National Lung Cancer Audit outlier policy 2019

The National Lung Cancer Audit (NLCA) publishes detailed information on the treatment of patients with lung cancer, including the outcome of that treatment.

Data for the NLCA is based on patient-level information collected by the NHS, as part of the care and support of cancer patients. The data for England is collated, maintained and quality assured by the National Cancer Registration and Analysis Service (NCRAS) at Public Health England. The data for Wales are collated, maintained and quality assured by Public Health Wales; a separate process for Welsh hospitals has been produced.

This policy outlines the steps to:

> identify poor performance in the NLCA
> provide standardised feedback to and communication with provider organisations.

This is in accordance with the Healthcare Quality Improvement Partnership's *Detection and management of outliers for National Clinical Audits*.
*

Case allocation

In order to determine performance of an individual organisation, it is necessary to allocate patients to each trust for analysis. Pathways are now more complex than ever, and patients may cross multiple geographic and organisational boundaries. The NLCA and the NCRAS have developed and refined an algorithm to improve this process of allocation, and we believe that we now have 95% accuracy. As an audit team, we take the quality of the data very seriously, since they form the basis of quality improvement.

Data quality

In England, data are submitted by trusts through their Cancer Outcomes and Services Dataset (COSD) submissions on a monthly basis. We encourage regular clinical validation of these submissions to minimise any issue further downstream. It is possible for trusts to amend their data through a repeat submission at any time before the patient record is finalised by the NCRAS.

The NLCA reports on all cases of lung cancer that are registered by the NCRAS and therefore the case ascertainment rate is by definition 100%. The completeness of the data is generally excellent, with 100% completeness for age, gender, socioeconomic status, and approximately 80% completeness for performance status (PS) and >90% completeness for stage. Completeness for the latter two variables is reported alongside other measures.

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* Healthcare Quality Improvement Partnership. *Detection and management of outliers for National Clinical Audits: Implementation guide for NACPOP providers.* London: HQIP, 2018. www.hqip.org.uk/wp-content/uploads/2018/05/implementation-guide_NCAPOP-suppliers_FINAL-2.pdf [Accessed 20 March 2020].

Identifying poor performance

Benchmarking in the NLCA is based on headline indicators which are important measures of the overall quality of care. These indicators are reviewed and set annually by the NLCA team with the guidance of additional clinical experts that make up the NLCA Clinical Reference Group. [†] Data submitted to the NLCA are analysed by a team at the University of Nottingham with appropriate statistical expertise and experience.

Raw proportions are used to benchmark against a median value or value based on clinical opinion within the project team.

For some indicators, statistical analysis of these proportions are 'case-mix adjusted' for clinical features, including age, sex, PS, socioeconomic status and cancer stage. This allows the identification of statistical outliers.

For the 2019 (2018 cohort of patients) NLCA, outlier status will be determined for the following case-mix adjusted indicators which reflect a range of processes and outcomes and are considered robust:

> surgery in all non-small-cell lung cancer (NSCLC)
> systemic anticancer treatment in NSCLC (stage IIIb/IV and PS 0–2)
> chemotherapy in small-cell lung cancer
> radical treatment in NSCLC (stage I–II,PS 0–2)
> pathological confirmation rate (stage I–II,PS 0–2)
> assessment by a lung cancer nurse specialist.

For the lung cancer clinical outcome publication 2019 (2019 cohort), outlier status will be determined for the following case-mix adjusted indicators:

> unit-level 30-day survival
> unit-level 1-year survival.

Methodology for identifying outliers

The analysis uses a multivariate logistic regression model to determine the probability that a result is significantly different from the national mean. The following variables are used in the model: age at diagnosis, gender, pre-treatment disease stage, performance status and socioeconomic status.

Following analysis two levels of significance are determined – an 'alert' level of 2 standard deviations from the mean, and an 'alarm' level of 3 standard deviations from the mean. These correspond to significance levels of 95% and 99.8% respectively. We have refined the analysis to allow us to report a case-mix adjusted percentage, rather than an odds ratio, a number that is more meaningful both to clinicians and the public. These results are graphically illustrated using funnel plots.

[†] Royal College of Physicians. Background, data collection and governance.
www.rcplondon.ac.uk/projects/outputs/data-collection-and-indicators [Accessed 20 March 2020].

The process for analysing the data will be double-checked and signed off by the senior analyst at the University of Nottingham and senior NLCA clinical lead.

