



Quality Assurance and Data Management Processes

Version 3

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1.0 Preamble

The Quality Assurance (QA) Data Management processes are used to assess, maintain and improve the quality of data provided by hospitals which will complement and extend the many in-built logic checks of the AuSCR online system (refer to Standard Operating Procedures Manual/Hospital User Manual). However, additional quality data checks are required to be run manually on a regular basis. Experience from other clinical quality registries indicates that these quality assurance data verification processes are usually done monthly, quarterly or annually. Overall, the AuSCR Management Committee is responsible for ratifying routine QA data management processes for AuSCR. Where possible, automated quality assurance systems, based on the creation and implementation of standard data quality reports, should be established and used routinely from the data tables sitting behind AuSCR online.

2.0 Roles and responsibilities of AuSCR staff

The Data Custodian for AuSCR is ultimately responsible for ensuring QA data management processes are undertaken by appropriately skilled staff. These QA data management processes include: documentation; audit trails; approved changes to the registry or data tables; routine quality assurance practices and reporting; in-house statistical analyses of group data for annual reports; and, data backup procedures.

The Data Custodian should assign the following roles and responsibilities within the AuSCR infrastructure:

The **Registry Coordinator** will oversee the QA processes and respond to queries in relation to these processes for AuSCR. They are also responsible for communicating QA issues to the Data Custodian, Management and Steering Committees and will resolve issues arising from such processes within the available resources of the project.

A designated **IT Database Officer/s** is to maintain the AuSCR system and implement upgrades to the AuSCR website, web tool and data tables ensuring an appropriate audit trail and systems backups are made. The organisation responsible for hosting the AuSCR server and database is not expected to change or view hospital data directly. The exception is for the “New Episode” or “New Patient” (data items) that cannot be modified by hospital staff directly. Where possible, AuSCR staff will endeavour to provide technology solutions to support hospital data management and data quality processes.

The IT Department for the Data Custodial organisation will also be responsible for notification to AuSCR Office staff when the system will be down e.g. for systems/software updates to maintain database integrity.

A **Data Manager** (an experienced epidemiologist or senior research fellow) for AuSCR 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 accuracy, and are in addition to, and/or may incorporate, any routine reports created by the IT Database Officer. All data analyses and reviews are to be performed on exported data and saved as separate files by the Data Manager. If there is the appropriate skill mix, the roles of Database Officer and Database Manager may be shared as agreed with the Project Coordinator and Data Custodian.

The **Registry Coordinator/Data Manager** will be responsible for liaising with hospitals about data discrepancies and will ensure the correct data are applied in AuSCR before locking episodes or merging patient records. In some cases the AuSCR Office staff will need to unlock episodes in order for hospitals to edit incorrect data. All QA changes to the database made by the Registry Coordinator/Data Manager, or approved AuSCR Office staff, are to be logged in the AuSCR data administration file (database/Excel spreadsheet).

3.0 Standard quality assurance data management procedures

Data entered into AuSCR are obtained using two main processes. Hospital data are entered by trained staff from participating hospitals, and then AuSCR Office staff coordinate a patient follow-up survey among eligible patients 90+ days from stroke onset. Based on evidence derived from a nested sub-study conducted within the first 18 months of AuSCR data collection, postal questionnaires are the method of choice for collection of the AuSCR follow-up data. A modified Dillman protocol is used whereby, after two comprehensive attempts with use of a postal survey have failed, an attempt using telephone contacts is made to obtain these data. The aim of the follow-up survey is to obtain information as close as possible to 90 days after stroke onset, but no longer than 180 days after stroke.

Table 1 outlines a summary of QA data management processes for AuSCR and the main person responsible for each QA/reporting activity. A set of QA reports will be developed and routinely implemented by the AuSCR data management team. These quality assurance reports are run as “programmed script files” that can be re-run at routine intervals. The software used will be at the discretion of the Data Custodial organisation.

It is important that an audit trail is maintained for QA Data Management Processes. 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 undertaken by the Data Manager or IT Database Officer. Any changes are then to be checked by the Data Manager following a data export to ensure that all the correct fields were modified. For most tables used in AuSCR, the system stores information on the user who created it (CreatedBy) and the date it was created (CreatedDateTime). There is also a modified by (ModifiedBy) and modified date (ModifiedDateTime) field which stores the last user to update this record. These fields can be used for simple auditing. A database administrator can access these data through the database administration tool described in the technical notes provided by SMS Technology (June 2009). In brief, **pgAdmin III** is an administration tool which can be used by Database Administrators to perform custom queries, analysis and updates of the data collected from AuSCR.

