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 2021 Outlier Policy for the National Oesophago-Gastric Cancer Audit (NOGCA) and sets out the process by which the performance of participating NHS organisations (English Trusts and Welsh Health Boards) will be assessed. It also applies to consultant surgeons in England participating in the Clinical Outcomes Programme.

This policy applies to data from patients diagnosed between April 2017 and March 2020 for organisational level statistics, and patients diagnosed between April 2015 and March 2020 for consultant level figures.

Results of the organisational level outlier analysis will be published in NOGCA's 2021 Annual Report and on the website of the Association of Upper Gastrointestinal Surgery of Great Britain and Ireland (AUGIS).

This document describes how performance indicators covered by the outlier policy will be presented, and the process for managing NHS organisations with indicator values that fall outside the expected range of performance (i.e. are flagged as a potential outlier). Indicators have been selected for which performance outside the expected range may raise concern about the quality of care provided.

This policy is based on HQIP's guidance for Outlier Management for National Clinical Audits:
https://www.hqip.org.uk/wp-content/uploads/2021/09/Appendix-10-HQIP-Outlier-guidance-v4.pdf

Changes to the Outlier Policy (October 2021)

In 2021, consultant-level outcomes will not be published as part of the Clinical Outcomes Programme. Consultant-level outcome figures will be provided to NHS organisations to support local quality assurance.

Background

The National Oesophago-Gastric Cancer Audit (NOGCA) is commissioned by HQIP and run as a partnership between the 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. The indicators are reported for 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 indicators. For surgical outcomes, these indicators are related to monitoring safety and we examine these using case-mix-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/trust-results/).

Principles for managing potential outliers

1. Performance indicators

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

This Outlier Policy applies to:

- 30-day postoperative mortality after elective surgical resection among patients treated with curative intent for OG cancer (case-mix adjusted).
- 90-day postoperative mortality after elective surgical resection among patients treated with curative intent for OG cancer (case-mix adjusted).

The Audit will periodically review the scope of this policy. We will communicate with NHS providers our intention to extend the policy to other indicators prior to publishing this information.

2. Expected performance

We define the expected level of performance for each indicator in relation to the average value for England and Wales, as derived from the NOGCA data.

3. Data quality

Alongside the performance indicators, 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 figures will be replaced with a statement about their poor data quality in the publication. The organisation will 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.

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 organisations 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 using appropriate statistical models. The models will be assessed in terms of their power of discrimination (e.g. 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 potential outliers will assess whether the indicator value for an organisation falls within the expected range of performance. This range is defined using statistically derived control limits which lie either side of the average postoperative mortality for England and Wales. The assessment will be based on the most recent audit period. For the 2021 Annual Report and Clinical Outcomes Programme, this corresponds to patients diagnosed between April 2017 and March 2020 for organisational level statistics, and patients diagnosed between April 2015 and March 2020 for consultant level figures. The indicator values for organisations and consultants will be shown on funnel plots.

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.

NHS provider values that are more than 3 standard deviations from the expected level will be deemed an 'alarm' and a potential 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 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 by the continuous monitoring analysis will be classified an 'alarm' and a potential outlier. 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, and will not be contacted as part of the outlier management process. 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.

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.

6. Management of a potential outlier

The following table describe the stages that will be followed when an NHS provider is flagged as a potential outlier. The table describes the actions to be taken, the people involved, and the time scales. It aims to be

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

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 were flagged as 'alarm' outliers, as defined in section 5 of this policy.

Stage	What action?	Who?	Within how many working days?
1	Providers with a performance indicator identified as a potential outlier 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 NOGCA records • details formally recorded and *process ends.* 'Case to answer' • potential outlier status persists • *proceed to stage 2*	NOGCA project team	10
2	For outliers at provider level, the Lead Clinician in the organisation is informed about the potential outlier status and asked to identify any data errors or justifiable explanation/s. For outliers at consultant-level, the consultant is additionally informed. All 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. 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 case to answer'</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 and *process ends* <u>'Case to answer'</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
5	The provider Lead Clinician will be contacted by telephone by the NOGCA Clinical Lead, prior to written confirmation of outlier status. Written confirmation is sent to the provider Chief Executive and copied to the provider Lead clinician and Medical Director. For outliers at consultant-level, the consultant is additionally telephoned 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. The NOGCA project team will inform HQIP and CQC / Welsh Government (as appropriate) of confirmed 'alarm' status. Chief Executive is informed that the NOGCA team will publish information of comparative performance which will identify healthcare providers.	NOGCA project team and provider Clinical Lead / consultant	5
6	Acknowledge receipt of the letter confirming that a local investigation will the undertaken with independent assurance of the investigation's validity for 'alarm' outliers, copying in the CQC/Welsh Government (as appropriate).	Provider chief executive	10

7	If no acknowledgement received, NOGCA will send a reminder, copying in HQIP and the CQC /Welsh Government. If no response received with 15 working days, CQC/Welsh Government notified of non-compliance in consultation with HQIP.	NOGCA project team	15
8	Public disclosure of comparative information that identifies NHS providers.	NOGCA Project team	NOGCA Annual Report publication date: 9/12/21

FURTHER NOTES:

Management of alert and alarm triggers.

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.