







# National Bowel Cancer Audit

# Methodology Supplemental Document 2020

**NBOCA: Methodology** 

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# Methodology Supplement

#### Methods - NBOCA 2020

- 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/hospital 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 National Cancer Registration and Analysis Service (NCRAS) 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-APC data at 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 outcomes: 90-day mortality after major resection; 30-day emergency readmission after major resection; two-year all-cause mortality after major resection; two-year cancer-specific mortality after major resection; adjuvant chemotherapy for stage III colon cancer; unplanned return to theatre; patients undergoing major resection for potentially curative disease and; 18-month stoma rate after major resection for rectal cancer. 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 adjuvant chemotherapy, are adjusted for patient case-mix.
- Potential outliers are reported back to trust/hospital/MDTs for *three* risk-adjusted outcomes (90-day mortality after major resection; 30-day emergency readmission after major resection; two-year all-cause mortality after major resection) in advance of the report being published in order that the results can be validated.

# 1. Data collection

All eligible English NHS trusts/hospitals and Welsh Health Boards submitted data to the audit for inclusion in the 2020 Annual Report. The focus of this report is patients in England and Wales submitted to the audit who were diagnosed between 01 April 2018 and 31 March 2019. Data is also available from previous audit periods and comparisons are made across years for certain outcomes.

Since March 2014, patient data has been collected via <a href="NHS Digital's Clinical Audit Platform">NHS Digital's Clinical Audit Platform</a> (CAP) system. 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 audit periods. The dataset is constantly reviewed with the aim of minimising the data collection burden and improving data completeness. All participating hospitals/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 annual report supporting document.

The majority of expected data had been submitted prior to our data linkage deadline in January 2020. Due to Covid-19, data checking procedures and final data submission deadlines did not occur. This means that some trusts/hospitals/MDTs may not have been able to submit full data on all their patients.

# 2. Data processing – national data opt-out

National data opt-out allows patients in England who do not want their personal confidential information to be used for purposes other than their individual care to register this fact with NHS Digital. This scheme replaced the registration of type 2 objections via GP practices in May 2018. If there was a pre-existing type 2 objection it was automatically converted.

The proportion of audit patients who have opted out has increased over time. According to NHS Digital, the proportion of patients who had requested a national data opt-out in England was 2.6% in <u>June 2020</u>, with variation by region, age and sex.

The initial deadline for health and care organisations to apply these opt-outs was March 2020, but due to Covid-19 this was subsequently delayed. In readiness for the March 2020 deadline, systems were in place to apply the opt-out to NBOCA collected data and this was done from February 2020. In previous years, type 2 objections/national data opt-outs were only applied to linked data (HES-APC, ONS, PHE datasets), but for the 2020 annual report this has also been applied to NBOCA collected data.

This means that the overall number of patients for whom data is presented is lower than in previous years. We estimate that approximately 900 patients have been removed for the 2018/19 audit year.

Table 1 Estimate of number of patients removed from previously published NBOCA data years due to application of national data opt-out in 2020

	2013-14	2014-15	2015-16	2016-17	2017-18
	N	N	N	N	N
Patients submitted prior to 2019 analysis*	30,630	30,973	30,697	30,647	31,676
Patients submitted prior to 2020 HES/ONS linkage	29,996	30,105	29,804	29,691	30,782
Number of patients removed between 2019 and 2020	634	868	893	956	894

<sup>\*</sup>these include patients excluded from 2019 Annual Report due to submission after data linkage

# 3. 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 Admitted Patient Care/Patient Episode Database Wales (HES-APC/PEDW)

HES-APC and PEDW are administrative databases that contain information about all patient hospital admissions and are derived centrally from data submitted by the hospital that they were admitted to. Linking audit data to HES-APC/PEDW allows the audit to obtain additional

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 RCS Charlson co-morbidity score) are both derived from HES-APC/PEDW for use in risk-adjustment. Ethnicity for patients diagnosed in Wales has been taken from PEDW.

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

# Office for National Statistics (ONS)

Linking audit data to mortality data from the 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 cause of death and place of death. Cause of death is used within the measurement of cancer-specific survival to classify deaths as cancer-related or other. Place of death was explored in the <a href="2018 Annual Report">2018 Annual Report</a>.

