroke Centre	SA		
	Stroke Physician	Flinders Medical Centre			
Ms Sandra Martyn	Director Statistical Standards	Health Statistics Centre Queensland Health	QLD		
Prof John McNeil	Head, Department of Epidemiology and Preventive Medicine	Monash University	VIC		

	Steering committee membership 2005 com					
Name	Position	Organisation	State			
Dr Michael Pollack	Director, Rehabilitation Medicine Chairman, Hunter Stroke Service Chairman, GMCT NSW	John Hunter Hospital	NSW			
Mr. Mark Simcocks	Consumer Representative		VIC			
Ms. Frances Simmonds	Manager, Australasian Rehabilitation Outcomes Centre (AROC)	Centre for Health Service Development	NSW			
		University of Wollongong				
Mr Peter Somerford	Acting Principal Epidemiologist	Public Health Division of the WA Health Department	WA			
Associate Professor	President Stroke Society of Australia	Stroke Society of Australia	VIC			
Mandy Thrift	NHMRC Senior Research Fellow	Baker IDI Heart and Diabetes				
	Head, Stroke Epidemiology	Institute				
	Adjunct Associate Professor, Monash University					

## Steering Committee membership 2009 cont

### MANAGEMENT COMMITTEE MEMBERSHIP

Prof Craig Anderson The George Institute for International Health	Chair
Prof Geoffrey Donnan National Stroke Research Institute	pilot project Director
Dr Dominique Cadilhac National Stroke Research Institute	project manager
Dr Natasha Lannin Rehabilitation Studies Unit, The University of Sydney	project manager
A/Prof Steven Faux Director, Sacred Heart Rehabilitation Services & St Vinc St Vincent's Hospital, Darlinghurst	cent's Pain Service
Mr Chris Price Divisional Director Stroke Services, National Stroke For	indation

A/Prof Chris Levi Director, Brain & Mental Health Priority Research Centre & Acute Stroke Services John Hunter Hospital

### **APPENDIX B**

## AUSCR Feedback: TRAINING

Date:

User/Participant:

Site:

Compiled by:

AuSCR TRAINING ACTIVITY ISSUE RAISED COMMENTS

Webtool

User Guide

Data Dictionary

General

Other:

## **APPENDIX C**

## AuSCR Hospital Training Initial Feedback

#### Method

Feedback was obtained from hospital staff within one week following AuSCR hospital training. The feedback involved an open-ended discussion about the AuSCR webtool, hospital user guide, data dictionary and the Registry in general.

#### AuSCR Webtool Feedback

The AuSCR webtool feedback that was received includes questions asked by staff members, problems encountered, suggested changes and comments particularly in relation to the import functionality of the webtool

#### Webtool Questions, Problems and Suggested Changes

- One person asked whether the Medicare number could be added later in the web-tool e.g. personal details page because this is not always in the medical record, but is required to register a 'new' patient in AuSCR and new patient details can't be modified in the web-tool without have to recreate a new person.
- The issue of medical record number being alpha numerical in one State was raised and therefore a need to adjust the database accordingly was identified.
- One person commented that home telephone is a required field but a few patients only have mobile numbers. This identified an error in the paper-based form as telephone number is not a required field.
- One person felt that the discharge destination did not offer sufficient options to cover all of the possible combinations and suggested a combination of boxes along the following lines:

Box 1. Discharge Destination (Home / Nursing / Death / Transfer Hospital (Acute) / Transfer Subacute Facility / Other) Box 2. Rehabilitation Status (Inpatient / Outpatient / NA / Other)

#### Webtool Import Function

• Hospital staff were interested in using the Excel import function to avoid duplication of information from existing systems. One person was keen to test it and stated that they would like to help with any information. Another was also keen, but expressed concern about the compatibility of the systems.

#### **Other Webtool Comments and Observations**

- One person commented that they were not sure how to cope with the volume of data entry.
- At one hospital the trainer observed that the staff member needed assistance with Excel functions.
- The trainer commented that the staff at one hospital "received the database well"

#### **Other Webtool Comments and Observations (continued)**

• A staff member at another hospital provided the following positive feedback:

"From what I saw on Friday I think you have a very solid platform and I think you've got all of the fundamentals right."

• One person identified that there is a new but increasing trend within hospitals for using PDAs or iPhone style devices to provide clinicians with mobile access to data systems (e.g. Ward Admission information). They were interested to know whether any consideration had been given to mobile data entry.

#### Hospital User Manual Feedback

When asked about the hospital user manual:

- One person commented that they would prefer issues to be highlighted rather than going through the whole database.
- One person mentioned that their hospital collects details for Next of Kin and Local Contact. It was suggested that they use the equivalent fields in the AuSCR database, ie Emergency contact for Next of Kin details and Alternate Contact for Local Contact details.

