**National Bowel Cancer Audit (NBOCA)**

**Detection and management of outliers**

**Purpose**

A potential outlier is a result that is further from the overall average value than would usually occur by chance alone.

This policy sets out the actions that NBOCA takes when data indicate that results for a Trust/MDT or consultant significantly deviate from the expected value for outcomes published as part of the Annual Report and/or Clinical Outcomes Publication. There is a separate policy for each below, starting with the Annual Report Publication Outlier Policy.

The inclusion criteria for each outcome is updated annually and published separate alongside this policy at <https://www.nboca.org.uk/resources/>

**Changes to the outlier policy**

We keep our outlier policy under regular review and we will always include the latest version on this web page.

The outlier policy was last updated on 06/09/2021.

**Contact us**

If you have any feedback or questions about this policy please contact the NBOCA Project Team via email: bowelcancer@nhs.net

**Annual Report Publication Outlier Policy**

**Key information**

The NBOCA Annual Report is an annual report of comparative patient outcomes reported by English NHS Trust/ Welsh MDT. This policy relates to the measures used for outlier reporting by NBOCA as part of the Annual Report.

Potential outliers are assessed on the following quality indicators at Trust/MDT level only:

This policy is based on HQIP’s Detection and Management of Outliers for National Clinical Audits: <https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/#.X19s63lKjIW>

**90 day post-operative mortality**

The outcome measure assessed for this publication is the 90-day mortality rate following major surgery to remove bowel cancer – that is the proportion of patients undergoing surgery (regardless of urgency or curative intent) who die from any cause within 90 days of their operation.

**30 day unplanned readmission**

Following discharge a number of patients will develop complications that can only be managed in secondary care, and require admission to hospital. This metric reflects this and is the proportion of patients undergoing major surgery to remove their bowel cancer who have an emergency readmission to hospital within 30 days.

**2 year post-operative mortality**

Two year mortality is analysed as the most common time for colorectal cancer to return is within the first two years after surgery. Patients are followed from the time of major surgery (regardless of urgency or curative intent) until death or for two years. The outcome assesses the number of patients who died within 2 years divided by the sum of the amount of time each patient was followed for. This means that the estimate compares not just the proportion of patients who died within 2 years but also how quickly they died.

**Data quality review process**

Each year the NBOCA team work with trusts to support them to review their data quality and completeness for the audit data used in each of the outlier-reported quality indicators. Following linkage of the audit data to Hospital Episode Statistics data and ONS mortality data, each trust is sent summaries of their data along with guidance on areas to check. They have the opportunity to improve completeness of data (e.g. staging data) before the final data submission deadline but any new patients added at this stage will not be included as they will not be linked to ONS mortality data or Hospital Episode Statistics data.

Following this data quality review process and the final submission deadline, the NBOCA team extracts the final dataset for use in the COP and Annual Report analysis. At this point potential outliers are formally identified.

**Definition of an Alarm:**

An estimate more than three standard deviations above the mean is deemed to be an alarm and the Trust/MDT will be required to undergo the outlier process shown set out below.

**Definition of an Alert:**

An estimate more than two but below three standard deviations above the mean is deemed to be an alert.

**Definition of a potential outlier:**

Providers flagged as an alarm are considered potential outliers. For outcomes with a one-year reporting period (90-day postoperative mortality, 30-day readmission, 2-year mortality), providers more than two standard deviations above the mean twice in three consecutive years are also considered potential outliers.

In addition, providers with fewer than 10 linked surgical cases in the analysis extract (and where this is fewer than expected), or with insufficient data for risk adjustment (overall data completeness less than 20% or ASA grade and/or TNM stage missing in more than 80% of patients) are also considered potential outliers.