# Radiotherapy Dataset (RTDS)

For the time period presented, RTDS data is only available for patients who received their radiotherapy in England. Therefore, for the majority of Welsh patients, receipt of radiotherapy is usually taken from the audit radiotherapy data item.

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 for Welsh patients, from the audit pre-operative treatment variable (capturing audit-only radiotherapy and chemotherapy patients).

Previously RTDS data was only available in calendar years therefore, for consistency, analyses for rectal cancer patients that use RTDS data are presented for patients diagnosed between 01 January and 31 December 2018.

#### **Systemic Anti-Cancer Therapy (SACT)**

The SACT dataset contains information about chemotherapy treatment received by patients such as regimen type, planned and actual number of cycles, dose and route of administration. Information on the complete dataset can be accessed <a href="here">here</a>.

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. SACT is not available for Welsh patients.

This year adjuvant chemotherapy use in patients undergoing major resection for stage III colon cancer is reported at trust/hospital/MDT level.

# **National Cancer Registry data**

The National Cancer Registration and Analysis Service (NCRAS) is run by Public Health England (PHE) and is responsible for cancer registration within England. In order for NCRAS to identify every cancer and ensure complete case ascertainment it uses a wide range of additional data sources including death certificates, histopathology and haematology records, radiotherapy records, hospice records and independent hospital records.

NBOCA had access to National Cancer Registry data for the first time in the 2019 annual report. Development work using this data source is ongoing. This year, this data source has been used to update missing data for sex, as well as providing all information on ethnicity for patients diagnosed in England. It has also been used as the denominator for case ascertainment for patients diagnosed in England.

# 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 NCRAS data for patients diagnosed in England and PEDW for patients diagnosed in Wales.

NCRAS records are only received for C18, C19 or C20 diagnoses. A patient was considered to be potentially eligible as a primary bowel cancer diagnosis if they had no tumour records with a diagnosis date between 01 April 2013 and 31 March 2018. Any subsequent records with histology recorded as carcinoid were ineligible. If multiple tumour records existed for the patient, the earliest diagnosis date at an NBOCA submitting trust/hospital was used where possible (Table 2).

In 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 between 01 April 2013 and 31 March 2018.

Table 2 NCRAS case ascertainment by year for England

	2015-16	2016-17	2017-18	2018-19
No. Patients identified in NCRAS	31,529	31,827	31,827	31,135
No. Patients identified in NBOCA	27,909	27,752	28,854	27,768
% case ascertainment	89	87	91	89

<sup>\*</sup>NCRAS denominator excludes records with no recorded diagnosing organisation and may include organisations from which NBOCA does not routinely collect data

# 5. Data completeness

Data completeness is defined as the proportion of patients with complete data for the variables age, sex, ASA grade, pathological TNM stage (tumour, node, metastasis staging) and site of cancer. This is because these seven variables are used for risk-adjustment. Mode of admission and number of co-morbidities are also used in the risk-adjustment model

but are collected from HES-APC/PEDW data and so are not included in the assessment of data completeness. Data completeness is only assessed in patients who underwent major resection 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 where this is recorded as M0 or M1. For the purposes of the audit, the following recorded tumour stages are considered to be missing data: Tx, T9, Nx, N9, Mx and M9.

Amongst patients undergoing major surgery, 4.2% were missing ASA grade, 9.3% were missing TNM T-stage, 9.3% were missing TNM N-stage and 9.4% were missing TNM M-stage. Mode of admission and Charlson co-morbidity score came from HES-APC/PEDW and were only missing in patients who were not linked to HES-APC/PEDW due to late inclusion. Virtually all patients had complete data on sex, age and site of cancer.

The removal of Duke's staging from the dataset and subsequent change in handling of pathological M-stage data led to a significant drop in overall data completeness in 2013/14, since this time data completeness has slowly risen (Table 3). Due to Covid-19 data completeness reports were not sent to each English NHS trust/hospital and Welsh MDT, which may explain the lack of improvement this year. Data completeness by trust/hospital/MDT can be found in Table A.1.

