Methods Supplement

Inclusion criteria

The Audit prospectively collects both clinical and demographic details for patients diagnosed with invasive epithelial oesophago-gastric (OG) cancer (ICD-10 codes C15 and C16), or high grade dysplasia (HGD) of the oesophagus. Patients are eligible for inclusion if they were diagnosed or treated in an NHS hospital in England or Wales, and were aged 18 or over at diagnosis.

Data collection

All NHS acute trusts in England involved in the care of both curative and palliative OG cancer patients were required to upload patient information into the Clinical Audit Platform (CAP) managed by NHS Digital. Information on the care pathway and outcomes were entered prospectively either manually or via a 'csv' file generated from other information systems. As many hospitals can be involved in the care of one patient, the hospital responsible for diagnosis or treatment uploaded the relevant data, which was then deidentified by NHS Digital. Data for each patient was then collated and analysed by the Clinical Effectiveness Unit (CEU), Royal College of Surgeons. Information on the proforma for data collection, and the data dictionary are available from <u>www.nogca.org.uk/</u>.

Welsh data were provided by NHS Wales Health Collaborative. This dataset did not provide access to information on surgical complication rates, details of chemotherapy or radiotherapy regimens or on patients diagnosed with oesophageal HGD. Consequently, results requiring these data are not reported for Welsh patients.

Linkage to other data sets

The Audit dataset was linked to various other national datasets. This process reduces the burden of data collection, enables the quality of the data submitted by hospitals to be checked by comparing data items shared by the different datasets, and allows the Audit to derive a richer set of results.

The Audit dataset was linked to extracts from the:

- ONS Death Register to provide accurate statistics on cancer survival
- Hospital Episode Statistics (HES) to provide additional information on hospital care both before and after the date of diagnosis, and to validate activity data provided by hospitals (eg, dates of procedures)
- Welsh hospital administrative database (Patient Episode Database for Wales PEDW) to determine case ascertainment for patients diagnosed in Wales
- The national radiotherapy dataset (RTDS) that provides information on the episodes of radiotherapy received by patients in England
- The national systemic anti-cancer therapy dataset (SACT) that provides information on the regimens of chemotherapy and immunotherapy delivered to patients in England
- The National Cancer Registration and Analysis Service dataset (NCRAS) to provide information on all cancer registrations in England and determine case ascertainment in the Audit

Data were linked using a hierarchical deterministic approach, which involved matching patient records using various patient identifiers (NHS number, sex, date of birth, and postcode).

Use of Hospital Episode Statistics

Hospitals Episode Statistics (HES) is the national hospital administrative database for all acute NHS trusts in England. Each HES record describes the period during which an admitted patient is under the care of a hospital consultant (an episode). Clinical information is captured using the International Classification of Disease (ICD-10) diagnostic codes and the Classification of Surgical Operations and Procedures (OPCS-4). The records of an individual patient are allocated the same anonymised identifier which enables the care given to patients to be followed over time.

Patients with oesophago-gastric (OG) cancer were identified in HES by searching records for the ICD diagnosis codes C15 and C16 in the first diagnostic field. As it is possible for a patient to have multiple HES episodes during a single admission to hospital, in order to determine the number of OG cancer patients in HES over the relevant timeframe, the date of diagnosis was taken as the admission date of the episode in HES where OG cancer was first recorded in the first diagnostic field.

Statistical analysis of data

The results of the Audit are presented at different levels:

1. Region: by Cancer Alliance for England, with Wales considered as three separate areas (Swansea Bay, North Wales and South Wales), and

2. Organisation: by English NHS trust / Welsh local health board.

The values of the various process and outcome indicators are typically expressed as rates and are presented as percentages. Averages and rates are typically presented with 95% confidence intervals (CI) to describe their level of precision. When shown graphically, regional rates are plotted against the overall national rate. English patients were allocated to the Cancer Alliance based on their NHS trust of diagnosis and not by region of residence. Welsh patients were similarly allocated to the region based on the local health board of diagnosis.

In descriptive analyses of continuous variables, the distribution of values is described using appropriate statistics (eg, mean and standard deviation or median and interquartile range). The results of categorical data items are reported as percentages (%). The denominator of these proportions is the number of patients for whom the value of the data item was not missing, unless otherwise stated. We follow the Office for National Statistics policy on the publication of small numbers to minimise the risk of patient identification from these aggregate results.

The statistical significance of differences between patient groups or geographical regions were tested using appropriate tests (such as a t-test for the difference between two continuous variables and a chi-squared test for the differences between proportions). Results of tests of differences were reported as "no evidence" for p-value >0.1, "weak evidence" for 0.05<p-value<0.1, "some evidence" for 0.01<p-value<0.05, and "strong evidence" for p-value<0.01.

Analyses specific to oesophago-gastric cancer

We derived risk-adjusted figures for each NHS surgical centre for the 30-day, 90-day and 1year mortality indicators and the longitudinal and circumferential margin indicators. The rates were adjusted to take into account differences in the case mix of patients treated at each centre using multivariable logistic models. The models were used to estimate the likelihood of the outcome (eg, death, a positive margin) for each individual having surgery, and these probabilities were then summed to calculate the predicted number of events for each NHS trust. The regression models were developed from the following patient characteristics: age at diagnosis, sex, index of multiple deprivation (IMD) quintile based on patient residential postcode, co-morbidities, performance status, T stage, number of positive nodes, site of tumour, receipt of neoadjuvant treatment and ASA grade.

The risk-adjusted outcomes after curative surgery are presented using funnel plots. Two funnel limits were used that indicate the ranges within which 95.0% (representing a difference of two standard deviations from the national rate) or 99.8% (representing a difference of three standard deviations) would be expected to fall if variation was due only to sampling error. The control limits were calculated using the "exact" Binomial method. Following convention, we use the 99.8% limits to identify 'outliers' as it is unlikely for an NHS organisation to fall beyond these limits solely by chance.

If the Audit identifies an NHS organisation as an outlier, we follow the process outlined in the NOGCA outlier policy (available on <u>www.nogca.org.uk/</u> website). This is based on the HQIP "Outlier management for National Clinical Audits" policy (www.hqip.org.uk/outliermanagement-for-national-clinical-audits/) and involves giving the organisation an opportunity to review their data and ensure the submitted records are complete and free of errors. If the organisation remains an outlier after this review, the Audit will contact the organisation's clinical governance lead, Medical Director and Chief Executive. The CQC will also be informed.

The results of NHS trusts with a case volume of less than 10 are not included in the funnel plots because such small samples lead to unreliable statistical estimates due to the play of chance.

Analyses specific to high-grade dysplasia (HGD)

For analyses looking at changes over time, a sensitivity analysis was performed on all key indicators by restricting analyses to data from trusts that had consistently submitted data in each two-year audit period since 2012. This was done to assess any bias in the results, as the number of trusts submitting data has decreased in every audit period since 2012. The results presented in the State of the Nation report represent all HGD records, with the results of the sensitivity analyses reported in the text where applicable. The results from all records versus those from the sensitivity analyses were not formally tested for differences.

Analysis of the odds of receiving active treatment was conducted using a multivariable logistic regression model. The patient characteristics included in the model as covariates were age at diagnosis, sex, deprivation quintile based on patient residential postcode, and co-morbidities.