



**Australian Stroke Clinical Registry**

## **OUTLIER/SPECIAL CAUSE VARIATION COMMUNICATION POLICY**

**Version 3.0**

**Approved: 02 September 2015**

## 1.0 Preamble

One of the main aims of the Australian Stroke Clinical Registry (AuSCR) is to monitor clinical care and outcomes associated with stroke or transient ischaemic attack (TIA). This policy document provides guidance for hospital-level outlier monitoring, investigation and reporting as part of addressing causes of variation. The AuSCR Office provides, to participating hospitals, an annual report with their adherence to processes of care and verified outcome data that is casemix adjusted. This permits hospitals which appear to have poor performance, relative to other hospitals, to investigate the factors that may underlie variation in performance. Further details of the methods used are detailed in this policy.

Appropriate statistical methods are used for identifying hospitals that appear to be ‘outliers’, or exhibit special cause variation, which occurs when greater than expected differences in patient outcome or processes of care are found. In brief, special cause variation occurs when the analysis of data provides evidence of variability in care that falls outside three standard deviations of the average value for a quality of care indicator or health outcome measure. If non-parametric analyses are warranted, then ‘outliers’ are those hospitals that fall outside the interquartile range for median values. Any aspect of special cause variation is required to be investigated by the hospital and it is the role of the AuSCR Office to ensure that hospital principal investigators are made aware of their results.

Table 1 below outlines examples of process of care and health outcome indicators used to flag outlier hospitals. For process of care and health outcome performance indicators, hospitals within the 2 SD limits are considered to be within ‘normal variation’. Those outside the 3 SD limits are considered to have ‘special cause variation’. This usually means (e.g. for processes of care) that hospitals above the 3 SD limits line may be considered as having ‘exceptional performance’, while those below the 3 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.

**Table 1: Examples of performance indicators used to flag an outlier hospital**

<b>Outlier flags</b>	<b>Proportion</b>
Health outcome	Risk-adjusted mortality rate at 30 days after admission
Process of care indicators	Patients admitted to a stroke unit
	Patients who received intravenous thrombolysis (tPA), if an ischaemic stroke
	Patients discharged on an antihypertensive agent if not deceased while in hospital
	Patients who received a care plan at discharge, if discharged home or to a residential aged care facility

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 that they are provided with support in understanding their data as part of investigating the potential cause of the variation. This process has been approved by the AuSCR Steering Committee and AuSCR consortium partners including the Stroke Society of Australasia, the peak body representing stroke clinicians in Australasia and the National Stroke Foundation, the peak advocacy body for stroke in Australia.

The process for investigating ‘special cause variation’ in health outcomes is outlined in Section 2.0. For process of care indicators, outlier communication will form part of the quality improvement activities within each of the participating hospitals (see Section 3.0 below).