Table 3 Percentage of patients undergoing major surgery with complete data on the 7 key items from the audit used in risk adjustment, by audit year

	2014-15		2015	i-16	2016-17		2017-18		2018-19	
	N	%	N	%	N	%	N	%	Ν	%
Total patients undergoing major resection*	18,978		18,760		18,705		18,704		16,178	
Complete data on 7 key items	15,665	82.5	15,351	81.8	15,570	83.2	16,096	86.1	13,980	86.4
Data completeness if TNM M-stage recorded	15,665	95.1	15,351	93.8	15,570	93.0	16,096	94.4	13,980	95.3

<sup>\*</sup> Total restricted to those eligible for HES/PEDW/ONS linkage, but includes those with date of surgery after 31st October 2019

# 6. Handling missing data

Multiple imputation using chained equations was used to fill in any missing risk factor information for the three 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, number of lymph nodes extracted, number of positive lymph nodes extracted, quintile of deprivation (based on the relevant Index of Multiple Deprivation (national ranking of residential area measuring its relative deprivation across seven domains for England and eight domains for Wales), length of hospital stay, and time from diagnosis to surgery. The proportions of missing data which required multiple imputation are detailed in the previous section for patients undergoing major surgery.

Vascular invasion and differentiation, were also included in the imputation model for 2 year mortality.

# 7. Definition of surgical urgency

NBOCA uses the pre-2004 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) classification of surgical urgency, despite there being an update to this.

**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 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 comorbidity)
- the mode of admission coded in HES-APC/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

All statistical analyses were performed using Stata version 15.1.

Most results 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 21 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. Adjusted outcomes

The audit currently reports outlier status for three risk-adjusted outcomes.

**90-day post-operative mortality** – defined as death within 90 days of the NBOCA date of surgery with date of death obtained from ONS.

**30-day unplanned readmission** - derived from HES-APC/PEDW for patients undergoing major surgery. Defined as an emergency admission to any hospital for any cause within 30

days of surgery. Emergency admissions include those via Accident and Emergency, general practitioners, bed bureaus (point of contact for GPs to arrange urgent admission), or consultant outpatient clinics.

**2-year all-cause mortality after major resection** - the observed rate is the number of patients who died within 2 years divided by the sum of the amount of time each patient is followed up for. Taking into account the amount of follow-up time means that the estimate compares not just the proportion of patients who died within 2 years but also how quickly they died.

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 and 30-day emergency readmission (see Table 4).

A Poisson model was fitted to estimate risk-adjusted two-year all-cause mortality after major surgery. Unlike the other outcomes, two-year all-cause mortality rate takes into account the length of time each patient was followed up for. The observed two-year all-cause 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 all-cause mortality rate.

Table 4 Variables used for risk-adjusted outcomes

Multivariable Regression Model Variables							
Patient Characteristics	Age (modelled as age plus age-squared)						
	Sex						
Morbidity	ASA grade						
and Presentation	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 all-cause mortality 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 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.

# 10. Funnel plots

Funnel plots are used to make comparisons between cancer alliances/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 all-cause 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 NBOCA Outlier Policy.

#### 11. Additional outcomes

# Major resection in patients with "potentially curable" disease

This outcome aims to evaluate variation in practice for patients who might be expected to undergo major resection.

For this analysis, patients diagnosed between 01 April 2018 and 31 December 2018 with an elective presentation (screening or GP referral source) of colon cancer were included. Rectal cancer patients were excluded from this analysis due to the heterogeneity in neo-adjuvant treatment and recent shift in practice to 'watchful waiting' in complete responders which may affect the major resection rate. Patients also required a pre-treatment staging of T2-T4 and no evidence of metastatic disease. The rationale behind this decision-making was to try to exclude those patients with 'too little' disease (i.e. T1 tumours which may be removed by local excision) and those with 'too much' disease.

Characteristics of patients undergoing major resection versus those not according to prescreening, screening and post-screening age groups were explored. Funnel plot methodology was used to explore variation in major resection rate within this homogeneous group at trust/hospital/MDT level.