Other Hospital User Manual feedback included the following questions/problems with the Emergency Department fields:

- When a patient is transferred from another hospital whether they record the date/time of arrival to the emergency department or the presentation to the transferring hospital's Emergency Department.
- As elective patients do not go through the Emergency Department there will be an issue with Emergency Department being a mandatory field.

#### **Data Dictionary Feedback**

#### Times

• One person made the following suggestion related to recording times for particular responses eg middle of the night, breakfast etc:

"I'd suggest that this should probably be handled on the server side rather than the data entry side. The main problem which I believe will occur is one person will put breakfast to be 07:00 while another will be 08:00 regardless of what the rules say. A solution would be to have a predefined set of constants e.g. "Breakfast" (as per the table in the manual) which on the server side is translated to be 08:00 before being committed to the database. The special time can be support then by adding an additional column to flag if it is a special time. (i.e. to translate 08:00, back to Breakfast)."

#### Type of Stroke

• One person queried whether venous infarct is included.

#### Cause of Stroke

• One person stated that there is a delay of up to 1-2 weeks after discharge in receiving the cause of stroke.

#### Discharge Destination/Mode

- Staff at one hospital commented that they do not have a clear discharge process between acute and rehabilitation and recognised that they need to develop a process to separate the two so that isolated acute capture is possible.
- One person queried the recording of patients who are discharged and managed at home but still a hospital patient for 6-8 weeks before discharge to community services. They were advised to use Other for Rehabilitation in the home program (RITH) and Hospital in the Home (HITH).

#### **Patient Information Sheet**

Some hospital staff were unsure of how to distribute the Patient Information Sheet to ensure all stroke patients across the different wards received it. One person mentioned that they would use the Stroke Liaison Nurse to cover the whole hospital.

Several people raised issues relating to how to capture patients, whether they should be keeping a record when notification is given to patients and how to do so. The suggestion of using an AuSCR checklist sticker was well received.

Specific questions relating to the Patient Information Sheet include the following:

- If the patient died before the Patient Information Sheet is given, what do I do?
- In cases of aphasia where the patient is estranged from their families, who should be given the information sheet in this instance?
- Should I be documenting in the medical record that I spoke/gave AuSCR information to the patient/ relative?

#### **Retrospective Cases**

- When asked about using a template letter for recording retrospective cases, some staff were not keen due to the extra workload but stated that they would consider doing so.
- Staff were generally happy to use a template letter for outliers or missed cases.

#### ICD Coding

- It was reported that at one site there would be a delay in ICD coding of 3 months and there would need to be a procedure established for AuSCR to ensure collection when they are ready.
- Another hospital commented that the ICD coding is currently done by the Resident on the ward because they do not trust the codes of the inexperienced coder.

#### **General Comments**

• One person made the following comment:

"I think the most valuable piece of information from this dataset will be the 3 month follow-up and as such this is what the reporting in the short term should probably focus on."

## **APPENDIX D**

## AuSCR Hospital Training One Month Feedback

#### Method

Feedback was obtained from hospital staff one month following AuSCR hospital training. The feedback involved an open-ended telephone discussion about the AuSCR webtool, Hospital User Manual, data dictionary and the registry in general. An interview template was used to ensure each of these aspects was discussed. These interviews were undertaken prior to the site visit as part of the formative evaluation.

#### Webtool

The AuSCR webtool feedback that was received included questions, problems encountered, suggested changes and the import functionality of the webtool

- In one hospital they felt it was difficult to obtain their username and password because it was not an automated system.
- The Webtool was found to be slow in one hospital
- Computer problems had also caused one hospital to be unable to access the website.
- Computer access was identified as an issue in one hospital where it was felt that there was always competition to get a seat or computer where the medical records are.
- One person needed clarification regarding locking and saving data.
- The facility to import data was reported as having the potential to complicate things according to one consultant and therefore not something that they wanted to do.
- Several comments were made regarding the database being simple and easy to use, with one respondent commenting that it "...doesn't take long to input the data per patient".

#### Hospital User Manual

- Most reported that they had only used the user guide a couple of times or that they had not needed to use it but that it was well laid out and easy to use.
- One person commented that they needed another copy as someone else had taken the copy they had been given.

#### Data Dictionary

• Most reported that they had not had to use the data dictionary but that it was straightforward.

#### Training & Support

- The training was reported as being good, straightforward and easy to understand.
- One person also commented that the support from the AuSCR Office was sufficient.

#### Patient Information Sheet

- One person commented that the patient feedback was very positive.
- Some commented that they currently hand out the information sheet but that they want to change this so that other nurses and doctors (including the resident and registrar) hand it out.
- One person queried whether they needed to document in the medical record for each patient that has received an information sheet. They mentioned that they had been instructed not to but they were keeping a log so that they know who has received it.

