



Australian Stroke Clinical Registry

PUBLICATION POLICY

Version 2.0

19 October 2009

1.0 Preamble

This document relates to the Australian Stroke Clinical Registry (AuSCR). This policy provides guidelines for the publication of AuSCR data. This is necessary so that each contributing hospital is clear about the use of AuSCR data once data have been provided to the AuSCR Data Custodian.

This policy covers AuSCR staff, members of the AuSCR Research Task Group, members of the AuSCR hospital network, members of the AuSCR Management and Steering Committees and any other individual requesting access to data from the AuSCR database. *This policy should be read in conjunction with the AuSCR Data Access Policy.*

The publication policy does not apply to site-specific data and, as such, hospitals are free to publish their own data at any time with acknowledgement of AuSCR as per section 1.7 of this policy. It is not, however, permissible to publish comparisons of local hospital data to AuSCR published data without prior approval from the AuSCR Management Committee.

1.1 Overview of AuSCR

The AuSCR is a data set of information relating to people with stroke admitted to hospitals. It is an electronic database containing data that have been uploaded from individual hospitals. The AuSCR database exists to assist efforts to understand quality of health care provided in Australia, plan services and assist prevention efforts and treatment decisions.

1.2 Data Security & Storage

Data security and storage is assured via the following strategies:

- Encryption of data
- Internal audit
- Disaster recovery plans
- Ongoing security training
- Form-based authentication
- Role-based access

This document should be read in conjunction with the AuSCR Data Security Policy which provides more information on this topic.

1.3 Confidentiality of Information

Information held by the AuSCR is confidential. The procedures for making a request for access to data held in the AuSCR Database are outlined in the *AuSCR Data Access Policy*.

Sharing AuSCR data with the general scientific community is an objective established from the onset of the AuSCR initiative and is supported by the AuSCR Management Committee. In preparation for this level of data sharing, each of the AuSCR hospital sites included the following wording in Patient Information sheets:

“Your information is protected and we are not allowed to identify you by law. The Stroke Registry will produce reports on factors that influence the success of stroke care and rehabilitation; aspects of such reports may be presented at conferences or submitted for publication in medical journals. It will not be possible to identify any individuals in any reports. To maintain absolute security and confidentiality, anyone wanting to use any of the data from the Registry will be required to obtain ethics approval from an Ethics Committee.”

This document should be read in conjunction with the *AuSCR Data Access* and the *AuSCR Data Security Policies* which provide more information on this topic.

1.4 Plans for Disseminating Registry Information

Information held by the AuSCR will be used to assess the performance of:

- quality of stroke care in Australia; and
- the AuSCR in collecting data about quality of stroke care.

This document should be read in conjunction with the AuSCR Quality Assurance Data Management Protocol which provides more information on Standard Quality Assurance Data Management Reports produced by the AuSCR.

AuSCR staff will use the information held in the Registry to compile reports. Aspects of these reports may be presented at conferences or submitted for publication in medical journals. All de-identified reports will contain aggregated data to ensure that confidentiality is maintained at all times.

All published work based on the data provided by the minimum data set of AuSCR is subject to this Publication Policy. While this does not include AuSCR activity reports (such as the AuSCR Annual Report) this does include (but is not limited to) manuscripts, abstracts and presentations.

The AuSCR Consortium will encourage generation of scientific knowledge based on data held by the Data Custodian. To ensure that the data and any limitations in scope or quality of the data provided has been properly understood by the user, pre-publication drafts of manuscripts must be submitted to the AuSCR Management Committee for review and potential advice on data interpretation. As outlined below, AuSCR and the founding members of the Management Committee must be acknowledged in the appropriate way in all publications and presentations. AuSCR reserves the right to dissociate itself from conclusions drawn from the data if it deems necessary.

1.5 Research Task Group

The purpose of the Research Task Group is to provide independent and unbiased review of external proposals seeking to use AuSCR data.

This document should be read in conjunction with the AuSCR Data Access Policy and the AuSCR Research Task Group Terms of Reference which provides further information on the roles and responsibilities of the AuSCR Research Task Group.

1.6 Requests for Access to AuSCR Data

Interested parties may present requests for access to the database for the purposes of scientific investigation. These requests will be reviewed by the Research Task Group on behalf of the Management Committee. Preference will be given to AuSCR Consortium partners, members of the Management Committee, and those who have contributed data to AuSCR.

This document should be read in conjunction with the AuSCR Data Access Policy which provides full details of accessing AuSCR data and information.

1.7 Authorship/Publication

The AuSCR Consortium expects that researchers who have been granted access to Registry information will, to the best of their ability, ensure that their research results are placed in the public domain.

AuSCR Specific Principles

1. There are a number of options for authorship of publications using AuSCR data which may include, in addition to members of the writing group, one or more of the members of the Management Committee and/or “the AuSCR Collaboration”. The appropriate authorship acknowledgement will depend on the number of core AuSCR variables of the AuSCR database used.
2. The contact author is responsible for following the publications rules, including that no appropriate author is left out and that no inappropriate author is included (“honorary/courtesy authorships” are not accepted in AuSCR).

The Research Task Group will be guided in relation to any issues of authorship and intellectual property by the National Health & Medical Research Council’s “Australian Code for the Responsible Conduct of Research”, 2007 which is available at <http://www.nhmrc.gov.au/publications/synopses/files/r39.pdf>.

