OUTLIER/UNWARRANTED VARIATION COMMUNICATION POLICY

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1.0 Preamble

The overarching aim 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. This policy aligns with the Australian Commission on Safety and Quality in Health Care *Framework for Clinical Quality Registries* report which identifies that clinical quality registries should generate risk adjusted reports which are provided back to participating hospitals to address significant variance and inform improvements in health care quality.[1] In addition, hospital identified reports on performance are provided biannually to some State Government Health Departments that fund the AuSCR.

The AuSCR Office provides, to participating hospitals, an annual report[2], accompanied by a site-specific supplemental data report, outlining a hospital's adherence to high priority processes of care, and verified outcome data that is case mix adjusted. Appropriate statistical methods are used for examining clinical variation, where hospitals have submitted more than 50 episodes of care for the reporting period.

- *Normal variation* is defined as hospital data that falls within two standard deviations (SD) of the mean for any individual performance indicator (e.g. health outcomes or process of care).

- *Outliers* are defined as hospital data that falls outside three standard deviations from the mean for any individual performance indicator, exhibiting greater than expected differences in patient outcome or processes of care.

  For process of care indicators, 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'. Conversely, for health outcomes (mortality), hospitals above the three SD limits line may be considered as having 'poor performance', while those below the three SD limits line may be considered as having 'exceptional performance'.

- *Unwarranted variation* is defined as an outlier indicating poor performance, i.e. below the three SD limit line for processes of care or above the three SD limit line for health outcomes.

This permits hospitals which appear to have poor performance, relative to other hospitals, to investigate the factors that may underlie variation in performance.

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 Data Custodian to ensure that hospital Principal Investigators (Lead Clinicians) are made aware of their hospital results.

The performance indicators used to flag outlier hospitals are summarised in Table 1. These indicators are subject to review by the AuSCR Management and Clinical Quality Improvement Committees annually, and may be subject to change. Care must be taken in interpreting these data when they are skewed because the control limits rely on the assumption that 95% of the distribution of data follows a bell-shaped curve. Both exceptional performance and underperformance, occurring over multiple reporting periods, should be investigated to ensure that the cause is not attributable to anomalies in the dataset.

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

Outlier flags	Proportion
Health outcome	Risk-adjusted mortality rate at 30 days after admission
Processes of care indicators	Patients admitted to a stroke unit
	Patients who received reperfusion therapy if an ischaemic stroke, with a door-to-needle time within 60 minutes of hospital arrival
	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, Steering and Clinical Quality Improvement Committees) will be followed to ensure that the results are made known to the hospital AuSCR Principal Investigator, and that they are provided with support in understanding their data as part of investigating the potential cause of the variation. Hospitals with both poorer than expected performance and better than expected performance will be asked to undertake an internal review, supported by the AuSCR Governance Committees. The methods of investigation and actions taken will differ (see Sections 3.0 and 4.0).

2.0   Formal reporting of special cause variation status

Data in AuSCR Annual Reports will be presented in a de-identified format. Individual hospital data will be identifiable via a unique identification number and each hospital will be provided with their own number to identify their own performance data. Individual hospital specific data reports will also be provided to hospitals as an adjunct to the Annual Report so that performance on additional quality of care metrics can be monitored.

Additional site-specific data reports (e.g. reports to hospital Chief Executive Officers) may also be produced as part of some government-based funding agreements. This adds a second mechanism for disseminating case mix adjusted health outcome findings and processes of care metrics to participating hospitals.

Hospital identified health outcomes and processes of care are also reported directly to some state government funders as part of contractual obligations. These reports will also be used to identify outliers and special cause variation status.

