NOGCA | National Oesophago-Gastric Cancer Audit

NOGCA Outlier policy

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The National Oesophago-Gastric Cancer Audit is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing, and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some with some individual projects, other devolved administrations and crown dependencies www.hqip.org.uk/national-programmes.

Introduction

This is the Outlier Policy for the National Oesophago-Gastric Cancer Audit (NOGCA) and sets out the process by which participating NHS Trusts / Welsh Health Boards' performance will be assessed. It also applies to consultant surgeons participating in the clinical outcomes programme. It is designed to provide transparency about how performance indicators covered by the outlier policy will be presented, and to describe the process for managing NHS organisations / surgeons with indicator values that fall outside the expected range of performance (i.e, are flagged as an "outlier").

This outlier policy is used in conjunction with those indicators for which performance outside the expected range raises concerns about the safety of the care provided. Not all of the indicators used by NOGCA fall within the scope of this policy.

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 requires doctors to demonstrate acceptable clinical performance.

The Medical Director of the NHS has emphasised that the responsibility for maintaining and providing accurate data rests with individual clinicians both in terms of the coding of their work and the submission of clinical data to national datasets, where available. To support clinicians in this requirement, HQIP on behalf of NHS England and the Welsh Government have funded various national clinical audits, including the National Oesophago-Gastric Cancer Audit. This Audit is run as a partnership between Association of Upper GI Surgeons, the British Society of Gastroenterologists, the Royal College of Radiologists, the Clinical Effectiveness Unit (CEU) at the Royal College of Surgeons of England, and NHS Digital.

NOGCA uses various indicators to evaluate the practice and outcomes of oesophago-gastric cancer care. These have been reported by Cancer Alliance / Welsh regions and NHS organisations (trusts / local health boards). From 2013, the postoperative outcomes of elective surgical resections performed with curative intent have also been published for consultants working in English NHS trusts.

The performance of NHS organisations providing OG cancer care can be benchmarked on various NOGCA 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 organisations with unexpectedly high or low outcomes.

Details of process and outcome indicators are published on the NOGCA website, along with the corresponding datasets (https://www.nogca.org.uk/).

Principles for managing providers identified as "outliers" on a performance indicator

The guiding principles adopted by the National Oesophago-Gastric Cancer Audit are outlined below. They are based on established practices and are consistent with the DH/HQIP outlier management policy. Information on selected indicators are made publically available and included in audit reports.

1. Performance indicators

Performance indicators are intended to provide a valid measure the quality of care delivered by a health care provider (surgeon or NHS organisation or Cancer Alliance).

This outlier policy applies to short-term postoperative mortality after an elective surgical resection among OG cancer patients treated with curative intent. Postoperative mortality is a common measure used to assess surgical performance, and is an important measure of patient safety.

The Audit will periodically review the scope of this policy with its clinical reference group. We will communicate with NHS providers our intention to extend the policy to other indicators 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, an agreed standard, or other audit data (e.g. from other national clinical audits). In general, we expect to define the performance target for indicators such as postoperative mortality from the NOGCA data. We will define the target (or the expected level of) performance to be the average for England and Wales.

3. Data quality

Alongside the performance indicator, the NOGCA will report two aspects of data quality, namely:

- *case ascertainment*: This is the number of patients entered into the Audit compared to the number eligible (estimated from an external data source). 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 analysis and reporting. Without complete data, there is a chance that risk adjusted indicator values may not describe practice accurately.

If an NHS organisation has data of insufficient quality, the outcome will be replaced with a statement about their poor data quality in the publication. The organisation will be automatically be considered an outlier.

NOGCA collates data on patients with OGC cancer from various sources. The primary data is submitted by English NHS trusts and by the Welsh Cancer Network for Welsh Health Boards. Patient information is also supplied by NHS Digital. The data are checked for completeness and accuracy by the NOGCA team when being prepared for statistical analysis. However, the responsibility for the accuracy and completeness of the patient data rests with the NHS organisations that submit records to the Audit as well as NHS Digital and the Welsh Cancer Network. Providers that do not meet the minimum standards required for the analysis.

4. Case-mix (risk) adjustment

The comparison of outcomes across health care providers must take account of differences in the mix of patients treated by NHS 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, and disease severity.

The Audit will produce risk-adjusted outcomes by using appropriate statistical models. The models will be assessed in terms of their power of discrimination (eg, that the model correctly identifies low-risk and high-risk patients) and calibration (how well the model predictions agree with the observed data). Judgment about the adequacy of a risk adjustment model will depend on the performance indicator selected and the clinical context.

5. Detection of a potential outlier

The first step in the process used to identify whether or not a provider is a potential outlier will assess whether its indicator value falls within the expected level of performance. This region is defined using statistically derived control limits which lie either side of the average postoperative mortality. The assessment will be based on the most recent audit period. For the 2019 Annual Report and 2019 Clinical Outcomes Programme, this corresponds to patients diagnosed between April 2015 and March 2018 for organisational level statistics, and patients diagnosed between April 2013 and March 2018 for consultant level figures. The indicator values for both organisations and consultants will be shown on a funnel plot.

The assessment of performance will involve using two sets of control limits. The first (inner) limit will indicate whether an indicator value for an NHS provider is more than two standard deviations from the expected performance level; this might happen because of random variation every 1 in 20 occasions. The second (outer) limit will indicate whether the value for a provider is more than three standard deviations from the expected level; this might happen because of random variation every 1 in 500 occasions.

Provider values that are more than 3 standard deviations from the expected level will be deemed an 'alarm', and labelled as an "outlier". Those NHS providers who fall between the 2 and 3 SD limits will be flagged as an 'alert' and their data will be analysed further in a second step.