3.1 Obtaining or reducing the amount of missing or inaccurate data

Hospital data

Missing acute care data, identified in routine QA reports, will be discussed with hospital sites through the Registry Coordinator or Data Manager. In instances where an AuSCR patient record within has been closed, and a hospital user requests for it to be reopened, it will be the responsibility of the Data Manager to do so in a timely manner.

Many hospitals transfer data for upload to the Data Manager. The Data Manager is responsible for backing up existing data, as well as undertaking cross-checks, probabilistic matching,

cleaning, validation and completeness checks of AuSCR data prior to upload. The Data Manager is also responsible for communicating with hospitals about the identified data discrepancies and will provide advice and support on the best approach to correct any errors, either prior to or following upload of data batch.

Patient follow-up survey data

Missing data from follow-up data collections will be addressed through a review of the responses received from telephone and mail data collection methods and procedures will be regularly reviewed to minimise missing data. Processes to minimise missing data will be initiated as part of staff training procedures, feedback to AuSCR users, instructions to patients and updates to the AuSCR Hospital User Manual. Where important contact information and outcome data are missing, alternative sources for obtaining this information will be investigated. For example: establishing potential data linkages with hospital administrative data; use of web-services to import data from hospital patient administrative systems; or applications to the National Death Index.

There are occasions where data returned via post on paper-based forms may have missing or conflicting responses. Where staff resources are available, staff will use telephone contact information to contact respondents and ask if they would be willing to provide a response to questions with missing information or clarify where the preferred response is not clear. This approach is to ensure that follow-up data are as complete as possible.

Table 1 Summary of Routine Quality Assurance Data Management Processes

AuSCR data	Quality Assurance Process	Responsibility
Hospital Data	All eligible cases have been registered	DM
<i>Verifications/missing data</i>	Stroke subtype and ICD10 codes are consistent	DM
	Dates of episodes follow in a chronological order	DM
	Arrival and admission dates follow in a chronological order	DM
	Missing data reports for non-mandatory fields, e.g. Medicare number	DM
	All fields that have a default value, e.g. 'unknown', which are not mandatory need to be verified if these are exceptionally high, i.e. >10%	DM
Processes of care and hospital discharge outcomes	Appropriate descriptive statistics are used to explore verified data.	DM
	Use of statistical models to adjust for differences in patient case mix (i.e. age, gender, ability to walk on admission and stroke type) will be undertaken before any assessment of hospital outcomes is made e.g. length of stay, deaths and discharge destination. Feedback about outliers will follow the Outlier/Special Cause Variation Communication Policy.	
Data discrepancies and Merging records	Probabilistic matching of cases for multiple episodes may pick up spelling mistakes or other data discrepancies in variables that cannot be edited by AuSCR users. These are to be verified and corrected before merging records and changing data tables.	DM
Follow-up Data	Missing data reports for non-mandatory fields e.g. hospitalisations, recurrent stroke, etc.	DM +/- ITDO
	All fields that have an 'unknown' as the default which are not mandatory will need to be verified if these are exceptionally high, i.e. >10%, and reported back to staff performing the Follow-up telephone assessments.	DM/ RC
	'Date to follow-up' reviewed to ensure that it is within the desired period (3 to 6 months post stroke).	DM
	Time between date of discharge and date data entered by hospital site.	DM
	Assessment of refusals (site of recruitment, % male, average age, etc).	DM/RC

AuSCR data	Quality Assurance Process	Responsibility
Health Outcomes	Use of statistical models to adjust for differences in patient case mix (i.e. age, gender, ability to walk on admission, stroke type) will be undertaken before any assessment of 3-6 month outcomes is made. The proportion of missing data is to be provided.	DM
Reports	Routine data analyses using verified data will be run for the preparation of reports for the Steering Committee & Management Committee, including the annual report. The proportion of missing data is to be provided.	DM
<i>Annual report</i>	The annual report to be created using cleaned and case-mix adjusted data by calendar year. The annual report is to be finalised within a six month timeframe.	MC/DM/PM/RC
<i>Education & liaison program</i>	Regular education and liaison about data collection will occur.	RC / PM
Administrative functions		
<i>Opt-out lists</i>	Tracking of patients and the data for opted out cases. Identification of sites where opt out rates are >1%	RC/DM DM
<i>Back-up & restore data</i>	Data back-up procedures are in place and restore functions tested	ITDO
<i>Automated QA reports</i>	Specification Creation of automated QA reports	DM/PM/MC ITDO/DM
<i>Data Analysis Files</i>	Files used for analysing data including log files created in statistical software are to be stored and backed-up according to the Data Custodian organisational policies and Good Clinical Research practice.	DM

PM: Project Managers; RC: Registry Coordinator; DM: Data Manager; ITDO: Information Technology Database Officer, MC: Management Committee.