The primary health **outcome measure** used to identify special cause variation 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, for ischaemic stroke and 50 or more episodes for haemorrhagic stroke. RAMR will be presented in two different ways. The first method will *exclude* patients transferred from another hospital, in-hospital strokes and patients with TIA. This method is a summary for patients treated at only one hospital and deaths are fully attributed to that hospital. The second RAMR method will *include* patients who were managed by more than one hospital for their episode of stroke care (i.e. include all patients treated at an individual hospital irrespective of whether they presented directly or were transferred). In this analysis, multiple episodes related to the same acute stroke event will be included, and mortality attributed equally to all hospitals involved in the provision of patient care for that stroke event. RAMR will be calculated by dividing the risk-adjusted hospital specific mortality by the risk-adjusted average hospital mortality, and then multiplying by the unadjusted proportion of deaths in the whole sample. Hospital-level risk adjustment models described by Katzan[3] and Cadilhac[4] will be used to calculate the risk adjusted hospital specific mortality rate. All RAMR models will be adjusted for age, sex, country of birth, Indigenous status, socioeconomic position, stroke type, stroke severity and previous history of stroke.

The adherence to **processes of care** by individual hospitals will also be assessed and reported back to hospital Principal Investigators to potentially identify the factors that might have influenced the differences observed in outcomes between participating hospitals. Analysis of adherence to processes of care will only be conducted for those hospitals that have submitted 50 or more episodes documenting the individual process of care per annum, or in the reporting period.

Paediatric data
Data relating to the performance of comprehensive paediatric hospitals will be reviewed separately, and only assessed when the thresholds for sample sizes have been met. These data will be reviewed in the first instance by the AuSCR Paediatric Sub-Committee.

3.0   Methods for investigating unwarranted variation in participating hospitals with poorer than expected performance

Health outcomes and processes of care data are reviewed annually as part of analysis for the AuSCR Annual Report. Annual review ensures that data are complete for the relevant 12-month time period, and therefore limit any impact of incomplete episodes of care on outlier status. Data are displayed as funnel plots to assist with the easy identification of outliers and benchmarks.

Hospitals are officially notified by the Data Custodian, and offered support, if they flag as a confirmed outlier within a single 12-month period.

Methods for investigating special cause variation for hospitals exhibiting poor performance are summarised in Table 2 and Figure 1.

Table 2: Summary of methods for investigating hospitals with poorer than expected performance

STAGE	METHOD
1	AuSCR Annual Report analysis, on hospitals that have submitted >50 episodes for the period, identifies hospital outlier status on an individual performance indicator based on admissions from the previous calendar year (i.e. 12-month data collection period).
2	The Data Custodian requests a review of the data for the hospital and individual performance indicator by the data analysts to identify any factors which may have contributed to an erroneous identification as an outlier. Review of the data will include an assessment of missing data, selection bias (based on case ascertainment for the 12-month reporting period), potentially erroneous or unusual patterns of data and sample size. For RAMR this will include investigation of the data relating to risk adjustment variables. Comparisons of data with previous years may also be undertaken (where relevant) alongside comparisons of on-demand (or live) data held for an individual hospital within the Australian Stroke Data Tool.
Outcome of Stage 2: Hospital NOT confirmed as an outlier (NO case for action)	
3A	AuSCR Management and Clinical Quality Improvement Committees informed of hospital outlier status and results of data review. Committees to inform Data Custodian whether any further actions are required.
4A	Where a hospital outlier status is attributed to a specific cause (e.g. erroneous data uploaded to the AuSCR), then the AuSCR Data Custodian may request that the hospital Principal Investigator provide corrected data.
5A	Where corrected data cannot be provided within the AuSCR Annual Reporting timeframe, then the Data Custodian may remove an outlier hospital from the AuSCR Annual Report with respect to the specific performance indicator on which they are an outlier. The Data Custodian would then advise the AuSCR Management and Clinical Quality Improvement Committees of this action, in addition to the hospital Principal Investigator. The Data Custodian may also seek guidance from the Management and Clinical Quality Improvement Committees about removal of erroneous data from the AuSCR archived dataset, if a hospital indicates that they have no capacity to provide corrected data.

