

National Vascular Registry – Outlier policy

Introduction

This document sets out the process by which surgeon and unit 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 hospitals / surgeons with indicator values that fall outside the expected range of performance (i.e. are flagged as an “outlier”).

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 funding is provided through the Healthcare Quality Improvement Partnership (HQIP), an arm’s length government organisation. HQIP acts as the data controller for the NVR and has responsibility for managing how NVR data are used. The NVR team act as agents for HQIP and are funded to undertake data collection, analysis and publication of results to agreed schedules.

Responsibility for data entry rests with local clinical vascular teams, supported by their NHS trust to ensure high quality data submission. Data collection for the index procedures (AAA repair, carotid intervention, and treatments for PAD) is currently provided through a bespoke online data collection tool, the NVD. This will be upgraded during 2013, and the NVR team is developing a new dataset to meet quality improvement and reporting standards. The NVR team will perform regular assessments of hospital performance by presenting casemix-adjusted outcomes on funnel plots for agreed measures. The measures will be selected from a variety of sources, such as the academic literature, NICE, and national commissioning targets. The results will be made publically available. Clinical teams will be given regular and sufficient notice of reporting schedules to allow them sufficient time to ensure that their data is up to date for each analysis and reporting cycle.

In addition to data analysis, the NVR team will also send to hospitals information on case ascertainment and coding quality, based on comparisons of NVR data with Hospital Episode Statistics (HES) data, or equivalent. NHS trusts have a duty to provide both HES and clinical audit data under national quality accounts.

Principles for managing providers identified as “outliers” on a performance indicator

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

1. Performance indicators

Performance indicators are intended to provide a valid measure of a provider’s (surgeon, unit or network) quality of care. For all major surgical procedures in the NVR, death will be an outcome measure. In addition, we will report stroke and cranial nerve injury rates following carotid surgery and amputation rates after lower limb revascularisation. Where appropriate, we will report process measures, such as the time from symptom to intervention for carotid surgery. We will also be reporting pathway progress for patients needing AAA repair and patients coming to intervention for PAD, particularly those with diabetic foot disease. It is intended that such indicators will provide information on service quality for the profession and the public.

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, clinical judgment (such as the standards outlined in VS quality improvement frameworks) or other audit data (e.g. from other national audits). 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 the funnel plots currently generated from NVD data.

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.

4. Case-mix (risk) adjustment

The comparison of outcomes across providers must take account of differences in the mix of patients treated by providers so that differences in outcomes are not due to the types of patient seen. This is achieved by adjusting the results for measurable factors that are associated with the performance indicator, such as age, sex, disease severity and co-morbidity.

The NVR will undertake casemix adjustment using validated statistical models. Where possible, we will use published risk-models such as the BAR score for elective AAA repairs. Some may be derived from within current datasets. We will publically report details of the risk-adjustment model and its performance characteristics. Judgment as to the adequacy of the model will depend on the performance indicator selected and the clinical context. It is not possible to provide universal, absolute values.

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 provider is a potential outlier. A statistical model will be used to define these limits using established methods. An outlier will be defined as a

surgeon/unit or network if values on an indicator are more than two standard deviations (SD) from the expected performance level. Those providers who fall between the 2 and 3 SD limits will be flagged as an ‘alert’. Provider values that are more than 3 standard deviations from the expected level will be deemed an ‘alarm’.

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 governance 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.
- Lead clinician in the provider unit: as the clinical lead for the team delivering care within the vascular unit under scrutiny.
- Provider clinical governance lead: responsible for clinical governance in the provider NHS trust

In addition, the provider Medical Director and Chief Executive may need to be involved.

The following table indicates the seven stages that may be needed in managing a potential outlier, the actions that need to be taken, the people involved and the time scale. It aims to be both feasible for those involved, fair to providers identified as potential outliers and sufficiently rapid so as not to unduly delay the disclosure of comparative information to the public.

Stage	What action?	Who?	Within how many working days?
1	<p>Providers with a performance indicator ‘alarm’ require careful scrutiny of the data handling and analyses performed to determine whether there is:</p> <p><u>‘No case to answer’</u></p> <ul style="list-style-type: none"> • potential outlier status not confirmed • data and results revised in NVR records • details formally recorded. <p><u>‘Case to answer’</u></p> <ul style="list-style-type: none"> • potential outlier status persists • <i>proceed to stage 2</i> 	NVR governance team	10

Stage	What action?	Who?	Within how many working days?
2	The Lead Clinician in the provider organisation is informed about the potential outlier status and requested to identify any data errors or justifiable explanation/s. All relevant data and analyses will be made available to the Lead Clinician. A copy of the request will also be sent to the Clinical Governance Lead of the provider organisation.	NVR Director and Clinical Lead	5
3	Lead Clinician to provide written response to NVR governance team.	Provider lead clinician	25
4	Review of Lead Clinician's response to determine: <u>'No case to answer'</u> <ul style="list-style-type: none"> It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data indicates provider is no longer an outlier. Data and results will be revised in NVR records. Details of the provider's response and the review result recorded. Lead Clinician notified in writing. <u>'Case to answer'</u> <ul style="list-style-type: none"> It is confirmed that, although the data originally supplied by the provider were inaccurate, analysis still indicates provider is an outlier; or It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status. <i>proceed to stage 5</i> 	NVR governance team	30
5	Contact Lead Clinician by telephone, prior to written confirmation of potential outlier status; copied to Provider clinical governance lead, Medical Director and Chief Executive. All relevant data and statistical analyses, including previous response from the lead clinician, made available to the Medical Director and Chief Executive.	NVR Director and Clinical Lead	5
6	Acknowledgement of receipt of the letter.	Provider chief executive	10
7	Public disclosure of comparative information that identifies providers (eg, in annual report of NVR).	NVR Project team	

Management of alert and alarm triggers.

Clinical teams and governance leads need to understand the meaning of these terms and the responses that they will require.

An “alert” indicates that the unit or surgeon has an indicator value (e.g., postoperative mortality rate) that is more than 2 SD from the expected level of performance. At this stage, the unit/NHS trust should divert sufficient time and resource to reviewing data and submitting more complete data to the NVR, if required. It is recommended that the NHS trust Clinical Governance team is involved at an early stage to provide assistance as required.

An “alarm” indicates that a unit or surgeon has an indicator value that is more than 3 SD from the expected level of performance. At this stage, the unit/trust should again invest the time and resource required to reviewing data and providing updated data to the NVR. In addition, consideration will be given to whether it is necessary to suspend the performance of certain index procedures. This will be more likely if poor performance is leading to significant patient harm. It is important to understand that these measures exist for patient safety and that such a suspension will be immediately withdrawn if it can be demonstrated after reviewing the data that performance was outside the “alarm” line because of data issues.

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. Concerns about clinical audit data (either case ascertainment or data quality) must be addressed by the unit/trust concerned. The role of the NVR is to provide consistent analysis and case mix adjustment of data received from units and to make reports on hospital describing the process and outcome of care publically available.

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 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.

Clinical Effectiveness Unit,

17 April 2013, version 1.0