National Bowel Cancer Audit

Methodology Supplemental Document

NBOCA: Methodology

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About HQIP, the National Clinical Audit and Patient Outcomes Programme and how it is funded:

The Healthcare Quality Improvement Partnership (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, and in particular, to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising more around 40 programmes 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 individual programmes, also funded by the Health Departments of the Scotland, Northern Ireland and the Channel Islands. www.hqip.org.uk.

Methodology – Supplemental document

Methods - NBOCA 2018

- All data for patients diagnosed with colorectal cancer from 01 April 2013 were submitted via NHS Digital's Clinical Audit Platform (CAP). Data are collected at a trust level in England and centrally from the Cancer Network Information System Cymru (CaNISC) system in Wales. Only patients with a new primary diagnosis of bowel cancer should be included.
- Historic data submitted via the Open Exeter system has been uploaded into the CAP system.
- Case ascertainment is calculated for English cancer alliances and trusts/hospitals using Hospital Episode Statistics (HES) data to estimate the denominators. For Wales and Welsh MDTs Patient Episode Data Wales (PEDW) is used to estimate the denominators.
- The audit dataset is linked to HES data at the patient level to obtain further information on patient care and follow-up for patients treated in England and PEDW for patients treated in Wales.
- Funnel plots are used to compare the following five outcomes: 90-day mortality after major resection; 30-day emergency readmission after major resection; two-year mortality after major resection; 18-month stoma rate after major resection for rectal cancer and proportion of colonic resections with 12 or more lymph nodes reported. Comparisons are made between English cancer alliances and Wales. Further comparisons are then made for individual English trust/hospitals and individual Welsh MDTs. All outcomes, *except lymph node yield*, are adjusted for patient case-mix.
- Potential outliers on the four risk-adjusted outcomes are reported back to trust/hospital/MDTs in advance of the report being published in order that the results can be validated.

1. Data collection

All eligible NHS trusts/hospital sites in England and Health Boards in Wales submitted data to the audit for inclusion in the 2018 Annual Report. The focus of this report is patients in England and Wales submitted to the audit who were diagnosed between 01 April 2016 and 31 March 2017. Data is also available from the previous audit and comparisons are made across years for certain outcomes.

Since March 2014, patient data has been collected via NHS Digital's Clinical Audit Platform (CAP) system. This can be accessed via https://clinicalaudit.hscic.gov.uk/nboca. This allows only one treatment record to be listed per patient and patients identified as being submitted to the audit in a previous year are excluded from subsequent audits. The dataset has been redesigned to contain fewer items, some of which are mandatory, with the aim of improving data completeness across all patients. All participating trusts in England individually submitted their data for this annual report to this system. The Welsh data was submitted centrally from CaNISC.

Historic audit data from Open Exeter was transferred to the CAP system and is available for review and editing if required. Further information about Open Exeter and the data transfer are available in Section 1.1 of the 2015 supportive document, found at www.nboca.org.uk/content/uploads/2017/07/NBOCA-annual-report-2015-supportive.pdf.

2. Data linkage

Patients are linked to additional datasets using their NHS number, date of birth, sex and postcode. This allows the audit to obtain further information about patient care.

Hospital Episode Statistics/Patient Episode Database Wales

Hospital Episode Statistics (HES) and Patient Episode Database Wales (PEDW) are administrative databases that contain information about patients' hospital admissions and are derived centrally from data submitted by the hospital that they were admitted to. Linking audit data to HES/PEDW allows the audit to obtain information about patient outcomes such as emergency readmissions and stoma provision. The mode of admission (elective or emergency) and number of co-morbidities (reported according to the Charlson co-morbidity score) are both derived from HES/PEDW for use in risk adjustment.

95% of patients undergoing major surgery at English trusts in the audit could be linked to HES; the equivalent for Welsh patients and PEDW was 99%. Estimates for 30-day unplanned readmissions or 18-month stoma rates exclude those patients not linked to HES/PEDW. Risk-adjusted mortality estimates for patients not linked to HES/PEDW relied on imputed data for co-morbidities and mode of admission (see Section 6).

Office for National Statistics

Linking audit data to mortality data from the Office for National Statistics (ONS) allows the audit to analyse patient mortality across England and Wales without increasing the data entry burden for sites. In addition to date of death, the audit has access to place of death and cause of death. Cause of death was used to produce a short report which can be accessed here: www.nboca.org.uk/reports/short-report-2-2017/. Place of death is used for the first time in the 2018 Annual Report (Chapter 7, End of Life Care).

Radiotherapy Dataset

The National Radiotherapy Dataset (RTDS) contains information about radiotherapy treatment received by patients including anatomical treatment site, treatment intent, first appointment date, number of attendances, prescribed and actual doses, and detailed information about exactly what type of radiotherapy was used.

RTDS data is only available for patients who received their radiotherapy in England. Therefore, for the majority of Welsh patients, receipt of radiotherapy is taken from the audit radiotherapy records (dataset item: PreOpInitialCancerTreatmentModality).