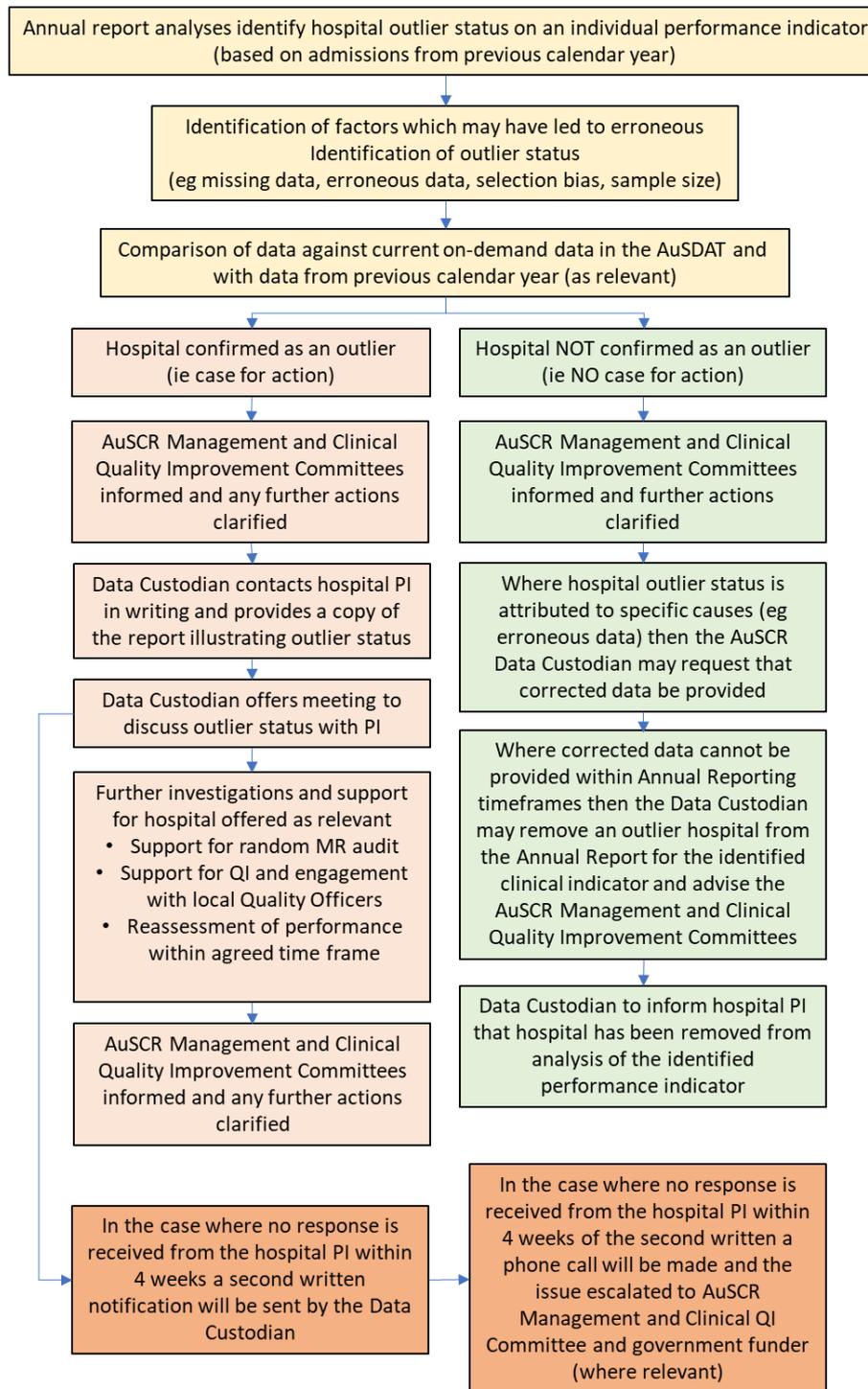| STAGE	METHOD
Outcome of Stage 2: Hospital confirmed as an outlier (i.e. case for action)	
3B	AuSCR Management and Clinical Quality Improvement Committees are informed of confirmed hospital outlier status following the data review by the Data Custodian. The Committees will support the Data Custodian to follow up poor performance on the individual performance indicator with the hospital Principal Investigator as required.
4B	The Data Custodian writes to the hospital Principal Investigator and provides a copy of the draft report illustrating outlier status of the individual performance indicator.
5B	The Data Custodian offers to meet with the hospital Principal Investigator to discuss outlier status.
6B	The Data Custodian may offer assistance with further investigations of relevant data held locally via completion of a random medical record audit. Assistance with engagement of local Quality Officers, or with quality Improvement support may be offered, as relevant, and within the means of the AuSCR. The Data Custodian will agree on a time frame with the hospital Principal Investigator in which hospital performance against the individual indicator will be reassessed.
7B	The Data Custodian informs the AuSCR Management and Clinical Quality Improvement Committees of the outcomes of discussions with the hospital Principal Investigator and proposed future actions. The Data Custodian will also report outlier status, and subsequent discussions with the hospital Principal Investigator to the relevant State Health Department funder *where this is specified under the contractual obligations*. In the case where the hospital has been an outlier on the same individual process of care across more than one reporting period (i.e. across two AuSCR Annual Reports) then the continued outlier status would be reported by the Data Custodian to the AuSCR Management and Clinical Quality Improvement Committees who would decide on the appropriate escalation process required.
Where the Data Custodian Receives No Response to Stage 4B	
5C	Where the Data Custodian has received no response from the hospital Principal Investigator within four weeks to the initial written notification, a second written notification will be sent to the hospital Principal Investigator.
Where the Data Custodian Receives No Response to Stage 5C	
5D	Where the Data Custodian has received no response from the hospital Principal Investigator within four weeks to the second written notification, a phone call will be made.
Where the Data Custodian Receives No Response to Stage 5D	
5E	Where the Data Custodian receives no response to a phone call, OR where the response received does not enable further investigation of the data, or plans for future reassessment of the data, then the matter will be escalated back to the AuSCR Management and Clinical Quality Improvement Committees for further action.