Process – annual report 2019

Date	Action	Responsibility
Day 1 – 23/12/19	All participating organisations will be sent summary data to their lung cancer clinical lead and nominated NCRAS contact within the cancer centre. This will include raw proportions, case mix-adjusted proportions, for the six measures listed in the 'Identifying poor performance' section, an indication of outlier status. The summary will be accompanied by a copy of this outlier policy.	NLCA
Day 1 (onwards)	Lung cancer teams may request a copy of their patient level data via the NCRAS.	Lung cancer clinical lead
Day 25 – 07/02/20	Deadline for an initial response from *alert- and alarm-*level negative outliers, acknowledging receipt of their outlier notification, to be received by the NLCA.	Lung cancer clinical lead
Day 50 – 13/03/20	Formal outlier letters will be sent to clinical leads, CEOs and MDs of *alarm-*level negative outlier organisations. Response and action plans are expected from *alarm-*level outliers, within 60 working days. In cases where data errors have been identified an organisations 'outlier' status will be reviewed on a case-by-case basis and correspondence managed accordingly. Where applicable, organisations will be signposted to the NLCA improvement toolkit as a resource for service improvement advice	NLCA
Day 110 – 22/05/20	Deadline for formal response and action plans, from *alarm-*level negative outliers to be received by the NLCA	Lung cancer clinical lead
Spring/summer 2020	NLCA annual report will be published with details of *alarm-*level outliers. An online spreadsheet will also be published containing more detailed data as well as identification of *alert-* and *alarm-*level negative and positive outliers. A further appendix will be made available online with the responses and action plans of those with *alarm-*level negative outlier status	NLCA/HQIP
	Alarm- and alert-level negative outlier formal responses to be sent to the CQC.	NLCA

CEOs = chief executive officers; CQC = Care Quality Commission; HQIP = Healthcare Quality Improvement Partnership; MD = medical director; NCRAS = National Cancer Registry and Analysis Service; NLCA = National Lung Cancer Audit.

Process – LCCOP

For the lung cancer clinical outcomes publication 2019, the outlier policy will be managed by the Society for Cardiothoracic Surgery. The policy is available on the following website: https://scts.org/_userfiles/pages/file/Audit%20and%20Outcomes/SCTS_thoracic_outlier_advice _approved%20exec%2009-10-15.pdf.

For more information please contact the NLCA team at NLCA@rcplondon.ac.uk

Appendix 1
Example initial summary letter to trusts (dates will be updated accordingly)

NLCA Annual Report Summary Data

Royal College of Physicians | National Lung Cancer Audit

🏠 Derby Hospitals NHS FT (RTG)

📍 East Midlands Strategic Clinical Network

👤 Clinical Lead: Paul Beckett

This brief report details the provisional results for patients diagnosed with lung cancer and first seen at your trust in 2016. Further details of the NLCA/NCRAS "trust first seen" algorithm is available on our website. The report includes details of your outlier status on our key measures and should be noted in conjunction with our outlier policy. This data will be put into the public domain in late January 2018 via the NLCA Annual Report.

ⓘ You have been identified as an "alarm" outlier on one or more of the key measures. You are invited to provide an initial response to the NLCA within by the end of 22nd December 2017.

📊 Data Completeness

Metric	Result	National mean
Number of Cases	400	-
Performance Status	85.0%	83.0%
Stage	95.0%	92.0%

📊 Process

Metric	Result	Adjusted result [1]	National mean
Pathological Confirmation	74.0%	73.0%	80.0%
NOS Rate	6.0%	12.0%	15.0%
PET before radical	99.0%	98.0%	90.0%
LCNS Assessed	66.0%	70.0%	75.0%
LCNS Diagnosis	75.0%	62.0%	80.0%

📊 Outcome

Metric	Result	Adjusted result [1]	National mean	95% significance [2]	99.8% significance [3]
Surgery in all NSCLC	21.0%	32.0%	23.0%	Not significant	Not significant
Chemotherapy in NSCLC	82.0%	45.0%	56.0%	Not significant	Not significant
Chemotherapy in SCLC	84.0%	63.0%	77.0%	Good practice	Not significant
One Year Survival	25.0%	22.0%	38.0%	Alert	Alarm