In general, treatment episodes were grouped into long-course, short-course and other, based on the number of attendances. The audit date of surgery was used to distinguish between radiotherapy only, pre-operative and post-operative treatment. RTDS data was used as the basis of the first definitive non-surgical treatment. If no RTDS data was available for a patient, information was updated from SACT data (see below) and, finally, from the audit pre-operative treatment variable (capturing audit-only radiotherapy and chemotherapy patients).

RTDS data is only available to the audit in calendar years, therefore analyses for rectal cancer patients that use RTDS data are presented for patients diagnosed between 01 January and 31 December 2016.

Systemic Anti-Cancer Therapy

The Systemic Anti-Cancer Therapy (SACT) dataset contains information about chemotherapy treatment received by patients such as regimen type, planned and actual number of cycles, dose, route of administration and reasons for modifying treatment.

Regimen start dates were compared to the audit dates of diagnosis and surgery to determine whether chemotherapy was given in the neo-adjuvant or adjuvant setting, or as standalone treatment. As for RTDS data, the SACT dataset is not available for Welsh patients.

3. Data processing – type 2 objections

Patients in England who do not want their personal confidential information to be shared outside of NHS Digital for purposes other than their direct care may legitimately register a type 2 objection with their GP practice. NBOCA does not receive HES or ONS data for patients who have registered a type 2 objection. This means NBOCA is unable to include mortality data or risk-adjusted results for these patients.

Table 1 shows the number of records that could not be linked to HES/ONS over the past five years. The total for 2016/17 is similar to the linkage obtained for 2015/16 data at the time of producing the 2017 Annual Report.

Table 1 ONS linkage by audit year (patients submitted prior to HES/ONS linkage deadline only)

		2012-13		2013-14		2014-15		2015-16		2016-17	
		N	%	N	%	N	%	N	%	N	%
All Patients	Total	31,368		30,666		31,020		30,703		29,951	
	Not Linked	646	2.1	774	2.5	958	3.1	925	3.0	1,427	4.8
Patients Undergoing Major Resection	Total	20,094		19,696		19,584		19,347		18,849	
	Not Linked	498	2.5	550	2.8	620	3.2	585	3.0	915	4.9

The proportion of audit patients who have opted out has increased over time. According to NHS Digital, the proportion of patients who had requested type 2 opt-out in England was 2.4% in March 2018, with variation by region. From May 2018, Type 2 objections are being replaced by the national data opt-out. More information can be found here: https://digital.nhs.uk/services/national-data-opt-out-programme.

4. Case ascertainment

Case ascertainment is expressed as a ratio of the number of bowel cancer patients reported to the audit compared to the total number of patients admitted for the first time to the participating units with a date of diagnosis of bowel cancer within the audit period, according to HES data for patients diagnosed in England and PEDW for patients diagnosed in Wales.

In HES/PEDW, a patient was considered to be diagnosed with primary bowel cancer when admitted to hospital for the first time with a diagnosis of bowel cancer (C18, C19 or C20 according to the International Classification of Diseases 10th Revision) in the primary

diagnosis field. It was assumed to be a first bowel cancer admission if no previous bowel cancer diagnosis could be identified in any of the diagnostic fields since 01 April 2011.

Case ascertainment for 2016/17 compared to previous audit years can be found in the 2018 Annual Report (Chapter 2, Methodology).

5. Data completeness

Data completeness is defined as the proportion of patients with complete data items on all seven of the variables: age, sex, ASA grade, pathological TNM stage (tumour, node, metastasis staging) and site of cancer, as these audit variables are used for risk adjustment. Mode of admission and number of co-morbidities are also used in the risk adjustment model but as these variables are collected from HES/PEDW data they are not included in the assessment of data completeness. Data completeness is only assessed in patients who underwent major surgery, because only in these patients could all seven data items be expected to be complete.

Where pathological M-stage is submitted as ‘not assessed’ (Mx) or ‘not recorded’ (M9) it is updated from pre-operative tumour staging when it is recorded as M0 or M1. Duke’s staging is no longer in the audit dataset and therefore cannot be used to update missing values of M-stage. For the purposes of the audit, the following recorded tumour stages are considered to be missing data: Tx, T9, Nx, N9, Mx and M9.

6. Handling missing data

Multiple imputation using chained equations was used to fill in any missing risk factor information for the four adjusted outcomes reported at trust/hospital/MDT and cancer alliance/Wales level. This method uses a patient’s other risk factors to predict their missing information, whilst taking into account the uncertainty due to their missing information.

In addition to the variables in the risk adjustment model and the outcomes, the following variables were included in the imputation model: pre-treatment staging, performance status, treatment intent, circumferential margin status, procedure, surgical urgency, mode of admission according to the audit, surgical procedure, number of lymph nodes extracted, number of positive lymph nodes extracted, Index of Multiple Deprivation (national ranking of residential area measuring its relative deprivation across seven domains), length of hospital stay, and time from diagnosis to surgery. The proportions of missing data for patients undergoing major surgery and therefore requiring multiple imputation, are detailed in the 2018 Annual Report (Section 2.5).

7. Definition of surgical urgency

The audit uses the pre-2004 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) classification of surgical urgency.