## 2.0 Process for investigating ‘special cause variation’ in health outcomes among participating hospitals

Stage	PROCESS	DETAIL
1	AuSCR data manager/s or epidemiologist/s advise the Data Custodian that an analysis of outcome data suggests a worse than expected outcome result providing evidence of suspected failure in quality of care for a particular hospital/s and creating an ‘outlier’ status.	<ul style="list-style-type: none"> <li>• In line with the agreed statistical methodology and quality assurance and data management processes policy and reporting timeframes</li> </ul>
2	AuSCR data managers/ or epidemiologist/s will undertake a review of the data to establish whether the statistical analysis is, or is not, influenced by poor quality data or data anomalies and whether an ‘audit’ or site-level data review is required.	<ul style="list-style-type: none"> <li>• Verification of mortality outcomes may also be investigated with National Death Index data to assess whether causes of death are due to stroke or other conditions</li> <li>• Identity of the hospital/s will be anonymous at Stage 2</li> </ul>
3	The relevant hospital’s principal investigator (PI) is contacted and provided with a report of their data (see Section 4) and is provided with up to two weeks to identify if there are any issues with their data that they may wish to have reviewed or reanalysed.	<ul style="list-style-type: none"> <li>• AuSCR Coordinator is responsible for communicating this information and feedback to data managers/epidemiologists</li> <li>• Reanalysis of data undertaken if justified and updated data is provided</li> </ul>
4	The AuSCR Management Committee, as well as the AuSCR Steering Committee Chair, is informed following review of the annual report data analysis about the results.	<ul style="list-style-type: none"> <li>• Outcome of the consultation and next steps are documented in the AuSCR Management Committee meeting minutes. Identity of the hospital/s is anonymous in Stage 4 documentation</li> </ul>
<b>Outcome of Stage 4: “No Case to Answer”</b>		
5	Management Committee members to inform the AuSCR Steering Committee Chair that the outcome of the data review had concluded that there was “no case to answer”.	<ul style="list-style-type: none"> <li>• No further action required</li> <li>• Identity of hospital/s will remain anonymous at Stage 5</li> </ul>
<b>Outcome of Stage 4: Data and Statistical Analysis sound: “Case to Answer”</b>		
6	The AuSCR Data Custodian will provide details of the identity of the hospital/s identified as outliers where this cannot be explained by data anomalies to the AuSCR Management Committee nominee (see Stage 7 below).	<ul style="list-style-type: none"> <li>• Annual report contains de-identified information on hospitals that are outliers that require follow-up</li> </ul>
7	At the request of the AuSCR Management Committee Chair, a nominated AuSCR Management Committee clinician member will make initial contact with the ‘outlier’ hospital or this role may be delegated to the AuSCR Coordinator responsible for that site/s.	<ul style="list-style-type: none"> <li>• AuSCR Coordinator to provide the AuSCR Management Committee clinician member with the relevant contact details</li> <li>• An informal approach will be made via a telephone call to the local PI at the hospital to advise that: <ul style="list-style-type: none"> <li>– Analyses of the AuSCR data had flagged results which indicate special cause variation that could not be explained by anomalies in the data which now requires a process of local review and audit to establish the reason;</li> <li>– It will be recommended that the local hospital Quality Assurance department/representative is informed, so the local PI should make contact with them at their earliest convenience since they may be able to offer support in understanding the cause of the variation; and</li> <li>– AuSCR will provide updated data to the hospital, as required</li> <li>– Information that may explain the special cause variation in outcomes will also be provided such as performance against process of care metrics (see Section 3.0)</li> </ul> </li> </ul>

Stage	PROCESS	DETAIL
8	The nominated AuSCR Management Committee clinician member will notify the AuSCR Management Committee Chair that the 'outlier' hospital had been contacted, and provide a status summary.	<ul style="list-style-type: none"> <li>• Details documented in AuSCR Management Committee meeting minutes. Site referred to by their AuSCR ID number in minutes</li> </ul>
9	If required, and agreed as part of funding agreements, the AuSCR Data Custodian will inform the Health Department of the outcome of the outlier review and plan to understand the cause of the variation in outcomes.	<ul style="list-style-type: none"> <li>• AuSCR Data Custodian to provide the results to the Health Department and detail the remedial steps that have been followed to work with the hospital to understand why variation in outcomes may be occurring</li> </ul>
10	The Health Department, usually through the Stroke Clinical Network, may engage with the hospital directly to support understanding why clinical variation is occurring.	<ul style="list-style-type: none"> <li>• AuSCR staff to provide all relevant information about the data and analysis methods to facilitate an open and transparent review</li> </ul>
11	Hospitals that have exceptionally good performance will also be assessed to understand if there are learnings that can be shared with other hospitals, or if there is bias in the data submitted	<ul style="list-style-type: none"> <li>• AuSCR data manager/s or epidemiologist/s advise the Data Custodian about whether there is the possibility of patient selection bias as part of a review of case-ascertainment</li> <li>• Among sites where selection bias is evident the AuSCR Coordinator will contact the site PI and discuss methods to improve case-ascertainment</li> <li>• Sites that consistently show exceptional performance and where there are no concerns with selection bias will be congratulated through a letter from the Chair of the Management Committee and Data Custodian and asked if they would like to share anything with other AuSCR sites that may explain why these outcomes are being achieved</li> </ul>
<b>After Stage 11: No response from Hospital/Unit to confirm that requested audit has taken place</b>		
12	The AuSCR Management Committee Chair will send a reminder letter to the local Hospital PI and ask for them to confirm or feedback their findings.	<ul style="list-style-type: none"> <li>• AuSCR may offer support to undertake an audit at the hospital to investigate special cause variation in outcomes if deemed appropriate and if funding permits, in particular if the data submitted to AuSCR by the hospitals are considered inaccurate or flawed</li> <li>• Verification of mortality outcomes may also be investigated with National Death Index data to assess whether causes of death are due to stroke or other conditions</li> </ul>