**Process and Timeframes**

The following actions and timeframes are actioned in the application of this policy:

|  |  |  |  |
| --- | --- | --- | --- |
| **Stage** | **What action?** | **Who?** | **Within how many working days?** |
| 1 | Potential outliers require careful scrutiny of the data handling and analyses performed to determine whether there is:‘No case to answer’• potential outlier status not confirmed• data and results revised in NBOCA records• details formally recorded‘Case to answer’• potential outlier status*Proceed to stage 2* | NBOCA team | 10 |
| 2 | Healthcare provider Lead Clinician informed about the potential outlier status and requested to identify any data errors or justifiable explanation/s. All relevant data and analyses should be made available to the Lead Clinician.A copy of the request must be sent to the provider organisation CEO and Medical Director. | NBOCA Clinical lead | 5 |
| 3 | Lead Clinician to provide written response to NBOCA which will be published in the Annual Report (see stage 8).Any corrections to data errors should be signed off by the Medical Director. | Provider Lead Clinician | 25 |
| 4 | Review of Lead Clinician’s response to determine:‘No case to answer’• It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data no longer indicates outlier status.• Data and results should be revised in NBOCA records. •Lead Clinician notified in writing copying in provider organisation CEO and Medical Director.‘Case to answer’• It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates outlier status; or• It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status.*proceed to stage 5* | NBOCA team | 20 |
| 5 | Offer Lead Clinician the opportunity to speak by telephone with the NBOCA Clinical Lead, prior to sending written confirmation of 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.NBOCA will inform the CQC (English Trusts)/ Welsh Government (Welsh MDTs) along with HQIP.CEO informed that the NBOCA will be publishing information of comparative performance that will identify providers. | NBOCA Clinical lead | 5 |
| 6 | Acknowledgement of receipt of the letter confirming that a local investigation will be undertaken with independent assurance of the validity of this exercise, copying in the CQC/ Welsh Government. | Provider CEO | 10 |
| 7 | If no acknowledgement received, a reminder letter should be sent to the CEO, copied to CQC/ Welsh Government. If not received within 15 working days, CQC/ Welsh Government notified of non-compliance, in consultation with HQIP. | NBOCA team | 15 |
| 8 | Public disclosure of comparative information that identifies providers.The written response from each potential outlier should be published in the Annual Report. Where re-analysis of corrected data has been carried out this should be stated, as well as confirmation as to whether or not outlier status persists. | NBOCA team |  |

**Clinical Outcomes Publication Outlier Policy**

The Clinical Outcomes Publication (COP) is a national programme of comparative patient outcomes reported by hospital trust and consultant **in England**. This policy relates to the measures used for outlier reporting by NBOCA only as part of COP.

This policy is based on the Outlier Management Checklist in HQIP’s Clinical Outcomes Publication Technical Manual which is accessible from: <https://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual/>

Potential outliers are assessed at **consultant and trust level** on the following quality indicator:

**90 day post-operative mortality**

The outcome measure associated with this publication is the 90-day mortality rate following planned removal of bowel cancer – that is the proportion of patients undergoing elective or scheduled surgery who die from any cause within 90 days of their operation.

**Data quality review process**

Each year the NBOCA team work with trusts to support them to review their data quality and completeness. Following linkage of the audit data to Hospital Episode Statistics data and ONS mortality data, each trust is sent summaries of their data and initial 90 day post-operative mortality results by consultant and for the trust as a whole, along with guidance on areas to check. They have the opportunity to improve completeness of data (e.g. staging data) before the final data submission deadline but any new patients added at this stage will not be included as they will not be linked to ONS mortality data.

Where the trust result or that of individual surgeons working at the trust are 2 standard deviations above the mean in the 90 day mortality measures, the NBOCA team writes to them specifically to flag this and recommends that they review their data before the final submission deadline. This effectively provides trusts with an early indication that they could be a potential outlier.

Following this data quality review process and the final submission deadline, the NBOCA team extracts the final dataset for use in the COP and Annual Report analysis. At this point potential outliers are formally identified.

**Definition of an Alert/Alarm:**

An estimate more than three standard deviations above the mean is deemed to be an alarm. An estimate more than two but below three standard deviations above the mean is deemed to be an alert.

**Definition of a potential outlier**

Providers flagged as an alarm are considered potential outliers.