Data for this report is based on patient-level information collected by the NHS, as part of the care and support of cancer patients. The data is collated, maintained and quality assured by the National Cancer Registration and Analysis Service, which is part of Public Health England (PHE). Validation of local data has been performed in collaboration with local lung cancer teams. [1] Adjusted for age, sex, stage, performance status, socio-economic status and co-morbidity :: [2] Less than 5 in 100 chance that the results are due to chance :: [3] Less than 2 in 1000 chance that the results are due to chance

Appendix 2
Example draft letter to 'Alarm'-level outlier trust (dates will be updated accordingly)

NLCA Outlier Letter
Derby Hospitals NHS FT RTG
East Midlands Strategic Clinical Network

Royal College of Physicians | National Lung Cancer Audit

For the attention of lung cancer clinical lead (Paul Beckett):

I am writing as the Senior Clinical Lead for the National Lung Cancer Audit at the Royal College of Physicians.

We are about to publish the results of the analysis of data on patients who were diagnosed in 2016. The purpose of this letter is to give you advance warning that your organisation has been identified as having results in one or more key areas that lies outside three standard deviations of the predicted rate ("alarm level"). We are required to put these data in to the public domain.

We have adjusted the data for case-mix, and full details are included in our outlier policy which we have included with this correspondence (https://www.rcplondon.ac.uk/projects/national-lung-cancer-audit). Briefly this model takes account of the age, gender, socioeconomic status, disease stage and performance status of the patient cohort. Following analysis two levels of significance are determined – an "alert" level of 2 standard deviations from the mean, and an "alarm" level of 3 standard deviations from the mean. These correspond to significance levels of 95% and 99.8% respectively. We have refined the analysis to allow us to report a case-mix adjusted percentage, rather than an odds ratio, a number that is more meaningful both to clinicians and the public. We have also highlighted "Good practice" where results are a statistical outlier but in a positive direction.

There are a number of possible reasons why your data may show you as an outlier. It may be that it is a real observation in which case we would be happy to help review your service and get in place a plan to improve outcomes. It may be that there is a data quality issue which has not been picked up in earlier validation. Alternatively it could be that there is some case-mix variable that we have not included in the model that is having a major impact in your population that is not present elsewhere in the country.

We would ask you to look at the data below and provide an initial response to us by the end of **22nd December 2017**. We anticipate that you will want to review the patient level data that has been used to carry out our analysis, and we will be contacting you seperately to make arrangements to share this data with you. Details of trusts performing outside "Alarm" limits will be included in the NLCA Annual report which will be published on **24th January 2018**. We will include the details of your initial response in the report.

We will be sending formal outlier letters to trust medical directors and CEOs with "Alarm" level results on **4th January 2018**. This letter will invite you to provide your formal response and action plan within 60 days of receipt. This formal response will be included in the online appendix to the Annual Report to be published on **29th March 2018**.

We would be happy at the RCP to discuss the data in more detail with you if there is anything that is not clear. We would also be happy to help put together a plan for service improvement if it does look as if there are issues that need to be addressed.

Dr Paul Beckett

Consultant Respiratory Physician, Senior Clinical Lead NLCA

Metric	Result	Adjusted result	National mean	95% significance [1]	99.8% significance [2]
Surgery in all NSCLC	21.0%	32.0%	23.0%	Not significant	Not significant
Chemotherapy in advanced NSCLC	82.0%	45.0%	56.0%	Not significant	Not significant
Chemotherapy in SCLC	84.0%	63.0%	77.0%	Good practice	Not significant
1 year survival	25.0%	22.0%	38.0%	Alert	Alarm

Appendix 3
Example draft letter to 'Alert'-level outlier trusts (dates will be updated accordingly)

NLCA Outlier Letter

Derby Hospitals NHS FT RTG

East Midlands Strategic Clinical Network

Royal College of Physicians | National Lung Cancer Audit

For the attention of lung cancer clinical lead (Paul Beckett):

I am writing as the Senior Clinical Lead for the National Lung Cancer Audit at the Royal College of Physicians.

We are about to publish the results of the analysis of data on patients who were diagnosed in 2016. The purpose of this letter is to give you advance warning that your organisation has been identified as having results in one or more key areas that lies outside two standard deviations of the predicted rate ("alert level"). We are required to put these data in to the public domain.