### 3.0 Process for investigating “special cause variation” in process of care indicators among participating hospitals

Stage	PROCESS	DETAIL
1	AuSCR data custodian epidemiologist/s advise the Data Custodian that an analysis of processes of care data suggests a higher or lower than expected rate providing evidence of success or failure in quality of care for a particular hospital/s creating a ‘special cause variation’ status.	<ul style="list-style-type: none"> <li>• In line with the agreed statistical methodology and quality assurance and data management processes policy and reporting timeframes</li> </ul>
2	The local PI is provided a copy of their annual report with a cover letter signed by the Chair of the Management Committee and Data Custodian indicating that their performance on some or all of the metrics is below that of other sites	<ul style="list-style-type: none"> <li>• The local PI of the ‘outlier’ hospital will be requested to confirm whether the AuSCR data are correct and will be notified in their letter that: <ul style="list-style-type: none"> <li>– Analyses of the AuSCR data had flagged results which indicate special cause variation that could not be explained by anomalies in the data which now requires a process of local review and audit to establish the reason;</li> <li>– It will be recommended that the local hospital Quality Assurance department/representative is informed, so the local PI should make contact with them at their earliest convenience since they may be able to offer support in understanding the cause of the variation; and</li> <li>– AuSCR will provide updated data to the hospital, as required</li> </ul> </li> </ul>
<b>After Stage 2: No response from Hospital/Unit to confirm that requested audit or remedial action has been taken</b>		
3	The AuSCR Data Custodian will send a reminder letter to the local PI requesting confirmation/feedback that the AuSCR data have been audited or remedial steps within the control of clinicians have been commenced.	<ul style="list-style-type: none"> <li>• AuSCR may offer support to undertake an audit at the hospital to investigate special cause variation in outcomes if deemed appropriate and if funding permits, if the quality of the data submitted to AuSCR are considered inaccurate or flawed.</li> </ul>

### 4.0 Formal reporting of special cause variation status

Data in the annual report will be presented in a de-identified format unless all hospitals have provided permission to be named in the report. Otherwise de-identified, but ID-coded data, is provided such that individual hospitals can identify their own information. Customised site-specific data reports may also be produced as part of some specifically funded participation arrangements. These are the main mechanisms for disseminating casemix adjusted health outcome findings. The AuSCR annual report will include details of the outcomes of AuSCR management processes undertaken to address identified outliers within a reporting time period.

The primary health outcome measure will be risk-adjusted mortality rate (RAMR) at 30 days after admission. These analyses will only be conducted using data from hospitals that have submitted 200 or more episodes per annum or per reporting period. Data from patients will be excluded if an inpatient stroke or a transfer from another hospital, since health outcomes may be influenced by these factors. Data for paediatric patients will also be excluded. Hospital-level risk adjustment models described by Katzan and colleagues<sup>1</sup> will be used to calculate the risk adjusted hospital specific mortality rate. All models will be adjusted for patient characteristics including age, sex, type of stroke, stroke severity and socioeconomic status and include hospital as a separate level in the statistical model. The adherence to processes of care by hospital are also provided to potentially identify the factors that might have influenced the differences observed in outcomes between participating hospitals.

1. Katzan IL, Spertus J, et al. Risk adjustment of ischemic stroke outcomes for comparing hospital performance: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45:918-944.