• Most people mentioned that they needed the missed patient letter and that they were happy to send it out to patients they had missed or for patients with dysphasia or those estranged from their families.

#### Time Commitment

- Several comments were made regarding the registry being a large time commitment or being too labour intensive, particularly when only one person is involved and this must be add on to their current workload.
- One person mentioned that they were trying to get the doctors and nurses to collect the data on the ward and another commented that they were looking to employ another research nurse to help.
- One person commented that it would be hard for them to continue without commitment from their hospital and that they felt frustrated being the only person driving it.
- One person mentioned that they were unsure it would "fly without an injection of funding".
- The importance of linking systems to save time was also raised.

#### Paper-based forms

- Some people commented that they were unsure of what to do with the paper-based forms as they had not received instructions regarding what to do with them.
- Most were keeping them in a file with one commenting that they could not file them with the medical record as it is not a hospital based form.
- One person reported having problems with faxing the paper-based forms.
- One person commented that electronic access was easier than completing paper-based forms.

#### Processes

- Some issues with processes were identified, particularly in obtaining ICD10 codes as there is often a three month delay in coding.
- Issues with obtaining data about strokes on other (non-stroke) wards were also identified.
- One person also commented that access to the medical records can also be difficult as "...everyone wants them".

#### **Action Required**

- Ensure training emphasises the uses of and difference between saving an episode and completing and locking an episode.
- Need to check that all hospital users have access to the Hospital User Manual and Data Dictionary and distribute additional copies as necessary.
- Include information in the Hospital User Manual about whether hospitals need to keep a record of patients who have received the information sheet and suggestions of ways in which they can do so.
- Provide hospitals with information about storing paper-based forms.
- Ensure all hospitals are provided with a copy of the missed patient letter.
- Continually work with hospitals to develop and improve processes, particularly in relation to capturing all hospital stroke patients and in obtaining ICD10 codes.

#### **APPENDIX E**



## FEEDBACK FORM

Thank you for taking the time to review the AuSCR online tool. The AuSCR project will see the development and implementation of the first Australian Stroke Clinical Registry. The AuSCR system is currently in its pilot phase and we appreciate your feedback about how the online tool, and the registry in general, may contribute to improving care for patients with stroke admitted to a range of different hospitals.

*Please place a tick in the box for the most applicable response:* 

I am a (clinical background)	Nurse	Physio	от	Speech P	Other
	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
The AuSCR online tool is easy to use					
The AuSCR online tool is well designed					
Data collection for AuSCR is simple					
Data collection for AuSCR is insufficient					
The data collection for AuSCR will be too time consuming to be practicable					
I think AuSCR online will not be used properly					
I think the report downloading options in AuSCR are an advantage to clinicians					
I think the ability to export hospital data from AuSCR will encourage use					
I think the ability to import some data from hospital databases into AuSCR is essential					
I don't understand the opt-out consent for patients					
I think the paper-based forms would be easier to use than the online system					
The AuSCR registry will provide data that my hospital can use to improve clinical practice					
My hospital has access to AuSCR as part of the pilot project					
I wish my hospital had access to AuSCR					

Please provide comments to support your answers and additional comments for the AuSCR staff:

Thank you (please write on the back of this form if there is insufficient space)

## **APPENDIX F**

## **Expenditure Summary**

Expenditure as at October 2009		
Income Received*		\$486,000
Expenses	Budget Allocation	Oct-09
Staff Costs		
Project Manager (Dominique)	\$34,541	\$42,175
Project Manager (Natasha)	\$34,541	\$34,541
Project Officers (TGI)	\$76,777	\$90,488
Part time Project Officer (NSRI)	\$25,592	\$15,566
Part time Epidemiologist	\$15,942	\$0
Data Quality Manager	\$29,759	\$29,759
Training Costs		
Training of data collectors	\$18,750	\$9,375
Hospital site visits and support cost	\$46,662	\$23,473
Administration		
Administration Support, Office Costs and Promotion	\$52,900	\$52,900
Project Management Travel	\$20,000	\$14,639
Committee meetings	\$18,700	\$12,348
Minimum dataset workshop	\$35,303	\$35,303
Reporting		
Reporting in compliance with tender, ethics and database	\$19,000.00	\$19,000
Information Technology Costs		
SMS consulting	\$99,837	\$101,650
Servers and associated Software	\$25,339	\$12,080
Installation / setup costs – datacentre	\$2,515	\$2,515
Monthly hosting cost elements	\$6,452	\$1,759
Technical support	\$13,390	\$12,098
Total	\$576,000	\$509,669
Balance for period		-\$23,669

\*\$360,000 from ACS&QHC; funding from Allergan Australia to be carried over in 2010