National Vascular Registry – Outlier Policy for individual consultants

Introduction

This document sets out the process by which consultant level performance will be assessed within the National Vascular Registry (NVR). It is designed to provide transparency about data handling and analysis, and a robust process for managing consultants with indicator values that fall outside the expected range of performance (i.e. are flagged as an "outlier"). This version of the outlier policy will be applied to the analyses by the NVR team carried out from 2024.

Background

The NHS mandate and "Good Medical Practice" require clinicians to provide accurate, up-to-date information about their clinical practice to ensure patient safety. Revalidation and the issuing of a licence to practice are predicated on demonstrating acceptable clinical performance.

The Medical Director of the NHS has made it clear that the responsibility for maintaining and providing accurate data rests with individual clinicians both in terms of coding of their work and the submission of clinical activity data to national audits where indicated.

In order to support clinicians in this requirement, the Department of Health has made available public funds to support national clinical audit. The Vascular Society has obtained financial support to set up and run the National Vascular Registry (NVR) in partnership with the Clinical Effectiveness Unit (CEU) at the Royal College of Surgeons of England. The NVR is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme. HQIP acts as the data controller for the NVR and has responsibility for managing how NVR data are used. The NVR team act as data processors on behalf of HQIP and manage the data collection, analysis and publication of results.

Responsibility for data entry rests with local clinical vascular teams, supported by their NHS trust / health boards. NHS trusts / health boards have a duty to provide both clinical audit data under national quality accounts, and to ensure high quality data are submitted. The collection of data on the eligible procedures (abdominal aortic aneurysm (AAA) repair, carotid intervention, and lower-limb interventions for peripheral arterial disease (PAD)) is performed through a bespoke online data collection tool. To support data collection, the NVR team will provide hospitals with information on case ascertainment and coding quality.

The NVR team perform regular assessments of hospital performance and make the results publicly available. The measures are selected from a variety of sources, such as the academic literature, NICE, and national commissioning targets, and cover clinical processes and patient outcomes. Reporting schedules will be regularly communicated to clinical vascular teams to allow them sufficient time to review their data and ensure it is up to date prior to analysis and reporting.

Principles for managing individual consultants identified as "outliers" on a performance indicator

The guiding principles adopted by the NVR are outlined below. Information about choice of indicators will be publicly available and included in reports.

1. Performance indicators

Performance indicators are intended to provide a valid measure of a consultant's quality of care. Postoperative death is the outcome measure for AAA repair, lower limb angioplasty, lower limb bypass and lower limb amputation. For carotid procedures the outcome measure is stroke and/or death within 30 days. Any additional outcomes will be selected based on their relevance to the procedure.

Where appropriate, we will report process measures, such as the time from symptom to intervention for carotid surgery. It is intended that such indicators will provide information on service quality for the profession and the public.

These performance indicators are usually based on the most recent three years of data submitted to the NVR, but trusts / health boards will be notified in advance if a specific indicator is based on a different time period. From 2024, the NVR will be reporting on outliers based on non-participation to the NVR, either in full or by not submitting any data for a given procedure, where the NHS trust/health board provides that procedure.

The timeframe for the current performance indicators can be found on our website.

2. Expected performance

The expected performance on an indicator may be defined in two ways. In some circumstances, it will be based on external sources such as research evidence and agreed standards of care (as outlined in VS Quality Improvement Frameworks). More generally, the expected level of performance will be derived from the NVR. This level will be calculated using statistical methods, and be presented using appropriate types of graphs, such as funnel plots.

3. Data quality

We will report three aspects of data quality, namely:

- case ascertainment: This is the number of patients entered into the NVR compared to the number eligible, derived from external data sources. This will help to inform clinicians, commissioners and the public about the generalisability of the reported outcomes.
- data completeness: this refers to the completeness of the data submitted by hospitals for each patient. Complete data is required for accurate analysis and reporting. Without complete data, indicator values for units may be unrepresentative of actual practice.
- data accuracy: this will be tested using consistency and range checks, as well as external validation against HES. It may involve other methods of validation such as peer review.

The NVR has extensive data validation rules to reduce the risk of missing values, and it is rare for the NVR not to be able to analyse the outcomes of a particular consultant because of poor quality data. If the data supplied by a consultant is so incomplete that the results of any analysis would be unreliable, it is automatically treated as a potential outlier.

4. Case-mix (risk) adjustment
The comparison of outcomes across health care providers must take account of patient characteristics so that differences in outcomes between providers are not due to the differences in the types of patient they treat. This typically involves taking into account a patient's age, sex, disease severity and the existence of any other co-morbidity.

We will report on details of the risk-adjustment model and its performance characteristics. The NVR team will use the national data to develop appropriate risk-adjustment methods for each procedure.

5. Detection of a potential outlier
Statistically derived limits around the expected level of performance (e.g. mean mortality following AAA repair) will be used to define whether or not a consultant is a potential outlier. A statistical model will be used to define these limits using established methods.

A consultant will be flagged as a potential outlier if the value on an outcome indicator is more than a specified number of standard deviations (SD) from the expected performance level. The threshold for being flagged an outlier has been set at 3 SD from the expected level and is defined as an 'alarm.' Those consultants who fall between 2 SD and 3 SD from the expected level of performance will be considered as an 'alert'. These thresholds are consistent with common practice[1].

It is important to note that these are definitions of statistically significant differences from expected performance. Such differences may not be clinically important if the indicator value is based on large numbers of patients. Where possible, the statistical methods used to generate the control limits will be refined so that they reflect clinically important differences.

