NA BCOP | National Audit of Breast Cancer in Older Patients

National Audit of Breast Cancer in Older Patients (NABCOP)
Outlier Policy

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1. Introduction

This document describes the outlier policy for the National Audit of Breast Cancer in Older Patients (NABCOP). It sets out the process by which participating NHS Trusts / Welsh Health Boards' performance will be assessed and the process the NABCOP Project Team will follow to manage any hospital that is found to fall outside the expected range of performance and therefore flagged as an outlier. The principles on which the policy is based follow established practices and are consistent with the DH/HQIP outlier management policy[1].

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, the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government have commissioned various national clinical audits, including the National Audit of Breast Cancer in Older Patients. This Audit is run by Association of Breast Surgeons and the Clinical Effectiveness Unit (CEU) at the Royal College of Surgeons of England, with support from the National Cancer Registration and Analysis Service (Public Health England) and the Wales Cancer Network.

2. Performance Indicators

NABCOP uses a variety of process and outcome indicators to evaluate the quality of care received by older patients with breast cancer. These indicators were drawn from relevant clinical guidelines and are based on recommendations (or standards of care) related to the management of older patients with breast cancer. Key among these documents are the guidelines published by the National Institute for Health and Care Excellence, including NICE Clinical Guideline (NG101) on Early and Locally Advanced Breast Cancer, published in 2018.

Information on the various indicators are made publically available and included in NABCOP Annual Reports. NHS organisations providing breast cancer care can benchmark their performance against their peers using these indicators. This outlier policy is used in conjunction with those specific indicators for which performance outside the expected range raises concerns about the safety of the care provided. Not all of the indicators used by NABCOP therefore fall within the scope of this policy.

The Audit will periodically review the scope of this policy with its Clinical Steering Group and Project Board. We will communicate with NHS providers any change in how the policy applies to the NABCOP performance indicators prior to publishing this information.

[1] http://www.hqip.org.uk/resources/detection-and-management-outliers-national-clinical-audits/

Details of process and outcome indicators are published on the NABCOP website (https://www.nabcop.org.uk/resources/nabcop-core-indicators/), along with the corresponding dataset for the prospective audit (in Year 2 and Year 3) – using the current data flows to the national registration services in England (https://www.nabcop.org.uk/).

Copies of the NABCOP Annual Reports are also available on the website.

3. Expected Performance

There are two potential approaches to determining whether an organisation is meeting expected levels of performance on an indicator. The first is to use an established benchmark or standard. An example of this is the 31 days target for patients to start treatment after their date of diagnosis. The second approach is to compare performance against the typical national level of performance. This national figure will be derived from the data provided by the national cancer registration datasets for England and Wales.

4. Assessing performance and data quality[2]

An important part of the assessment process is to ensure that the data are of sufficient quality for an analysis to meet adequate standards of completeness and accuracy. NABCOP is provided with data on English NHS trusts by the National Cancer Registration and Analysis Service (NCRAS), and on Welsh Local Health Boards by the Welsh Cancer Network. Because of this, the Audit has excellent case-ascertainment and this ensures the Audit results reflect the whole patient population.

Another important aspect of data quality is data completeness. This concerns the degree to which hospitals submit to the registration services all the relevant data items on individual patients, such as age, tumour characteristics and types of treatments received. Gaps in the submitted data can result in the indicator values for NHS providers not being representative of actual practice.

Both the NCRAS and the Welsh Cancer Network follow an internal checking and quality control process before supplying the data to NABCOP. On receipt by NABCOP, the data are further checked and prepared for statistical analysis. Once data are received by NABCOP, it is not possible for the Audit to request changes to demographic, staging, pathology and treatment information. Data may be corrected by NCRAS or the Welsh Cancer Network. The responsibility for the accuracy and completeness of the patient data rests with the NHS organisations that submit records to NCRAS / Welsh Cancer Network.

5. Risk-adjustment to remove the effect of differences in patient case-mix

The comparison of outcomes across NHS providers must take account of differences in the mix of patients that they treat so that differences in provider outcomes are not due to the types of patient

[2] In the rare circumstances in which information provided to the NABCOP by NCRAS or WCN could reasonably suggest the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients, the NABCOP will implement the escalation process described in Table 3 in the following guidance published February 2019: https://www.hqip.org.uk/wp-content/uploads/2019/02/NCAPOP-Cause-for-Concern-Guidance-Final-E-and-W-Feb-2019.pdf

seen. This is achieved by adjusting for patient characteristics that are associated with the performance indicator, such as age, disease severity and co-morbidity.

The Audit will produce risk-adjusted outcomes by 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 outputs fit with the observed data). Judgment as to the adequacy of a model will depend on the performance indicator selected and the clinical context.

6. Detection of a potential outlier

The first step in the process used to identify whether or not a provider is a potential outlier will be to 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 (e.g. the last four years of data) and indicator values will be produced for this specified period. The indicator values will be typically 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'.

It is important to note that these are definitions of statistically significant differences from expected performance. Such differences may not be clinically important if the indicator value is derived from data on large numbers of patients.

There will be some hospitals whose caseload is very low, such that it will not be possible to produce statistically robust performance indicators at hospital level. The minimum caseload will be determined by appropriate statistical methods.