## Adjuvant chemotherapy after major resection for stage III colon cancer

This outcome measures the proportion of patients who received standard adjuvant chemotherapy, according to NICE guidelines, following major resection for pathological stage III colon cancer.

Patients undergoing major resection for pathological stage III colon cancer between 01 December 2015 and 31 August 2018 were included to give large enough numbers for trust/hospital/MDT level analyses.

Previously, adjuvant chemotherapy rates have only been reported for English NHS hospitals/trusts because Systemic Anti-Cancer Therapy (SACT) data is not available for Wales. Recent audit development work which was published as a <a href="mailto:short report">short report</a>, highlighted that due to a lack of detail about specific regimens within HES-APC, it was likely that there was some overestimation of adjuvant chemotherapy use.

Subsequent methodological work has shown that it is possible to assign regimens within HES-APC using OPCS-4 codes. Specific combinations of chemotherapy procurement and delivery codes are identified within HES-APC using the National Tariff Chemotherapy Regimens List. This also means that it is now possible to identify adjuvant chemotherapy regimens within PEDW for Wales for the first time.

Patients were considered to have received adjuvant chemotherapy if they had a linked SACT record demonstrating receipt of a standard adjuvant colorectal chemotherapy regimen within 4 months after their NBOCA date of surgery. Alternatively, they could have a chemotherapy code (OPCS-4 procedural code) recorded within the same 4 month period within HES-APC or PEDW. Regimens considered to be standard adjuvant therapy included: 5-fluorouracil alone, 5-fluorouracil and oxaliplatin (FOLFOX), capecitabine alone or capecitabine and oxaliplatin (CAPOX).

SACT data for 01 January 2016 to 31 Dec 2018 was used. These date ranges were used to take into account SACT data completeness (reduced in the last quartile of this audit period) and provide all patients with a minimum of 4 months to receive adjuvant chemotherapy following surgery.

Variation in the use of adjuvant chemotherapy at trust/hospital/MDT level was explored using funnel plot methodology. These funnel plots currently show unadjusted chemotherapy rates and are not yet outlier reported.

## **Unplanned Return to Theatre (URTT)**

This outcome is derived from HES-APC/PEDW for patients undergoing major surgery and is defined as the presence of an OPCS code listed in Table 5 in HES-APC/PEDW within 30 days of surgery. The majority of listed OPCS codes are only valid on days 1-30 after surgery to avoid classifying the original surgical procedure as an URTT.

Further details of validation performed using a combined NBOCA-NELA dataset were published in the <u>2019 methodology supplement</u>.

This year, observed and adjusted results for this measure are reported at hospital/trust/MDT level using funnel plot methodology, but there is no formal outlier reporting.

Table 5 OPCS codes considered to be URTT

	OPCS code											
Codes	G731	S242	S424	S573	S608	T301						
valid on day	S068	S572	S571	S577	T283	T302						
0						T303						
	G35	G711	G76	H17	H531	J72	M258	N249	S472	T282	T343	T419
	G36	G712	G78	H19	H541	L703	M264	P111	S474	T283	T348	T423
	G52	G713	G822	H29	H558	M021	M274	P131	S476	T288	T349	T428
	G53	G714	G824	H303	H568	M025	M292	P134	S478	T289	T361	T431
	G584	G715	G828	H304	H581	M062	M359	P138	S571	T301	T362	T432
	G588	G718	H04	H305	H582	M136	M37	P253	S572	T302	T365	T463
	G589	G72	H05	H308	H583	M151	M624	P258	S573	T303	T368	T468
Codes	G591	G731	H06	H311	H588	M162	M651	Q552	S577	T304	T369	T469
valid on	G601	G733	H07	H312	H589	M168	M733	S068	S608	T308	T374	T488
days	G602	G734	H08	H33	H62	M191	M734	S242	S628	T309	T384	T554
1-30	G608	G738	H09	H412	H662	M193	M735	S352	T252	T312	T388	T571
	G61	G74	H10	H418	J021	M202	M736	S358	T253	T313	T398	T77
	G63	G751	H11	H444	J04	M212	M737	S359	T259	T315	T411	T963
	G674	G752	H122	H448	J18	M218	M738	S422	T262	T316	T412	
	G69	G753	H13	H464	J212	M221	M763	S423	T272	T318	T413	
	G702	G754	H14	H468	J241	M223	M764	S424	T273	T331	T414	
		G755	H15	H469	J69	M228	N242	S428	T278	T341	T415	
		G758	H16	H47	J701	M229	N248	S438	T279	T342	T418	