We have adjusted the data for case-mix, and full details are included in our outlier policy which we have included with this correspondence (https://www.rcplondon.ac.uk/projects/national-lung-cancer-audit). Briefly this model takes account of the age, gender, socioeconomic status, disease stage and performance status of the patient cohort. Following analysis two levels of significance are determined – an "alert" level of 2 standard deviations from the mean, and an "alarm" level of 3 standard deviations from the mean. These correspond to significance levels of 95% and 99.8% respectively. We have refined the analysis to allow us to report a case-mix adjusted percentage, rather than an odds ratio, a number that is more meaningful both to clinicians and the public. We have also highlighted "Good practice" where results are a statistical outlier but in a positive direction.

There are a number of possible reasons why your data may show you as an outlier. It may be that it is a real observation in which case we would be happy to help review your service and get in place a plan to improve outcomes. It may be that there is a data quality issue which has not been picked up in earlier validation. Alternatively it could be that there is some case-mix variable that we have not included in the model that is having a major impact in your population that is not present elsewhere in the country.

We would ask you to look at the data below, but we do not need a formal response from you and we will not be sending a formal outlier letter to your trust medical director and CEO. We anticipate that you will want to review the patient level data that has been used to carry out our analysis, and we will be contacting you seperately to make arrangements to share this data with you. Details of "alert" level outliers will not be included in our Annual Report which will be published on **24th January 2018**, but will be included in an online spreadsheet at the same time.

We would be happy at the RCP to discuss the data in more detail with you if there is anything that is not clear. We would also be happy to help put together a plan for service improvement if it does look as if there are issues that need to be addressed.

Dr Paul Beckett

Consultant Respiratory Physician, Senior Clinical Lead NLCA

Metric	Result	Adjusted result	National mean	95% significance [1]	99.8% significance [2]
Surgery in all NSCLC	21.0%	32.0%	23.0%	Not significant	Not significant
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Chemotherapy in SCLC	84.0%	63.0%	77.0%	Good practice	Not significant
1 year survival	25.0%	22.0%	38.0%	Alert	Not significant

Data for this report is based on patient-level information collected by the NHS, as part of the care and support of cancer patients. The data is collated, maintained and quality assured by the National Cancer Registration and Analysis Service, which is part of Public Health England (PHE). Validation of local data has been performed in collaboration with local lung cancer teams. The results have been adjusted to take into account the patient casemix. Variables considered are age, gender, performance status, disease stage, socio-economic status and co-morbidity.
[1] Less than 5 in 100 chance that the results are due to chance :: [2] Less than 2 in 1000 chance that the results are due to chance

Appendix 4
Frequently asked questions

It is important to highlight to providers that they are an outlier but it will cause angst and pressure especially when the CEO gets the letter. Is it definitely a good idea to give the advance warning message to the clinical lead first?
We understand that it will not be a letter clinical leads will want to receive, however if the audit is to continue we have to be more effective in changing practice. The NLCA team will respond to any queries and will need to make sure all appropriate steps have been taken before publication.

For surgery rates in NSCLC, will a provider only be considered an outlier if the rates are low in the 'good performance status' group? Why is PS mentioned in the indicator for chemotherapy in advanced NSCLC patient group but not in the surgery rates?
Chemotherapy is only recommended by the National Institute of Health and Care Excellence (NICE) for stage IIIb/IV patients with good PS hence restricting the patient group. For surgery we include all patients and the data are case-mix adjusted.

If trusts in England request patient level data how long will it take to come to trusts?
Colleagues at the NCRAS will send data securely, and as soon as possible after a request for the data has been received, to the clinical leads or a nominated member of their team.

If a provider is an alert or alarm-level outlier, what level of detail do you require as an initial response if they are not able to alter the data?
This will be up to the provider. An example might be that due to major issues with data submissions the provider believes that the results are not valid. The NLCA team will then decide how best to use this information.

As there are methodological differences in measuring deprivation levels in England and Wales, will this hinder the comparisons?
In the NLCA analysis the Townsend Index method of measuring deprivation is used for both Wales and England. In all the studies that we have published, the association of socioeconomic status is present in the outcomes but it is not as influential as PS and stage.

If an alert- or alarm-level outlier does not respond to the NLCA and there is no appreciable change over time is seen in their results, will the appropriate regulatory body be informed?
Annually the NLCA submits annual report data for trusts in England to the Care Quality Commission (CQC). If a trust identified as an outlier does not respond the NLCA will continue to submit their data to the CQC and the trust will be flagged as an outlier.