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, www.icmje.org).

The AuSCR Project Coordinator will maintain an up-to-date bibliography and repository of all publications pertaining to AuSCR. Lead authors are required to provide AuSCR with the most recent version of all publications and accepted abstracts.

In addition to adhering to the User Agreement as outlined above, the following limitations regarding access to data must be adhered to:

- Patient-specific data shall remain confidential under all circumstances.
- Investigator and site-specific data shall remain confidential and shall not be used in publications, presentations, or other public use. Following completion of a data access application data release may be granted, but only summary and de-identified data are released. Please refer to the AuSCR Data Access Policy for further information.
- Any use of the data must not compete with or interfere with the development, operation, or marketing of the AuSCR database, unless approved in writing by the Management Committee.
- Industry sponsors will not have any editorial control over final publications or presentations either using AuSCR data or prepared by AuSCR investigators.

Authorship Criteria

Authorship is substantive participation where all of the following conditions are met:

- (1) Conception and design, or data acquisition, analysis or interpretation;
- (2) Drafting the article or revising it critically for important intellectual content;
- (3) Final approval of the version to be published.

All others who have contributed, but do not meet all of the criteria listed above, should be named in the acknowledgements with a description of their contribution.

- Where authorship is attributed to a group, such as the AuSCR Management Committee, all members of the group who are named as authors should meet the criteria for authorship.
- Publications should include information on sources of financial support for research.

Acknowledgements

AuSCR should be acknowledged in any publication using data provided by the Registry.

In all cases where journal policies permit, all founding members of the Management Committee will be acknowledged as authors as they have contributed to the design, data acquisition, and analysis of AuSCR data. Individuals coordinating data collection at individual local hospitals but who do not meet the criteria for authorship should be cited as AuSCR Local Hospital Principle Investigator and named in the Acknowledgement section of the manuscript as appropriate.

Submission of Publications to the Research Task Group

The purpose of the Research Task Group is to provide independent scientific review of applications seeking access to AuSCR data. Please refer to the *Research Task Group Terms of Reference* and *AuSCR Data Access Policy* for further information. The Management Committee may request that the Research Task Group provide an unbiased review of a publication; such a review would be provided back to the Management Committee.

Tracking of Data Use and Publications

If AuSCR data are used in publications, authors will be required to:

1. Include recommended language describing AuSCR methods and data gathering;
2. Cite AuSCR sponsors;
3. Provide a manuscript to the AuSCR Management Committee for review prior to planned submission; this review may be undertaken by an appointed member of the Management Committee or the Research Task Group;
4. Inform the AuSCR Steering Committee of acceptance or rejection of the manuscript;
5. Provide manuscript or abstract citation to the AuSCR Office upon acceptance and
6. Provide URL to the published work, if possible.

Publication Review Timeline

Manuscripts resulting from work by AuSCR staff or from AuSCR data must be submitted to the Management Committee prior to the date of submission for review. Please be aware that there is a lead time to allow the AuSCR Data Custodian to review the use of AuSCR data. Thus, lead authors should liaise with the AuSCR Project Coordinator to ensure sufficient time to meet the targeted scientific meeting or peer-reviewed journal deadlines.

1.8 Unusual Situations

It is expected that most users of AuSCR data will follow these guidelines in good faith and that most analyses will be of reasonable quality. The Research Task Group does not intend to review manuscripts for scientific quality, preferring to let the peer-review process sort out quality. It is recognized that AuSCR data may even be used to support publications with conflicting results. However, we do anticipate the possibility of some unusual circumstances.

Egregiously Poor Manuscripts. If a review of a proposed manuscript reveals that it is egregiously poor in terms of language, writing or sensible substance, the Research Task Group can recommend to the authors that it not be submitted without significant revision. If the authors choose to submit the manuscript anyway, the Management Committee will have three options: 1) request that the group authorship credit be withheld; 2) request that the authors publish a statement to the effect that while AuSCR data were used, the AuSCR Management Committee did not find this manuscript of sufficient merit to warrant submission for publication, and/or; 3) revocation of privileges to use AuSCR data in the future.

Failure to Follow User Agreement. If users inadvertently violate the User Agreement, it is likely that they will self-correct as infractions are discovered. If users deliberately violate the User Agreement, the sole sanction available to the AuSCR will be to revoke access to the AuSCR data. This may include reporting the violation to the relevant Human Research Ethics Committee.

Fraudulent Use of Data. Open access to hospital sites raises the possibility that individuals could obtain access to data under false pretenses. Should the Management Committee discover an attempt to publish data obtained fraudulently, the data user will be sanctioned through Steering Committee communication with them or their academic supervisor(s). As soon as the Management Committee becomes aware of any breach of the Data Use Agreement, immediate steps will be taken to end the violation. In extreme and/or deliberate cases, this may include discontinuing the user's data access and/or reporting the violation to the relevant Human Research Ethics Committee.

Journal Objections: It is possible that journal editors may object to a group authorship format with the caveat that the AuSCR names credited in the manuscript have gathered data but have not participated in writing the manuscript. The Research Task Group can authorise exceptions to the authorship policy or can negotiate with journal editors as needed on a case by case basis.

Flow chart of Publication Process