#### Two-year cancer-specific mortality

Cancer-specific mortality was defined as death from any cause within 90 days of surgery or death with bowel cancer or cancer of an unspecified site as the underlying cause in the 91 days to two years after surgery. ONS defines the underlying cause of death for each patient as "the disease or injury which initiated the train of morbid events leading directly to death...". The observed two-year cancer-specific mortality rate for a trust/hospital/MDT is the number of patients with a cancer-specific death within two years divided by the sum of the amount of time each patient is followed up for.

Risk-adjustment was carried out using indirect standardisation (Section 9). A competing risks flexible parametric survival model, with death from other causes as the competing event, was used to estimate the expected number of cancer-specific deaths for a trust/hospital/MDT.<sup>2</sup> The flexible parametric survival model uses regression splines to model the baseline cause-specific hazards. Knot locations for the splines were chosen to be at 3, 6 and 12 months.

The standard risk factors (Table 4) were used in the risk adjustment model. The effect of the following risk factors was allowed to vary with time by introducing interactions between each risk factor and epoch of follow-up (before or after 3 months): TNM stage T4, TNM stage N1, TNM stage N2, distant metastases, ASA grade 2, 3 and 4/5. As with the other risk-adjusted outcomes, 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 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.

This year, for the first time, this measure is reported at cancer alliance/Wales level and hospital/trust/MDT level alongside two-year all-cause mortality for patients undergoing major resection. Observed and adjusted rates are reported, but only all-cause mortality will be outlier reported at present.

#### Stoma outcomes

Historically, the audit has outlier-reported 18-month stoma rate for datasets containing multiple years of surgical data and the proportion of patients reported to have received an APER in the most recent year of audit data.

This year, development work has been carried out to refine this measure with the use of two separate, but related, performance indicators trialled in its place. These two performance indicators are (i) unclosed diverting ileostomy at 18 months for anterior resections and (ii) the proportion of rectal cancer resections with creation of a permanent stoma. Four years of data for patients undergoing rectal major resection between 01 April 2014 and 31 March 2018 were used but, in future years, the new indicators will combine 5 years of data.

#### Historic 18-month stoma rate

This was estimated for rectal cancer patients undergoing major surgery. Patients undergoing an abdomino-perineal excision of the rectum (APER) or Hartmann's procedure according to the audit were assumed to have had a stoma at the time of their primary procedure. This was classified as permanent in patients having an APER. HES-APC/PEDW data were used to capture whether anterior resection patients received a stoma.

In patients having an anterior resection or Hartmann's procedure, subsequent stoma reversal was also obtained from HES-APC/PEDW. A procedure code for reversal of ileostomy/colostomy within 18-months of surgery was assumed to mean that the patient had their stoma reversed. To make comparisons between providers, the observed 18-month stoma rates were adjusted for case-mix using the same risk factors as for 90-day mortality (except cancer site).

## Unclosed diverting ileostomy at 18 months for anterior resections

The methodology described above was used to determine stoma status at the time of surgery for patients undergoing anterior resection. If the stoma coded as being created in HES-APC/PEDW was an ileostomy, the patient was eligible for inclusion.

A procedure code for stoma reversal within 18-months of surgery was assumed to mean that the patient had their ileostomy reversed. To make comparisons between organisations, the observed 18-month ileostomy rates were adjusted for case-mix using the same risk factors as for 90-day mortality (except cancer site).

#### Proportion of rectal cancer resections with creation of a permanent stoma

This is calculated by dividing the number of rectal cancer patients undergoing an APER (including pelvic exenteration) and Hartmann's procedure by the total number recorded as undergoing a major resection.

#### References

- 1. Burns EM, Bottle A, Aylin P et al. BMJ. 2011; 343: d4836
- 2. Hinchliffe SR, Lambert PC. BMC Med Res Methodol. 2013;13:13.