



Australian Stroke Clinical Registry

AuSCR DATA CUSTODIANSHIP POLICY

Version 2

Approved 17 October 2016

1.0 Scope of Data Custodianship Policy

The scope of this policy is currently limited to the responsibility for information collected and held within the AuSCR database which, since July 2016, has been incorporated within the Australian Stroke Data Tool (AuSDaT). The AuSCR database includes clinical information collected for hospital admissions, registered patients' follow-up data, information about opt-out consents and information about participating hospitals.

Out of Scope: This guideline is not a framework for information management and does not include detailed processes required to facilitate effective and secure information management.

These Data Custodianship guidelines adhere to the Australian Commission on Safety and Quality in Health Care's *Operating principles and technical standards for Australian clinical quality registries* (2008). It is recommended that they be read in conjunction with the following documents:

1. AuSCR Quality Assurance & Data Management Processes Policy
2. AuSCR Data Access Policy
3. AuSCR Data Security Policy
4. AuSCR Publication Policy

2.0 The Need for Data Custodianship

Full utilisation and protection of AuSCR data and data management processes cannot be achieved unless the underlying data are acquired, maintained and managed in a coordinated and tractable manner.

The AuSCR Consortium (The Florey Institute of Neuroscience and Mental Health [Stroke Division], The George Institute for Global Health, the Stroke Foundation and the Stroke Society of Australasia) uses a coordinated information management model based on the appointment of a Data Custodian.

The Data Custodian is an eligible agency that:

- is responsible for collecting and maintaining AuSCR data in an appropriate manner;
- has the capacity to make AuSCR data readily and publicly available;
- can appoint a suitable individual to ultimately be responsible for data custodianship by this agency; and
- can provide, or acquire, sufficient financial and human resources to maintain the AuSCR Office operations, as per agreed policies and contractual arrangements.

3.0 The Benefits of Data Custodianship

Custodianship is at the heart of information management because it establishes accountability for information, and identifies authoritative sources that give users a measure of consistency and certainty. In addition, custodianship is a means of:

- providing a trustee and standards bearer for information;
- eliminating unnecessary duplication in the collection and maintenance of information;
- managing information on behalf of the entire AuSCR consortium;
- providing a sound stroke information infrastructure; and
- facilitating the collection of information.

The AuSCR Data Custodian manages information as trustee in a partnership with national, state, regional and local AuSCR users to enable the integration of AuSCR information for the benefit of the entire community.

Custodial activities, including negotiations with other registries and users and development of information products, must take place for the betterment of the whole stroke community rather than any individual agency. The overriding philosophy in all these activities should be one of a trustee acting in

partnership for all consortium partners and AuSCR participants. Custodianship reinforces the concept of one individual/agency being ultimately responsible and accountable for the information that others might use. This gives users confidence in the level of integrity, timeliness, precision and completeness of information, and consequently in the quality and soundness of decisions made based on the information.

4.0 Data Custodianship Objectives

The objectives of data custodianship are to:

- Ensure data quality, protection, documentation and management including backup and storage of paper-based and administrative electronic information according to agreed registry policies and ethics approval requirements.
- Ensure the security, confidentiality, and privacy of data that is consistent with AuSCR Data Security Policy, incorporating Australian Information Commissioner Act 2010, the Federal Privacy Act 1988 (including the Australian Privacy Principles from March 2014) and State and Territory legislation.
- Ensure consistency of data management practices so that goals for integrated information can more readily be achieved.
- Maximise the value of investments in data collection and maintenance from a consortium perspective.
- Increase certainty regarding accountabilities for data.
- Minimise data duplication and enable integration.

5.0 Data Custodianship Principles

In pursuing the above objectives, the following six principles will act as a guide for assessing the appropriateness of possible actions.

Principle 1

Each dataset has a single, designated custodian, without exception.

The AuSCR dataset will always have a designated official custodian. Absence of custodianship implies absence of accountability, and therefore absence of any assurance of quality, integrity, availability and relevance of underlying data. In addition, there can be no more than one custodian for any given dataset. If a dataset had more than one custodian, it would admit the possibility of more than one source, multiple standards, and unclear accountability for the dataset.