7. Management of a potential outlier

The management of a potential outlier involves various people:

- The NABCOP Project Team: the team responsible for managing and running the audit nationally.
- Project Board: This includes chair of the project board and will oversee strategic direction and be responsible for monitoring all aspects of delivery of the project.
- NABCOP local site leads: These are the main clinical points of contact and clinical audit department leads for the audit locally.
- In addition, the provider Medical Director and Chief Executive may need to be involved.

The following table describes the seven stages that will be followed in managing a potential outlier, the actions that need to be taken, the people involved and the maximum time scales. It aims to be fair to NHS providers identified as potential outliers and sufficiently rapid so as not to unduly delay the publication of comparative information. The process applies to providers flagged as an “alarm” in the initial analysis. NHS providers should invest the time and resources required to review the data when identified as a potential outlier. If after a review of their data, their level of performance is still beyond the 3 SD control limit, the provider will be flagged as an outlier in the subsequent Annual Report.

Stage	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: **‘No concern that there is poor performance’** • potential outlier status not confirmed • data and results revised in NABCOP records • details formally recorded • Process ends **‘Concern about possible poor performance’** • potential outlier status persists • *proceed to stage 2*	NABCOP Project Team	10
2	The NABCOP Clinical Contact at the provider organisation is informed about the potential outlier status and requested to identify any data errors or justifiable explanation/s. Aggregate results to support the review of data will be made available to the Clinical Contact. A copy of the request will also be sent to the Clinical Governance Lead of the provider organisation.	NABCOP Project Team NABCOP National Clinical Leads	5
3	NABCOP Clinical Contact to provide written response to NABCOP Project Team about the reasons for the outlier status. The response should include information about the review of their patient data and an initial review of local practice.	NABCOP Local Leads	25
4	Review of Lead Clinician’s response to determine: ‘**No concern that there is poor performance’** • Evidence is provided the data originally analysed contained sufficient inaccuracies to produce the unexpected performance value. • Details of the Trust / provider’s response will be recorded and shared with NCRAS / Cancer Network Wales.	NABCOP Project Team	30

Stage	Action	Who?	Within how many working days?
	• NABCOP Clinical Contact Provider and Clinical Governance Lead notified in writing of this conclusion. • *Process ends* **'Concern that there is poor performance'** • There is insufficient evidence to conclude the data originally supplied were so inaccurate to suggest this was the only reason the level of performance was beyond the 3 SD control limits; or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of "outlier" status. • *proceed to stage 5*		*Continued on next page…* *…continued from previous page.*
5	• Contact NABCOP Clinical Contact by telephone, prior to written confirmation of outlier status • Written confirmation copied to Provider clinical governance lead, Medical Director and Chief Executive. The project team will also inform the relevant regulator such as the CQC. • Medical Director and Chief Executive will be requested to undertake a local investigation according to HQIP "Detection and management of outliers" document. • All relevant statistical analyses, including previous response from the NABCOP clinical contact, made available to the Medical Director and Chief Executive. • Chief executive advised to inform relevant bodies about NABCOP's concerns including commissioners, NHS Improvement and relevant Royal Colleges • NABCOP will proceed to publishing information of comparative performance that will identify providers. A response from the outlier provider can be published as appropriate	NABCOP Project Team NABCOP National Clinical Leads	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 regulators (e.g. CQC) NABCOP Project team will send a reminder within 5 days if not received within 10-day timeframe. The CQC / regulator will be notified of non-compliance if not response is received.	Provider Chief Executive	10
7	Public disclosure of comparative information that identifies providers (e.g. NABCOP Annual report).	NABCOP Project Team	

8. Management of "alert" and "outlier" 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 hospital site has a value that is between 2 and 3 SDs from the expected level of performance. Providers flagged as “alerts” will not be subject to the review process as outlined in section 7.

An “outlier” indicates that a hospital site has an indicator value that is more than 3 SD from the expected level of performance. As outlined in section 7, the Trust/Health Board should invest the time and resource required to reviewing data and providing updated data to the NABCOP. 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 “outlier” line because of data issues.

Hospital sites should be aware that while the NABCOP has a duty to report on the data it holds, the NABCOP is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the clinical teams/sites/NHS Trusts/Health Boards providing the service to patients. Issues with clinical audit data (either case ascertainment or data quality) must be addressed by the unit/trust/board concerned. The role of the NABCOP is to provide consistent analysis and case mix adjustment of data received from hospitals and to make reports on the process and outcome of care publically available.

9. The role the NABCOP Project Team

The primary role of the NABCOP Project Team is to support clinical teams in providing high-quality, robust clinical audit data. It is anticipated that “outlier” status will be triggered rarely and that a regular reporting cycle will help to drive up clinical quality. Where such triggers are activated, the NABCOP Project Team will seek to provide additional help to providers wanting to review data entry and quality.

Hospital sites or clinicians with concerns about data quality are urged to contact the NABCOP Project Team at the Clinical Effectiveness Unit of the Royal College of Surgeons of England at the earliest opportunity to discuss them (https://www.nabcop.org.uk/contact/).