3.2 Data verification processes

3.2.1 Hospital data

The quality of hospital data is the responsibility of the participating hospitals and the role of AuSCR Office and the Data Custodian is to support the accurate and complete capture of data to maintain confidence of both providers and recipients of the registry data.

3.2.1.1 Validation of number of strokes reported to AuSCR (to ensure all eligible cases are registered)

Complete registration of eligible cases is a fundamental principle for a disease registry. Verification of completeness of case registration will occur through regular reviews of ICD10 discharge codes for stroke from participating health services. The most expedient and low cost option for conducting these verification processes will be undertaken in conjunction with participating hospitals and, where feasible, also in cooperation with state-based health departments. Data from hospitals will be requested based on the calendar year corresponding with the AuSCR annual reporting cycles. The frequency of collection of these data will be based on site preferences (e.g. once a year, quarterly, etc) and episode data completion for the time period of interest

3.2.1.2 Verification of AuSCR data using site visits and random audits of medical records

Regular QA data management activities will be undertaken to determine the reliability of AuSCR data.

AuSCR Office staff will conduct pre-arranged hospital site visits to verify data quality. The process will involve direct discussions with staff, as well as a random audit of a set number of medical records to compare data entered in the AuSCR web tool. The data quality site visits are scheduled based on available resources for travel, with new sites prioritised over existing sites.

An initial audit of 10% of cases is conducted after the first 50 to 100 AuSCR registrants have been entered by a new site. After the first year of participation, a random audit of 2% to 5% of medical records will be conducted by AuSCR Office staff approximately every two years. The amount of random auditing, and the decision on which variables will be regularly audited, will be based on reviews of routine site data verification processes conducted by the Data Manager, level of participation in submitting regular data into AuSCR and the results of previous medical records audits. Cases for audit will be selected in the most recent time period (past 12 months since last audit) to reflect current data quality issues to be resolved with hospital staff.

These requirements for data verification processes have been included as part of the AuSCR Participation Agreement for hospitals.

3.2.1.3 Performance metrics used to assess the quality of AuSCR data

The QA processes to be measured, assessed and reported back to the Management Committee by AuSCR Office staff include formal and informal assessments as per the following:

a) Hospital participation

- Number of staff during site visits that could recall standards and definitions
- Direct participant feedback
- Telephone queries logged by AuSCR Office staff from hospitals
- Direct feedback elicited during routine site visits
- Surveys conducted at regular intervals to obtain feedback on use of AuSCR and ways that AuSCR could be improved

b) Review of key person(s) responsible for the process of hospital data collection for AuSCR

Regular assessments of the processes of data collection for AuSCR in participating hospitals will be conducted to understand and describe the different approaches to data collection and data entry by whom and where (e.g. clinical staff, ward clerks and health information managers). This information may be shared in newsletters and other forms of communication with hospitals so that there is shared learning and more effective methods advocated for where local circumstances are conducive to applying the effective approaches.

c) Completeness of patient ascertainment (refer 3.2.1.1 above)

d) Accuracy of data provided to the clinical registry

Data obtained from site audits of medical records will be used to provide a summary report on the following:

- Percentage of variables that were 95% complete
- Percentage of variables that accorded with the definitions within the data dictionary
- Percentage of variables that were accurately entered in the web-tool and/or recorded on the paper version of the acute episode datasheet

- Evidence that data cleaning has been undertaken where discrepancies were noted and clarified
- When data for annual reporting have been locked following requests for missing data to be completed (with a least two reminders to hospitals to provide these data by a set date) AuSCR Office will include in the annual report:
 - Percentage of variables that were 95% complete
 - Case ascertainment for each active hospital in that calendar year
 - Percentage of missing data from follow-up questionnaires
 - Response rate to follow-up questionnaire
 - Percentage of cases that opt-out of AuSCR

e) Timeliness of data collection

- Time between patient discharge and entry of hospital data will be assessed
- Time between stroke and patient follow-up
- Extent of cases that exceed the maximum 6 months post stroke onset follow-up eligibility due to delay in hospital data entry

f) Web-tool functions

- Reproducibility of results from 'live' reports automatically created in AuSCR will be checked at regular intervals by the data manager/ coordinator
- Review of data extraction, programming and data transfer procedures
- Proportion of failed transmissions or extractions
- Proportion of incomplete or aborted extractions
- Software programming problems identified
- Assessments of in-built data logic checks, to show that these are working correctly, by the AuSCR Data Manager performing a manual assessment on a subset of data and conducting cross verifications

g) Completeness and accuracy of data and follow-up

- Monitor completeness of data to assess the extent of cases not being included in follow-up process e.g. invalid or missing patient address
- Extent of discrepancies between follow-up data and returned paper based follow-up forms e.g. only completed follow-up entries are allocated "Completed", whereas the others are to be allocated different status
- Extent of completeness of follow-up data in relation to patient's health status

3.2.2 Follow-up data collection

All staff performing follow-up data collection will be required to routinely undertake training and review processes. AuSCR Project Managers/Coordinators will support knowledge transfer for new staff to enable the correct use of the AuSCR web-tool and paper-based forms as well as understanding of data dictionary variable terms and policies for data collection to ensure

systematic data collection and minimisation of missing data for non-mandatory fields. See also Sections 1 and 3.2.1.3.g.