Principle 2

The AuSCR Data Custodian will operate as a trustee on behalf of the AuSCR Steering and Management Committees and the entire community of data users.

Custodians do not “own” data within their care, but rather act in the interests of all data users. Custodial activity takes place for the betterment of the whole community, rather than any one agency, including the custodian’s own agency. The result is an emphasis upon collaboration, teamwork, cooperation and sharing.

Principle 3

The Data Custodian must adhere to the agreed standards for the datasets within their care on behalf of the AuSCR Steering and Management Committees and Consortium Partners.

The adherence to agreed standards for how data will be collected, described and used is the most important commitment that an agency makes in its role as custodian. Custodians must adhere to the data

management standards developed by the AuSCR Steering and Management Committees. These include standards for documentation, description, format, structure, classification, collection, accuracy, consistency, quality, access and retention of data and associated metadata.

Principle 4

Custodians are the authoritative source for datasets within their care.

The Data Custodian is the definitive source for information from or about the AuSCR dataset. This lessens confusion for users and overcomes accuracy and reliability problems that may be encountered when supposedly identical information is held separately by several agencies; where several agencies contribute information to a common database, or where information provided by different agencies is combined. The preferred data custodian should have a track record of large data set management, knowledge and/or experience of the Australian health care system. Priority may be given to organisations with relevant stroke linkages and those who have obtained or are working towards accreditation (see section below headed '*Guidelines for Identification of the Data Custodian.*')

Principle 5

The Data Custodian is accountable for the integrity of datasets within their care.

The success of the Data Custodian will be measured in terms of their ability to ensure continuous integrity of data – where integrity includes such things as relevance to user needs (currency, rigour, coverage, etc.); assurance of security, privacy, and quality of stored data compared to established standards; documentation and protection of data; and the ability to integrate and compare AuSCR data with other datasets. A custodian may delegate some of its custodial responsibilities to another agency, but cannot delegate their underlying accountability for the data. The custodian always remains accountable for the integrity of the dataset. As such, the custodian must ensure that its full responsibilities can still be fulfilled through any delegation of responsibilities.

Principle 6

The Data Custodian will ensure that datasets are available to qualified and approved users.

To derive the maximum benefit from data through data sharing, the custodian will ensure that datasets within their care are made available and are accessible to all qualified users. Such access will conform to access standards established for the AuSCR dataset and adhere to the AuSCR Data Access Policy. *Please refer to the AuSCR Data Access Policy for full details of the standards.*

6.0 Identification and Appointment of the AuSCR Data Custodian

The AuSCR Data Custodian is appointed for a term of up to five (5) years, with an option to request an extension for up to a further five years, to be approved by the AuSCR Management and Steering Committees. Subsequent to this first renewal, a submission will be required from the existing custodian for a further extension. At this time, applications may be sought from other interested and suitable agencies.

Whilst the guiding principles above refer to appropriate custodianship of the data, it is also imperative that any potential data custodian has the capacity to maintain, provide or acquire the necessary resources to manage AuSCR operations appropriately and sustain the functionality of the AuSCR Office. During any period of data custodianship, or transition to new data custodianship, the quality and continuity of service for users and the viability of the registry should not be compromised. Prior to the conclusion of the data custodial term, the guidelines and processes outlined below will be used to select the new data custodian.