Elective: Operation at a time to suit both patient and surgeon e.g. after an elective admission

Scheduled: An early operation (usually within three weeks) but not immediately life-saving. This category often includes patients treated on cancer pathways with targets.

Urgent: As soon as possible after resuscitation and usually within 24 hours

Emergency: Immediate and life-saving operation, resuscitation simultaneous with surgical treatment. Operation usually within two hours.

The audit uses the pre-2004 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) classification of surgical urgency, despite there being an update to this. The arguments to maintain the pre-2004 NCEPOD definition are that the classification based on this definition correlates strongly with:

• known risk factors for emergency treatment (age, socio-economic deprivation and presence of co-morbidity)
• the mode of admission coded in HES/PEDW
• the observed 90-day mortality

Introducing a new classification system for a key characteristic of the surgical procedure would make it impossible to compare outcomes in different audit periods which would in turn make it impossible to monitor trends in outcome over time, which is one of the key functions of the audit.

8. Statistical analysis

Most results reported in this audit report are descriptive. The results of categorical data items are reported as percentages (%). The denominator of these proportions is in most cases the number of patients for whom the value of the data item was not missing.

Results are typically grouped by cancer alliance/Wales and/or trust/hospital/MDT. England's 19 cancer alliances were used in the analyses, and compared to Wales as a nation. The results for Wales are reported according to where the multidisciplinary team who discussed the patients' management were located, rather than by trust/hospital.

9. Funnel plots

Funnel plots are used to make comparisons between cancer alliance/Wales or between trust/hospital/MDTs on the following outcomes: 90-day mortality after major surgery; 30-day emergency readmission after major surgery; two-year mortality after major surgery; and 18-month stoma rates for rectal cancer patients undergoing major surgery. The rate for each cancer alliance/Wales or for each trust/hospital/MDT is plotted against the total number of patients used to estimate the rate. The 'target' is specified as the average rate across all cancer alliances/Wales or trust/hospital/MDTs.

The funnel limits depend on the target rate and the number of patients included in the estimate; rate estimates have greater uncertainty when estimated from fewer patients. Results fall outside the inner limits if they are statistically significantly different from the target at a 0.05 level, and outside the outer limits if they are statistically significantly different from the target at a 0.002 level.

The inner funnel limit is the threshold for an "alert" and the outer funnel level is the threshold for an "alarm". This implies that 95 per cent of the trust/hospital/MDTs are expected to be within the inner funnel limits and 99.8 per cent within the outer funnel limits, if they are all performing according to the target.

If all trust/hospital/MDTs in this report had the same underlying rate for a particular outcome, four would be expected to lie above and four below the inner limits, and 0.2 above and 0.2 below the outer limits by chance alone.

Cancer alliances/Wales and trust/hospital/MDTs with results outside the outer (99.8%) funnel limit are considered potential outliers and have been contacted according to the

recommended HQIP procedure which can be accessed here:
www.hqip.org.uk/resource/detection-and-management-of-outliers-for-national-clinical-audits/

10. Adjusted outcomes

A previously peer-reviewed model for risk adjustment of post-operative mortality in bowel cancer patients was used. Multivariable logistic regression was carried out to estimate risk-adjusted 90-day post-operative mortality, 30-day emergency readmission, and 18-month stoma rates for rectal cancer patients undergoing major surgery (see Table 2).

A Poisson model was fitted to estimate risk-adjusted two-year mortality after major surgery. Unlike the other outcomes, two-year mortality rate takes into account the length of time each patient was followed up for. The observed two-year mortality is the number of patients who died within two years divided by the sum of the amount of time each patient is followed for. For example, in two trust/hospital/MDTs with the same proportion of patients dying within two years, the site in which patients die earlier will have a higher two-year mortality rate.

Table 2 Variables used for risk-adjusted outcomes

Multivariable Regression Model Variables	
Patient Characteristics	Age (modelled as age plus age-squared) Sex
Morbidity and Presentation	ASA grade Charlson co-morbidity score (according to HES/PEDW) Mode of admission (according to HES/PEDW)
Cancer	T-stage (pathological) N-stage (pathological) M-stage (pathological) Site of tumour

An interaction between age and distant metastases was also included in the models. This is because once patients have metastatic disease the effect of age is found to be far less important than in patients without metastases.

The model for two-year survival additionally included interactions between epoch (0-3 months after surgery vs. 3-24 months after surgery) and all of the risk factors, to allow each risk factor to have a different effect dependent on time from surgery. For example, the effect of ASA grade is much larger peri-operatively than in the longer-term, whilst cancer stage has a bigger influence on mortality long-term. The model for 18-month stoma rate did not include cancer site as it includes only rectal cancer patients.

Patients with missing date of surgery were excluded, and multiple imputation was used to fill in any missing information on the risk factors (see Section 6). Trusts were excluded from the listed analyses if overall data completeness was less than 20% or ASA grade and/or TNM stage was missing in more than 80% of patients included in the analyses.

The adjusted outcomes were estimated using indirect standardisation. The observed number of events for a trust/hospital/MDT was divided by the number expected on the basis of the multivariable regression model. The adjusted rate was then estimated by multiplying this ratio by the average rate in all patients included in the analysis.