3.2.3 Review of registry fields

Any proposed changes to the registry fields and the data dictionary or general operating policies need to be reviewed and ratified by the Management Committee. Major changes to the registry fields (e.g. addition of completely new variables) or changes to policy related to data collection and quality monitoring require a second level of review and ratification by the Steering Committee. Any changes to data collection must also be approved through the relevant ethical review processes. Ratification will be obtained before any changes are initiated by the Data Custodian and registry staff.

3.3 Outliers and exceptions

In making assessments of whether the quality of care differs across health services, it is important to make statistical adjustments for variation in patients' outcomes that are associated with differences in patient characteristics that are beyond the control of clinicians. Careful consideration of results at a hospital level, and seeking explanations for observed variances in individuals from sample data, is needed prior to any reporting of findings. In cases where clear exceptions exist, individuals may be excluded from sample data to ensure results are not misleading. Documentation of decisions to remove cases from samples for data analysis purposes is to be maintained by the Data Manager and, as required, reported in the annual reports or other documents used to feedback AuSCR data about hospital performance. In the event that an outlier hospital is identified, an agreed process endorsed by the AuSCR Management Committee will be followed, to ensure that the results are made known to hospital staff and are provided with support in understanding their data as part of investigating the potential cause of the variation.

Outliers and exceptions in AuSCR occur when analysis of data highlights variability in care which falls outside three standard deviations (SD) of the average value for a quality of care indicator or health outcome measure. For process of care and health outcome performance indicators, hospitals within the two SD limits are considered to be within 'normal variation'. Those outside the three SD limits are considered to have 'special cause variation'. This usually means (e.g. for processes of care) that hospitals above the three SD limits line may be considered as having 'exceptional performance', while those below the three SD limits line may be considered as having 'poor performance'. Care must be taken in interpreting these data when they are skewed because the control limits rely on the assumption that the distribution of data follows a bell curve. Both exceptional and underperformance should be investigated to ensure there is not an anomaly in the data. If non-parametric analyses are warranted, then results that fall outside the interquartile range for median values when adjustment for case-mix has been made will require investigation. Procedures to communicate directly with participating health services about 'outlier' results will follow the ***Outlier/Special Cause Variation Communication Policy***.

3.4 Statistical analyses of aggregated and de-identified data

“Data output must be regarded as credible by clinicians if it is to drive clinical practice change”².

All data to be used in reports or publications are to be cleaned and verified prior to analyses being undertaken. Routine, re-analysis of data will be undertaken by another independent and adequately qualified AuSCR consortium member to ensure findings are reproducible.

3.5 Education and liaison program

Ongoing liaison between the AuSCR data management team and participating hospitals will be an integral part of maintaining high quality data. The AuSCR Office liaison service will provide:

- Guidelines and updates for the data collection e.g. Hospital User Manual and Standard Operating Procedures Manual
- Information to hospital staff on how the data are collated and the importance of the quality and accuracy of the data provided to AuSCR e.g. quarterly newsletters and annual reports
- The opportunity for AuSCR staff and staff at participating hospitals to communicate on an informal level. This would include seminars for staff at which users of the data present their projects.

4.0 Summary

- Programmed routine data verification procedures are to be instigated by the Data Custodian or appropriate designee.
- All missing data are to be verified with hospital sites. This process may occur more frequently within the first six months of participation in AuSCR.
- Data management procedures are to be documented so that a record of changes is available to enable audit of AuSCR Quality Assurance processes and procedures.
- Any changes to the AuSCR registry system and policies are to be ratified by the Management and/or Steering Committee following an assessment of the impact of the change. All major changes are required to be reviewed by the Steering Committee.
- Regular opportunities for education and liaison with participating hospitals are integral to ensuring data quality is maintained in AuSCR.

5.0 References

1. Dehar M, Casswell S, Duignan P. Formative and process evaluation of health promotion and disease prevention programs. *Evaluation Review*. 1993;17:204-220
2. Australian Commission on Safety and Quality in Health Care. Operating principles and technical standards for Australian clinical quality registries. 2008:131