6. Management of a potential outlier
The management of a potential outlier involves various people:

- The NVR team: the team responsible for managing and running the audit nationally. This comprises the Director of the CEU at the Royal College of Surgeons and the Chair of the Audit and QI committee of the Vascular Society in his/her role as the clinical lead for the audit.
- The individual consultant and lead clinician of the vascular unit (i.e., the clinical lead for the team delivering care within the vascular unit under scrutiny).

In addition, the provider clinical governance lead (responsible for clinical governance in the provider NHS trust), the provider Medical Director, and Chief Executive may need to be involved.
Any consultant going through the outlier process is encouraged to seek support from the Professional Standards Committee of the Vascular Society if they feel this is required.

The following table indicates the seven stages that will be followed in managing a potential outlier, the actions that need to be taken, the people involved and the maximum time scales. It aims to be feasible and fair to providers identified as potential outliers and sufficiently rapid so as not to unduly delay the publication of comparative information. If after a review of their data, their level of performance is still beyond the 3 SD control limit, the consultant will be flagged as an outlier.

[1] Spiegelhalter DJ. Funnel plots for comparing institutional performance. Stat Med 2005; 24: 1185-202.

7. Cause for concern

In the rare circumstances in which information submitted to the NVR could reasonably suggest the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients, the NVR will implement the escalation process described in Table 3 in the following guidance published February 2019: https://www.hqip.org.uk/wp-content/uploads/2019/02/NCAPOP-Cause-for-Concern-Guidance-Final-E-and-W-Feb-2019.pdf

Stage	What action?	Who?	Within how many working days?
1	Consultants with a performance indicator value beyond the alarm threshold require careful scrutiny of the data handling and analyses performed to determine whether there is: 'Alarm status not confirmed' • potential outlier status not confirmed • data and results revised in NVR records • details formally recorded. 'Alarm status confirmed' • potential outlier status persists • *proceed to stage 2*	NVR Team	10
2	The individual consultant and the Lead Clinician in the provider organisation are informed about the potential outlier status and requested to identify any data errors or justifiable explanation/s. All relevant data and analyses by the NVR will be made available to the consultant and Lead Clinician.	NVR Director, the individual consultant and Clinical Lead	5
3	Consultant and Lead Clinician to provide written response to NVR governance team.	Provider Lead Clinician	25

Stage	What action?	Who?	Within how many working days?
4	Review of response to determine: <u>'Alarm status not confirmed'</u> • It is confirmed that the data originally supplied by the individual consultant contained inaccuracies. Re-analysis of accurate data indicates that the level of performance is now within the alarm control limits, and the consultant is not flagged as an outlier. • Data and results will be revised in NVR records. Details of the consultant's response and the review result recorded. • Consultant and Lead Clinician notified in writing. <u>'Alarm status confirmed'</u> • It is confirmed that, although the data originally supplied by the provider were inaccurate, analysis still indicates that the level of performance is still beyond the alarm control limits, and the consultant is an outlier; or • It is confirmed that the originally supplied data were accurate, thus confirming that the consultant is an outlier. • *proceed to stage 5*	NVR Team	20
5	Contact consultant by telephone, prior to written confirmation of outlier status; copied to Provider clinical governance lead / Medical Director. For consultants working in Wales, the Senior Responsible Officer for the Vascular Network will also be notified. All relevant data and statistical analyses, including previous response from the individual consultant, will be made available to the Provider clinical governance lead / Medical Director.	NVR Director and Clinical Lead NVR Team	5
6	For consultants working in England, the NVR team will notify NHS England that there is a consultant who is an alarm level outlier. The name of the individual consultant will **not** be provided to NHS England – just the name of the trust involved.	NVR Director and Clinical Lead NVR Team	5
7	For consultants in England, a trust action plan is required, following A practical guide for responding to concerns about medical practice, 2019.	Provider clinical lead	

8. Management of alert outlier triggers.

An "alert" indicates that the individual consultant has an indicator value (e.g., postoperative mortality rate) that is between 2 and 3 SDs from the expected level of performance.

Stage	What action?	Who?
1	Consultants with a performance indicator value beyond the alert threshold require careful scrutiny of the data handling and analyses performed to determine whether there is an issue with the data. Consultants flagged as "alerts" will not be subject to the full review process as outlined in section 6. This is because 1 in 20 consultants would be expected to have this size of difference from the national average simply from random variation alone.	NVR Team
2	The individual consultant and the Lead Clinician in the provider organisation are informed about the alert status. All relevant data and analyses by the NVR will be made available to the consultant and Lead Clinician. It is not expected that there will be a full re-analysis of a consultant's data if any corrections are made to it.	NVR Director, the individual consultant and Clinical Lead
3	Consultant and Lead Clinician to provide written response to NVR governance team.	Provider Lead Clinician
4	NVR team to confirm alert level status to the individual consultant. For consultants working in England, the Trust clinical director for that area of care and the Trust medical director will be notified. For consultants working in Wales, the LHB clinical director for vascular surgery and Senior Responsible Officer for the Vascular Network will be notified.	NVR Team
5	For consultants in England, a trust action plan is required, following A practical guide for responding to concerns about medical practice, 2019.	Provider clinical lead

The role of the NVR

The primary role of the NVR is to support clinical teams in providing high-quality, robust clinical audit data. It is anticipated that "alarms" will be triggered rarely and that a regular reporting cycle will help to drive up clinical quality. Where such triggers are activated, the NVR team will seek to provide additional help to providers wanting to review data entry and quality.

Units should be aware that while the NVR has a duty to report on the data it holds, the NVR is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the clinical teams/units/NHS trust providing the service to patients. Issues with clinical audit data (either case ascertainment or data quality) must be addressed by the unit/trust concerned.

Units or clinicians with concerns about data quality are urged to contact the NVR team at the Royal College of Surgeons of England at the earliest opportunity to discuss them.