For those providers that are flagged as an 'alert', NOGCA will then analyse their performance over time using an appropriate continuous monitoring technique such as a risk-adjusted CUSUM or EWMA chart[1]. The technique involves sequentially looking at the outcomes of the operations as they occurred during the audit period, and provides insight into a provider's performance that complements the initial cross-sectional funnel plot. Providers that are flagged as an 'alarm' by the continuous monitoring analysis will be classified as an 'alarm outlier' overall. Providers that are not flagged as an 'alarm' will be considered to be false positives and regarded as performing within the expect range of performance. They will not contacted as part of the outlier management process. Providers will be considered an alarm regardless of whether the continuous monitoring chart triggered early in the audit period unless they have already been contacted in relation to this trigger point AND performance has since improved.

It is important to note that these are definitions of statistically significant differences from expected levels of 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.

[1] See Cook et al BMJ Qual Saf 2011; 20: 469e474. doi:10.1136/bmjqs.2008.031831

6. Management of a potential outlier

The management of a potential outlier involves various people:

- The NOGCA project team: the team responsible for managing and running the audit nationally
- Lead clinician in the NHS provider OG cancer unit: as the clinical lead for the team delivering care within the identified provider
- Provider clinical governance lead: responsible for clinical governance in the NHS provider
- The Medical Director and Chief Executive of the NHS provider as well as the Care Quality Commission may need to be involved.

The following table describe the seven stages that will be followed when a NHS provider is identified as having unexpected indicator values (ie, is flagged as an outlier). The table describes the actions to be taken, the people involved, and the time scales. It aims to be both feasible for those involved, fair to health care providers identified as potential outliers, and sufficiently rapid so as not to unduly delay the disclosure of comparative information to the public.

The table below refers to NHS providers whose indicator value was flagged as 'alarm' outliers. This includes those providers flagged after the first as well as the second phase of the analysis. 'Alert' outliers are not part of the process below because they are subject to the secondary review process and providers that remain a concern after this process are re-classified as an 'alarm' outlier (section 5). Publications will continue to show NHS providers who fall between 2 and 3 SDs away from the expected level in funnel plots for reasons of transparency.

Stage	What action?	Who?	Within how many working days?
1	Providers with a performance indicator suggesting 'outlier" status will have their data reviewed and the analysis double-checked to determine whether there is: <u>'No evidence of being an outlier'</u> • potential outlier status not confirmed • data in records updated and results revised • details documented • *process ends.* <u>'Evidence of outlier status remains'</u> • potential outlier status persists • *proceed to stage 2*	NOGCA project team	10

Stage	What action?	Who?	Within how many working days?
2	For outliers at provider level, the Lead Clinician in the 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).	NOGCA team and provider Clinical Lead	5
3	Lead Clinician / consultant to provide a written response to NOGCA project team about reasons for the outlier status. The response should include information about the checking of data and an initial review of local practice. Revised data will be submitted to the audit if appropriate.	Provider lead clinician / consultant	25
4	Review of Lead Clinician's / consultant's response to determine: <u>'No evidence of being an outlier'</u> • It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data indicates the provider is no longer an outlier. • Data and results will be revised in NOGCA records. Details of the provider's response and the review result recorded. • Lead Clinician / consultant notified in writing. • *process ends* <u>'Evidence of outlier status remains'</u> • It is confirmed that, although the data originally supplied by the provider were inaccurate, analysis still indicates the 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*	NOGCA project team	20

Stage	What action?	Who?	Within how many working days?
5	Contact Lead Clinician by telephone, prior to written confirmation of potential outlier status. When written confirmation sent, it is copied to Provider clinical governance lead, Medical Director and Chief Executive. For outliers at consultant-level, the consultant is additionally telephoned prior to written confirmation. Medical Director will be requested to undertake a local investigation as described in the HQIP "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 is advised to inform the relevant bodies about the NOGCA finding, including commissioners, NHS Improvement and relevant Royal Colleges. The NOGCA project team will inform HQIP and CQC / Welsh Government (as appropriate).	NOGCA project team and provider Clinical Lead / consultant	5
6	Acknowledgement of receipt of the letter, confirming that a local investigation will the undertaken. NOGCA will send a reminder if it is not received within the 10-day timeframe. HQIP / CQC / Welsh Government notified of non-compliance if no response received.	Provider chief executive	10
7	Public disclosure of comparative information that identifies NHS providers (eg, in the annual report).	NOGCA 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., postoperative mortality rate) that is more than 2 SD from the expected level of performance. At this stage, the NHS organisation should divert sufficient time and resource to reviewing data and submitting more complete data to the National Oesophago-Gastric Cancer Audit. It is recommended that the Clinical Governance team at the NHS organisation 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 NHS organisation should again invest the time and resource required to reviewing data and providing updated data to the National Oesophago-Gastric Cancer Audit. In addition, consideration will be given to whether it is necessary to suspend the performance of certain index

procedures. This will be more likely if poor performance is leading to significant patient harm. It is important to understand that these measures exist for patient safety and that such a suspension will be immediately withdrawn if it can be demonstrated after reviewing the data that performance was outside the “alarm” line because of data issues.

The role of the National Oesophago-Gastric Cancer Audit

The primary role of the National Oesophago-Gastric 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 NHS organisations and make reports describing the process and outcome of care publically available.

NHS organisations should be aware that, while the National Oesophago-Gastric Cancer Audit has a duty to report on the data it holds, and support organisations 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 / NHS organisations providing the service to patients. Concerns about clinical audit data (either case ascertainment or data quality) must be addressed by the clinical unit / NHS organisation concerned.

It is anticipated that “alerts” and “alarms” will not be a common occurrence. When such events occur, units and/or clinicians with concerns about data quality are urged to contact the NOGCA team at the earliest opportunity to discuss them.