Note: actions referred to as being undertaken by the Data Custodian may also involve support as appropriate from AuSCR Coordinators and Data Managers.

No further action is required unless this hospital is identified as an outlier in a second consecutive 12-month period, *or* where an AuSCR contract with a state health department outlines additional processes. In the event that a hospital is an outlier for a second consecutive period, the Data Custodian, and the AuSCR Management and Clinical Quality Improvement Committees will decide on an appropriate escalation process for this hospital.

4.0 Methods for investigating outliers in performance among participating hospitals with better than expected performance

STAGE	METHOD
1	AuSCR Annual Report analysis identifies hospital outlier status on hospitals that have submitted >50 episodes for the period, for an individual performance indicator based on admissions from the previous year.
2	The Data Custodian requests review of the data for the hospital and individual performance indicator to identify any factors which may have contributed to the identification as an outlier (e.g. selection bias as measured by case ascertainment results for the period in question or inclusion of patients treated only in a stroke unit).
In cases where selection bias is evident from Stage 2	
3A	The Data Custodian will contact the hospital Principal Investigator and discuss methods to improve case ascertainment and limit selection bias.
	The Data Custodian inform the AuSCR Management and Clinical Quality Improvement Committees of the findings. Where recommended, a random medical record audit may be requested by the Data Custodian.
In cases where NO selection bias is evident from Stage 2	
3B	The Data Custodian inform the AuSCR Management and Clinical Quality Improvement Committees of the findings.
	Hospitals that show exceptional performance will be congratulated via a letter from the Chairs of the AuSCR Steering, Management and Quality and Improvement Committees and will be asked if they would like to share any learnings with other AuSCR sites about how these results were achieved.

Note: actions referred to as being undertaken by the Data Custodian may also involve support as appropriate from AuSCR Coordinators and Data Managers.

AuSDaT, Australian Stroke Data Tool; MR, medical record; PI, principal investigator; QI, quality improvement

Figure 1: Flowchart summary of process for investigating hospitals with poorer than expected performance on an individual indicator.

References

1. Australian Commission on Safety and Quality in Health Care, *Framework for Australian clinical quality registries.* Sydney. ACSQHC, March 2014.

2. https://auscr.com.au/about/annual-reports/

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

4. Cadilhac DA, Kilkenny MF, et al. Risk-adjusted hospital mortality rates for stroke: evidence from the Australian Clinical Registry (AuSCR).