**Process and Timeframes**

The following actions and timeframes are actioned in the application of this policy:

|  |  |  |  |
| --- | --- | --- | --- |
| **Stage**  | **Action Required**  | **Who?**  | **Timing (max working days)**  |
| **1**  | When an individual flags up with one or more of their performance indicators as a potential outlier (positive or negative), these should lead the NCA provider to carefully scrutinise the data (to ensure the validity of the statistical results, taking into account statistical threshold levels, data accuracy and risk adjustment). Where potential outlier status is not confirmed data and results should be revised in NCA records and the details formally recorded. When, after further scrutiny, potential outlier status persists proceed to stage 2.  | NBOCA team | 10  |
| **2**  | The lead clinician in the Trust for that department and the individual involved should be informed by phone about the potential outlier status and requested to confirm, again, that the data submitted was complete, accurate and validated. They are asked to identify any data errors or justifiable explanations for a negative potential outlier and reasons why the results might be better than average for a positive potential outlier. All relevant data and analyses should be made available to the lead clinician and individual. A follow up letter of the request should be sent to the medical director and chief executive of the provider organisation, copied to the department clinical lead, clinician, setting out concerns.  | NBOCA clinical lead | 5  |
| **3**  | For negative potential outliers, the department lead clinician, in conjunction with the individual clinician, should provide a written response to the NBOCA clinical lead with a copy to the Trust medical director and chief executive. This response will be published alongside the provider’s outcomes. Any corrections to data errors should be signed off by the Medical Director. For positive potential outliers a written response is invited but not required.Negative potential outliers: proceed to stage 4. | Provider lead clinician  | 25  |
| **4**  | Review of lead clinician’s response to determine:**‘Following review, no remaining concerns’*** It is confirmed that the data originally supplied by the provider contained inaccuracies. Reanalysis of accurate data no longer indicate potential outlier status \*
* Data and results should be revised in NBOCA records. Details of the provider’s response and the review result recorded
* Lead clinician and medical director notified in writing
* Request from the NBOCA lead to Trust lead clinician as to why the original data was inaccurate and what had been put in place to prevent a re-occurrence

**‘Following review, concerns remain’** * It is confirmed that although the data originally supplied by the provider was inaccurate, analysis still indicates potential outlier status; or
* It is confirmed that the originally supplied data was accurate, thus confirming the initial designation of potential outlier status

*Proceed to stage 5*  | NBOCA clinical lead  | 30  |
| **5**  | Contact lead clinician and individual by telephone, prior to written confirmation of potential outlier status, addressed to the chief executive and medical director, copied to the Trust lead clinician and individual clinician. In the case of a negative outlier, all relevant data and statistical analysis, including previous response from the lead clinician, made available to the medical director and chief executive. We would expect that the medical director and departmental clinical lead would initiate a local review and might wish to triangulate this information with other governance information to see if any further action is required. The medical director/chief executive should be advised, to inform the GMC Employment Liaison Adviser (ELA). The medical director/chief executive should be informed that the NBOCA supplier will proceed to publishing information of comparative performance that will identify individuals and providers including outliers. In the case of a positive outlier, discussion as to possible explanations and whether there are any aspects of individual or local practice that might be shared and/or celebrated.  | NBOCA clinical lead  | 5  |
| **6**  | Acknowledgement of receipt of the letter, and, in the case of a requirement to inform the ELA, confirmation that this has taken place.  | Provider medical director/chief executive  | 10 |
| **7**  | Public disclosure of comparative information that identifies outlier status. †*not to be delayed by a failure of a provider organisation to comply with timescales of the outlined process* | NBOCA clinical lead  | Timetable determined by NBOCA PT† |
| **8**  | If non compliance with point 6, reminder letter to be sent to chief executive/medical director.  | NBOCA clinical lead  | Within 5 working days of Stage 6 deadline expiry  |
| **9**  | Failure of the chief executive/medical director to comply with point 6 would lead the NBOCA lead to disclose non compliance to the GMC and CQC in consultation with HQIP medical director.  | NBOCA clinical lead in conjunction with HQIP medical director  | 15 |

\* Under exceptional circumstances, e.g. large discrepancy in the number of cases submitted to NBOCA and that performed, the audit may accept confirmation of mortality status from the Trust, signed off by the Medical Director.