National Bowel Cancer Audit – Outlier policy

Introduction

This document sets out the process by which surgeon and unit level performance will be assessed within the National Bowel Cancer Audit (NBOCA).

It is designed to provide transparency about how comparative performance indicators will be presented, and describe the 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. In addition, revalidation will require clinicians to demonstrate acceptable clinical performance.

The responsibility for maintaining and providing accurate data rests with units/ Trusts and individual clinicians. Trusts should ensure that that the coding is correct and complete data is submitted.

To support clinicians in this requirement, the Department of Health has funded various national clinical audits, including the National Bowel Cancer Audit. This audit is run as a partnership between Association of Coloproctology and the Health and Social Care Information Centre.

NBOCA uses various metrics to describe the practice and outcomes of colorectal cancer care. These have been reported by Cancer Networks, and NHS trusts. From 2013, the postoperative outcomes of elective surgical resections performed with curative intent will also be published at consultant-level.

Comparative performance measures are provided on various indicators. For surgical outcomes, these indicators are related to monitoring safety and we examine these outcomes using casemix-adjusted indicators and funnel plots to identify units with unexpectedly high or low outcomes.
Principles for managing providers identified as “outliers” on a performance indicator

The guiding principles adopted by the National Bowel Cancer Audit are outlined below. They are based on established principles and are consistent with the DH/HQIP outlier management policy. Information on selected indicators will be made 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 elective surgical resections with a curative intent, 90 day postoperative mortality will be the outcome measure used to assess performance.

Over time, the Audit may report comparative performance on other measures. We will communicate with providers our intention to adopt other measures prior to publishing this information.

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 or other audit data (e.g. from other national audits). In general, we expect to define the performance target for indicators such as postoperative mortality from the NBOCA data. We will define the target (or expected level of) performance to be the average for England and Wales.

3. Data quality
We will report three aspects of data quality, namely:

- case ascertainment: This is the number of patients entered into the Audit 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 casemix analysis and reporting. Without complete data, such adjustments 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.

NBOCA will undertake casemix adjustment using appropriate statistical models. 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.
5. Detection of a potential outlier
Statistically derived limits around the expected level of performance (e.g. mean postoperative mortality) will be used to identify whether or not a provider is a potential outlier. The limits will be shown on a funnel plot and will be derived using established statistical methods.

Two sets of limits will be defined. The first (inner) limit will indicate whether an indicator value for a provider is more than two standard deviations from the expected performance level. The second (outer) limit will indicate whether an indicator value for a provider is more than three standard deviations from the expected 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’, and labelled as an “outlier”.

It is important to note that these are definitions of statistically significant differences from expected performance. In some circumstances, statistically significant differences may not be clinically important, especially if the indicator value is based on large numbers of patients. In such circumstances, 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 NBOCA project team: the team responsible for managing and running the audit nationally.
- Lead clinician in the provider unit: as the clinical lead for the team delivering care within the identified provider.

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 when a provider is identified as having unexpected outcomes (i.e., is an outlier). The table describes the actions that need to be taken, the people involved and the time scales. 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.
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<th>Stage</th>
<th>What action?</th>
<th>Who?</th>
<th>Working days</th>
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| 1     | Providers with a performance indicator ‘alarm’ require careful scrutiny of the data handling and analyses performed to determine whether there is:  
• ‘No evidence of being an outlier’  
  • potential outlier status not confirmed  
  • data and results revised in NBOCA records  
  • details formally recorded.  
• procedure ends.  
• ‘Evidence of outlier status remains’  
  • potential outlier status persists  
  • proceed to stage 2                                                                 | NBOCA project team                        | 10           |
| 2     | For outliers at unit level, 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.  
For outliers at consultant-level, the consultant is additionally informed.  
Relevant data and analyses will be made available to the Lead Clinician (and consultant as required). | NBOCA team and provider Clinical Lead     | 5            |
<p>| 3     | Lead Clinician / consultant to provide written response to NBOCA about reasons for the outlier status. Revised data will be provided if appropriate.                                                   | Provider lead clinician                   | 21           |</p>
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| 4     | Review of Lead Clinician’s response to determine:  
  ‘No evidence of being an outlier’  
  • 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 NBOCA records. Details of the provider’s response and the review result recorded.  
  • Lead Clinician notified in writing.  
  • process ends  
  ‘Evidence of outlier status remains’  
  • 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.  
  • proceed to stage 5 | NBOCA project team | 21 |
| 5     | Contact Lead Clinician by telephone, prior to written confirmation of potential outlier status; copied to Medical Director and Chief Executive.  
For outliers at consultant-level, the consultant is additionally CONTACTED prior to written confirmation.  
All relevant data and statistical analyses, including previous response from the lead clinician, made available to the Medical Director and Chief Executive. | NBOCA project team and provider Clinical Lead | 5 |
| 6     | Acknowledgement of receipt of the letter. | Provider chief executive | 10 |
| 7     | Public disclosure of comparative information that identifies providers (e.g., in annual report). | NBOCA 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., 90 day postoperative mortality rate) that is more than 2 SD from the expected level of performance. At this stage, the unit/Trust should divert sufficient time and resource to reviewing data and submitting more complete data to the National Bowel Cancer Audit. 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 National Bowel Cancer Audit.

The role of the National Bowel Cancer Audit

The primary role of the National Bowel Cancer Audit is to provide regular information about practice and outcomes that will help to improve the quality of clinical care. It will undertake appropriate analysis of data received from units and make reports describing the process and outcome of care publicly available.

Units should be aware that, while the National Bowel Cancer Audit has a duty to report on the data it holds, and support Units to submit accurate data, the Audit is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the clinical teams/units/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.

It is anticipated that “alerts” and “alarms” will be triggered rarely. When such triggers occur, the NBOCA team will provide help to providers wanting to review data entry and quality. Units or clinicians with concerns about data quality are urged to contact the NBOCA team at the earliest opportunity to discuss them.