NATIONAL EMERGENCY LAPAROTOMY AUDIT – OUTLIER POLICY

This is the Outlier Policy for the National Emergency Laparotomy Audit (NELA). It sets out the process by which participating **hospital** performance will be assessed and the process the NELA Project Team will follow to manage any **hospital** that is found to fall outside the expected range of performance and therefore flagged as an outlier.

This policy is drawn from the DH/HQIP "Detection and management of outliers. Guidance prepared by National Clinical Audit Advisory Group, 2011"

1. Performance Indicators

Performance indicators are intended to provide a valid measure of a provider's quality of care. NELA looks at structure, process and risk-adjusted outcome measures for the quality of care received by patients undergoing emergency laparotomy. These are drawn from standards of care such as those detailed in recent NCEPOD reports, and the Department of Health/Royal College of Surgeons of England's "Higher Risk General Surgical Patient (2011)". A full list of standards is provided on the NELA website at - http://nela.org.uk/article.php?newsid=1192
These indicators will include, but not be limited to, use of risk assessment, seniority of attending clinicians, critical care utilisation, length of hospital stay and mortality. It is intended that such indicators will provide information on service quality for patients, healthcare professionals, policy makers 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 standards and guidelines, research evidence, clinical consensus, or other audit data (e.g. from other national audits). This approach will predominantly apply to process measures, and will be based on the proportion of patients in that hospital who received care that met a particular standard.
In other circumstances, the expected level of performance will be derived from the NELA data, such that hospitals are compared against peers. This level will be calculated using statistical methods, and be presented using appropriate types of graphs, such as funnel plots. Such measures will be risk-adjusted for case-mix where appropriate.

At present, the only measure subject to the processes described in this outlier policy is risk-adjusted mortality.

3. Data Quality

We will report three aspects of data quality, namely:
• case ascertainment: this is the number of patients entered into the NELA compared to the estimated number eligible, derived by analysing external data sources such as Hospital Episode Statistics (HES) data. This will help to inform clinicians, commissioners and the public about the generalisability of the reported outcomes and to highlight hospitals where case reporting is incomplete.
• 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 ONS/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 incorrectly attributed to differences in care, when they are in fact dependent on differences between hospitals in the types of patient seen. This is achieved by adjusting for measurable factors that are associated with the performance indicator, such as age, sex, disease severity and co-morbidity.

5. Detection of a potential outlier

Statistically derived limits around the expected level of performance will be used to define whether or not a provider is a potential outlier. The magnitude of these limits will reflect the amount of uncertainty in the indicator estimated for each provider.

Potential outliers will be identified where indicators are more than a specified number of standard deviations (SD) from the expected performance level. Provider values that are more than 3 SD above the expected level will be flagged and are regarded as potential "outliers". Those providers who fall between the 2 and 3 SD limits above the mean value will be considered as an 'alert'. These thresholds are consistent with common practice.

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. There will be some hospitals whose caseload is very low, such that it will not be possible to produce statistically robust performance indicators at hospital level. The minimum caseload will be determined by appropriate statistical methods.

6. Management of a potential outlier

The management of a potential outlier involves various people:

- The NELA Project Team: the team responsible for managing and running the audit nationally. This comprises the Chair of the Audit, Clinical Lead and the team responsible for managing and running the audit nationally.
- Project Board: This includes Chair of the Project Board and will oversee strategic direction and be responsible for monitoring all aspects of delivery of the project.
- NELA local site leads: These are the Surgeon, Anaesthetist and Clinical Audit Department leads for the Audit locally.
- In addition, the provider Medical Director and Chief Executive may need to be involved.

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. The process applies to

providers flagged as a potential "outlier" in the initial analysis. If after a review of their data, their level of performance is still beyond the 3 SD control limit, the provider will be flagged as an outlier. This process also applies to providers on the second occasion that their risk-adjusted outcomes are above 2 SD within 3 reporting cycles, termed "double-alert hospitals".

Stage	Action	Who?	Within how many working days?
1	Providers with a performance indicator suggesting "outlier/double-alert" status require careful scrutiny of the data handling and analyses performed to determine whether there are: **'No outliers identified'** • potential outlier/double-alert status not confirmed • data and results revised in NELA records • details formally recorded **'Potential outliers identified '** • potential outlier/double-alert status persists • proceed to stage 2	NELA Project Team	10
2	The Lead Clinician in the provider organisation is informed about the potential outlier/double-alert 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.	NELA Project Team NELA National Clinical Lead	5
3	Lead Clinician to provide written response to NELA Project Team.	NELA Local Leads	25
4	Review of Lead Clinician's response to determine: **'No outliers identified'** • It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data indicates that the level of performance is now within the 3 SD/2 SD control limits, and the provider is not flagged as an outlier/double-alert (as appropriate).	NELA Project Team	30

	• Data and results will be revised in NELA records. Details of the provider's response and the review result recorded. • Lead Clinician notified in writing. **'Outliers confirmed'** • 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 3 SD/2 SD control limits, and the provider is an outlier/ double-alert (as appropriate); or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of "outlier/double-alert" status and that the provider is in fact an outlier/ double-alert (as appropriate). • NELA will notify appropriate authorities of potential outlier status. • proceed to stage 5		
5	Contact Lead Clinician by telephone, prior to written confirmation of outlier status; copied to provider Clinical Governance Lead, Medical Director and Chief Executive. Medical Director and Chief Executive will be requested to undertake a local investigation according to DH "Detection and management of outliers" document. All relevant data and statistical analyses, including previous response from the Lead Clinician, made available to the Medical Director and Chief Executive. Chief Executive advised to inform relevant bodies about NELA's concerns, and that NELA will proceed to publishing information of comparative performance that will identify providers.	NELA Project Team NELA National Clinical Lead	5
6	Acknowledgement of receipt of the letter. NELA Project Team will send a reminder after 5 days if not received by then.	Provider Chief Executive	10
7	Public disclosure of comparative information that identifies providers (e.g., NELA report).	NELA Project Team	

7. Management of "alert" and "outlier" 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 hospital site has a risk adjusted outcome that is between 2 and 3 SDs above the expected level of performance. "Alert" providers will be notified of their status, and we would recommend that they perform an internal review of their care provision. Providers flagged as "alerts" in a single reporting cycle will not be subject to the review process as outlined in section 6. Providers will be subject to the process outlined in section 6 on the second occasion that they exceed the 2 SD threshold within 3 reporting cycles (termed "double-alert hospitals").

An "outlier" indicates that a hospital site has a risk-adjusted outcome that is more than 3 SD from the expected level of performance. As outlined in section 6, the unit/trust should invest the time and resource required to reviewing data and providing updated data to the NELA.

Hospital sites should be aware that while the NELA has a duty to report on the data it holds, the NELA is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the clinical teams/sites/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. The role of the NELA is to provide consistent analysis and case mix adjustment of data received from units and to make reports on the process and outcome of care publically available.

The role the NELA Project Team

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

Hospital sites or clinicians with concerns about data quality are urged to contact the NELA Project Team at the Royal College of Anaesthetists at the earliest opportunity to discuss them.