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, May 2017". I accordance with HQIP's instructions, it comes onto force on 1st November 2017, for data collected after 1st November 2016. As such, it applies to NELA patient data collected in Year 4 (between 1st December 2016 and 30th November 2017).

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.

Statistically derived limits around the target (expected) performance will be used to define if a provider is a potential outlier: more than two standard deviations from the target is deemed an 'alert'; more than three standard deviations is deemed an 'alarm'. Potential outlier status is defined as:

- Hospitals flagged as "alarm" in a single reporting period. NELA calls these "alarm level outliers".
- Hospitals flagged as "alerts" or "alarms" twice within 3 consecutive reporting cycles. NELA calls these "double-alert level outliers".

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.

- The provider Medical Director and Chief Executive will need to be involved in ensuring that an appropriate review is undertaken locally.
- CQC – The Care Quality Commission will also be notified at specific times of the process as required by the Detection and management of outliers for National Clinical Audits document. CQC are included in the guidance so as to provide them with assurance that organisations are engaging appropriately in the process. The CQC will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process at alert and alarm level.

The following table indicates the eight 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 "alarm level outlier". This process also applies to providers on the second occasion that their risk-adjusted outcomes are above 2 SD within 3 consecutive reporting cycles, termed "double-alert level outliers".

Stage	Action	Who?	Within how many working days?
1	Providers with a performance indicator suggesting outlier status require careful scrutiny of the data handling and analyses performed to determine whether there are: **'No outliers identified'** • potential alarm level/double-alert level outlier status not confirmed • data and results revised in NELA records • details formally recorded **'Potential outliers identified '** • potential alarm level/double-alert level outlier status persists • proceed to stage 2	NELA Project Team	10
2	The Lead Clinician in the provider organisation is informed about the potential alarm level/double-alert level 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. In the case of "double-alert level outliers", this will include all data covering the	Clinical lead Clinical governance lead CEO Medical Director	5

	relevant periods, not just the most recent. A copy of the request will also be sent to the Clinical Governance Lead, Chief Executive and Medical Director of the provider organisation. Experience has shown that early involvement of the senior organisational leadership is important in driving engagement locally.		
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 no longer indicates alarm level/double-alert level outlier status. • 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 copying in provider organisation CEO and Medical Director. **'Outliers confirmed'** • It is confirmed that, although the data originally supplied by the provider were inaccurate, analysis still indicates alarm level/double-alert level outlier status; or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of alarm level/double-alert level outlier status. • proceed to stage 5	NELA Project Team	20

5	Contact Lead Clinician by telephone, prior to sending written confirmation of alarm level/double-alert level outlier status to CEO copied to Lead Clinician and Medical Director. All relevant data and statistical analyses, including previous response from the Lead	NELA Project Team NELA National Clinical Lead	5

	Clinician, made available to the Medical Director and CEO. In case of alarm level/double-alert level outlier status, NCA supplier to inform CQC[1] and Provider CEO advised to inform commissioners, NHS Improvement[2] and relevant royal colleges. CEO informed that the NCA supplier will be publishing information of comparative performance that will identify providers.		
6	Provider response regarding outlier notification: - Acknowledgement of receipt of the letter. - Confirmation that a local investigation will be undertaken with independent assurance of the validity of this exercise for alarm level/double-alert level outliers - Provider to copy letter to the CQC[1] NELA Project Team will send a reminder after 5 days if not received by then.	Provider Chief Executive	10
7	If no acknowledgement received, a reminder letter will be sent to the CEO, copied to CQC[1]. If not received within 5 working days, CQC[1] and NHS Improvement[2] notified of non-compliance.	NELA Project Team	5
8	Public disclosure of comparative information that identifies providers (e.g., NELA report). **Action for non-compliant providers:** Notify CQC[1] and NHS Improvement[2] that a provider has not complied with their obligations under the guidance.	NELA Project Team	

7. 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 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 (via CEO, Medical Director, and local NELA leads), 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 level outliers").

An "alarm" 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 for both alarm-level and double-alert level triggers.

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 "alarm" and "double-alert level " 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.

[1] clinicalaudits@cqc.org.uk

[2] nhsi.medicaldirectorate@nhs.net