NATIONAL EMERGENCY LAPAROTOMY AUDIT – OUTLIER POLICY
Updated July 2023

This is the Outlier Policy for the National Emergency Laparotomy Audit (NELA). It will apply from the beginning of NELA Year 10 (1st April 2023) onward. 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 HQIP Outlier Guidance document.

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 "Updated recommendations for the perioperative care of the High Risk General Surgical Patient (2018)". A full list of standards is provided on the NELA website at - https://www.nela.org.uk/Standards-Documents#pt. 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. (*Risk Adjustment information can be found under Technical documents on the NELA Website - https://www.nela.org.uk/reports*)

At present, the only measure subject to the processes described in this outlier policy is risk-adjusted mortality. However, we cannot provide assurance on the quality of care delivered by providers who have submitted insufficient data, or whose case ascertainment is too low to permit risk adjustment calculations. These providers are considered to potentially meet outlier status.

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. (a) Detection of a potential outlier in risk adjusted mortality performance

Statistically derived limits around the target (expected) performance will be used to define if a provider is a potential outlier: a provider with adjusted mortality rate above the upper 95% control limit meets 'alert' status; a provider above the upper 99.8% control limit meets 'alarm' status (this roughly corresponds to control limits of two standard deviations and three standard deviations from the target, respectively). Potential outlier status is defined as:

- Hospitals flagged as "alarm" status in a single reporting period. NELA calls these "alarm level outliers".
- Hospitals flagged as "alert" status for the current year, and also an alert or alarm status in either of the previous two consecutive reporting cycles. NELA calls these "double-alert level outliers".
- Hospitals flagged as "alert" status in a single reporting period are termed "single-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.

5. (b) Detection of a potential outlier in case ascertainment

i) Providers who are red, amber, green (RAG) rated as 'red' on case ascertainment (<55%) will be considered outliers for case ascertainment.

ii) Providers who have submitted insufficient data for risk adjustment mortality calculations to be performed are considered potential outliers for case ascertainment. Sites who perform fewer than 10 included procedures/year are excluded from this calculation. The percentage case ascertainment threshold required for mortality calculations varies depending on the volume of cases at that site, however it is not possible to identify the required percentage in advance. Hence providers should ensure that their case ascertainment is as high as possible. A site will

therefore be listed as an outlier for case ascertainment if they submit insufficient data to perform risk adjusted morality calculations.

Sites are encouraged to review their projected case ascertainment figures in the regular data summaries produced here, and to use the data available on the QI dashboards on the webtool to ensure their data entry and case ascertainment do not fall below expected levels. The outlier policy on case ascertainment may not be applied where there are concerns over the accuracy of case ascertainment calculations. It would be expected that such concerns will have been raised throughout the audit year, rather than at the end of the audit year. The process for addressing case ascertainment queries is outlined at https://www.nela.org.uk/Case-Ascertainment-Queries#pt

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 Leads 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 local clinical leads and clinical audit department leads for the audit within each participating hospital.
   - 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) and Welsh Government will also be notified at specific times of the process as required by the Outlier Management for National Clinical Audits document (https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/#.YKI2M6hKg2w). CQC and Welsh Government are included in the guidance so as to provide them with assurance that organisations are engaging appropriately in the process. The CQC and Welsh Government will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process at alert and alarm level.

a) The following table indicates the stages that will be followed in managing a potential outlier **in risk adjusted mortality performance**, 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 for risk adjusted mortality 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 standard deviation 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 standard deviations within the current and either of the previous two consecutive reporting cycles, termed "double-alert level outliers". Based on updated guidance from HQIP, any hospital whose risk-adjusted outcomes are above 2 standard deviations within the current reporting cycle only (single alert status) will be escalated to CQC and HQIP, however, these

hospitals are not subject to a formal trust notification or response process as outlined in the table below. CQC will include such information as part of their 'soft' intelligence and it may come up in a trust inspection.

Stage	Action	Who?	Within how many working days?
1	Providers with a performance indicator suggesting outlier status for risk adjusted mortality 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 for risk adjusted mortality persists • proceed to stage 2	NELA Project Team	10
2	The NELA Lead Clinician in the provider organisation is informed about the potential alarm level/double-alert level outlier status for risk adjusted mortality 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 relevant periods, not just the most recent. A copy of the request will also be sent to the 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.	NELA Clinical lead CEO Medical Director	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:	NELA Project Team	20

	'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, including 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		

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 Clinician, made available to the Medical Director and CEO. In case of alarm level/double-alert level outlier status, NELA to inform **CQC[1], HQIP[2], and Welsh Government** of confirmed status. CEO informed that the NELA will be publishing information of comparative performance that will identify providers.	NELA Project Team	5
6	Provider response regarding outlier notification: - Acknowledgement of receipt of the letter. - Confirmation that a local investigation will be undertaken, with independent	Provider Chief Executive	10

	assurance of the investigation's validity, copying letter to the CQC[1] and Welsh Government		
7	If no acknowledgement received, a reminder letter will be sent to the CEO, copied to CQC[1], HQIP[2], and Welsh Government. If not received within 15 working days, CQC[1] and Welsh Government notified of non-compliance in consultation with HQIP.	NELA Project Team	15
8	Public disclosure of comparative information that identifies providers (e.g. NELA report). **Action for non-compliant providers:** Notify CQC[1] and Welsh Government that a provider has not complied with their obligations under the guidance.	NELA Project Team	

(b) Due to the timescales required for data linkage with external data sources, it is not possible to retrospectively review data after a site is flagged as an outlier for case ascertainment. Therefore, providers should examine the case ascertainment figures that are shared with them in their quarterly performance reports and seek to address any deficits prior to the calculation of outlier status at the time of the annual report. The process for addressing case ascertainment calculation queries is outlined at https://www.nela.org.uk/Case-Ascertainment-Queries#pt

Providers will be notified of their outlier status for case ascertainment as per stage 5 onwards of the process above.

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 the upper 95% and upper 99.8% control limit relating to the expected level of performance. "Alert" providers will be notified of their status (via CEO, Medical Director, and local NELA leads), and NELA 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 upper 95% control limit within the current and either of the previous two reporting cycles (termed "double-alert level outliers").

An "alarm" indicates that a hospital site has a risk-adjusted outcome that is above the upper 99.8% control limit relating to 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, 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 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 publicly 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] HQIP PM and AD