Guidelines for Identification of the Data Custodian

Potential Data Custodians will be identified from agencies that best satisfy the following essential and desirable criteria:

Essential

- Has qualified capacity and a track record in overseeing and maintaining large datasets on behalf of multiple organisations and individuals
- An organisation with a strong research environment or an academic institute with experience in managing large data sets and data analysis. Data centre/management staff will not be under the employment of a participating hospital.
- Demonstrated ability to ensure the integrity of large datasets with adherence to agreed policies.
- Is able to maintain the register according to the six Data Custodian Principles outlined above and can make and implement appropriate decisions, with the AuSCR Management Committee, regarding the maintenance and operational processes of the registry within the available resources for the project.
- Recognising the challenges in maintaining the financial security of the AuSCR, the Data Custodian must demonstrate an ongoing commitment to attempting to securing funding to support the core processes of the AuSCR registry throughout their Custodianship including the 18 months prior to the end of their term in order to provide sufficient time to seek an alternative Custodian should on-going funding not be forthcoming for the incumbent custodian.
- Has knowledge and/or experience of the Australian health care system, and appropriate resources and infrastructure, including information technology services, to coordinate data capture and/or maintain the dataset and associated documentation and participating site support. This includes:
 - Provision of a five business days per week helpdesk for hospitals contributing data and for patients
 - Having a nominated individual who is a senior academic to be accountable as the data custodial agency representative
 - Having, within the organisation, nominated individuals to act as the National Registry Coordinator and the National Data Manager
 - The ability to ensure secure hosting and backup of data plus support from qualified IT experts. The hosting and support service for the AuSDaT is currently provided by Amazon Web Services [Sydney]) 24/7.

Desirable:

- Relevant stroke linkages
- Knowledge and understanding of other relevant databases/registries such as Australasian Rehabilitation Outcomes Centre Database (AROC)

Process for Appointing the Data Custodian

- The process should commence at least twelve months prior to the end of any currently agreed custodial term.
- A Data Custodial Renewal Working Group will be convened consisting of members of the AuSCR Steering and Management Committees plus, as appropriate, external independent parties from the stroke and registry fields.

- Relevant documentation to inform an *Expression of Interest* process will be collated including the specific selection criteria outlined above, which will guide the selection process. Potential applicants will be identified and advised of the opportunity.
- Applicants for the data custodianship will prepare a notice of compliance with the AuSCR Data Custodian Policy for the Working Group and submit an application outlining how they meet the selection criteria.
- The working group will make a recommendation, or submit a shortlist as appropriate, to the AuSCR Management Committee which will then be forwarded to the AuSCR Steering Committee for a final decision for the appointment.
- In the instance where there is any conflict of interest for members of the AuSCR Steering or Management Committees who either may be employed by an organisation bidding for the data custodianship, or otherwise perceive or be perceived by others that they have a conflict of interest, those members will declare their conflict of interest and be excluded from all further discussions about the applications. Failure to declare this conflict of interest in a timely manner will preclude that application being considered.
- Upon acceptance of the appointment by the Data Custodian from the Chair of the Steering Committee, the role of the Data Custodian shall become official.
- There should be a sufficient transition period allowed for handover and operational establishment of the registry processes at the newly appointed Data Custodial agency
- As part of the transition in the AuSCR Data Custodianship, amendments to all ethics applications (and associated governance authorisations) must be submitted. Whilst a cooperative process, it is the responsibility of the new custodian with the support of the AuSCR staff to implement these requirements. For this reason, it is recommended that the process for appointing the Data Custodian commence *at least* 12 months prior to the completion of the current AuSCR Data Custodianship term.

Issue Resolution

Where issues or infractions of data custodianship rights and obligations arise regarding the AuSCR dataset, resolution shall be attempted through each of the following escalation levels (beginning at the lowest level and proceeding one level at a time):

1. Data Custodian
2. AuSCR Management Committee
3. Chair of the AuSCR Steering Committee
4. AuSCR Steering Committee
5. Ethics committee notification

The guiding principle in issue resolution must be to protect the privacy of those people registered in the AuSCR dataset. The escalation pathway should be guided by the significance of the issue.

Relinquishment

If the appointed AuSCR Data Custodian determines that they can no longer fulfil their role then the Data Custodian may relinquish their role to another agency. Intent to relinquish custodianship must be given to the Management Committee, who will then commence the process for appointing the Data Custodian as per Section 6.0. The Data Custodian must allow for a sufficient transition period for handover and operational establishment of registry processes for the newly appointed Data Custodian agency before accountability for AuSCR is relinquished, which includes notification to Ethics committees.