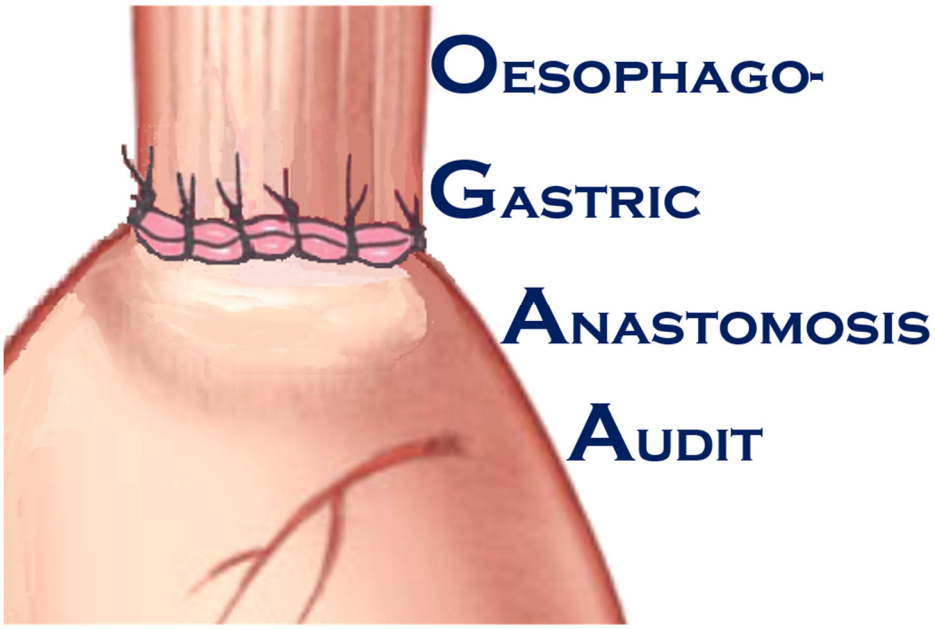

Oesophago-Gastric Anastomosis Audit Protocol 2018

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Supporting organisations

West Midlands Surgical Research Collaborative

Providing REDCap Access

Academic Department of Surgery

Association of Laparoscopic Surgeons GB&I

Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

Lay Summary

Oesophageal cancer is the sixth leading cause of cancer related death affecting up to 450,000 people globally each year. The main surgical treatment for oesophageal cancer is an oesophagectomy - an operation to remove part of the oesophagus and stomach followed by a join between the remaining oesophagus and stomach. The techniques involved to create this join vary and can involve various stitching methods and stapling devices. A proportion of these joins will breakdown and this results in the patients becoming very unwell with a resulting increase in the risk of death. The strategies to manage this complication again vary and include:

- No surgical intervention
- An endoscopic intervention or
- A further surgical procedure.

This international audit will look at the rates of breakdown of these joins, commonly termed a ‘leak’, how they are managed and the effect on the patient outcomes. The information collected from this audit will help to develop recommendations on how to prevent and manage this serious complication.

Abstract

Background

Oesophageal cancer is the sixth leading cause of cancer related mortality affecting up to 450,000 people globally each year. The incidence continues to increase rapidly and despite advances in modern treatment 5-year survival remains at around 15 to 20%. Oesophagectomy is a mainstay in curative treatment for those with oesophageal cancer however the technique and outcome varies greatly.

Aim

The aim is to audit current oesophagectomy outcomes against the standards identified in current literature.

Audit Standard

1- Anastomotic leak rate should be less than 10%

2- Major post-operative morbidity should be less than 20%

3- 30 day mortality rate should be less than 5% and 90 day mortality rate should be less than 10%

Primary Audit Objectives

1- Assess the variation in anastomotic leak rates

2- Assess which anastomotic technique is associated with optimal patient outcome

3- When anastomotic leak occurs what treatment options are associated with improved clinical outcomes

Endpoints

A staged data collection protocol will identify patient demographics, operative and peri-operative details and outcome markers. Key outcome measures will include post-operative mortality, morbidity including grade of leak and length of stay. Management techniques used for anastomotic leaks will also be assessed (e.g. conservative management, oesophageal stent, endo-luminal VAC therapy and re-operation).

Methods

A nine month multicentre prospective audit will be performed globally starting in April 2018 and co-ordinated by University Hospitals Birmingham. This will include patients undergoing oesophagectomy over 6 months and encompassing a 90-day follow up period. A pilot data collection period will occur at University Hospitals Birmingham and 3 other UK hospitals in 2017**.** Sites will be required to pre-register for the audit and obtain local study approval prior to commencement of the study.

During the study sites will be required to record data contemporaneously via a dedicated encrypted server through the Research Electronic Data Capture (REDCap) web application secure online database. The REDCap database will provide a standardised data collection proforma assessing key information to answer the primary audit question. The report of the audit will be prepared in accordance with the guidelines as set by the STROBE (strengthening the reporting of observational studies in epidemiology) statement for observational studies. All unit results will be anonymised to all but the auditors and the specific unit. Unit results will not be shared to other units or the collaborators as a whole. The study will be defined as audit not research in concordance with NHS Health research authority (Appendix 2).

Discussion

This multicentre international audit will be collected by both surgeons and trainees alike to provide greater insight into the complexities of oesophagectomy and outcome. This observational study may highlight trends in improved survival associated with specific operative techniques which can be further assessed and analysed through research to improve outcomes in oesophageal cancer.

Introduction

The techniques used for oesophagectomy can vary greatly amongst countries, units and surgeons. This is also true for outcomes and historically oesophagectomy has been associated with significant morbidity and mortality. Achieving a “textbook outcome” for patients undergoing oesophagectomy is exceptionally challenging. The Dutch Upper Gastrointestinal Cancer Audit (DUCA) group found that despite tailored oesophageal cancer care only 29.7% of patients undergoing oesophagectomy would achieve a “textbook outcome” (25). In the UK 90-day mortality for oesophagectomy has improved markedly from 5.7% in 2007-09 to 3.2% in 2013-15 and through further prospective analysis we seek to identify current mortality rates and trends in oesophagectomy technique that could be further analysed to potentially improve outcome (2). Leak rates post oesophagectomy are currently in the region of 10% and are a significant contributor to morbidity and mortality (3, 10, 12-19). 30 day mortality in patients with a demonstrable leak is around 17-35% whereas the 30 day mortality of patients with an intact anastomosis is 2-3% (4, 5). Operative and anastamotic technique has long been evaluated as a potential mechanism by which to minimise leak and improve patient outcomes.

Numerous studies have advocated varying techniques comparing handsewn and mechanical options for anastomoses (6, 7). There is some evidence to show that a mechanical anastomosis using a linear stapler has a reduced leak rate and reduced stricture rate as compared to a handsewn anastomosis however results vary markedly between surgeons and units (8). Site of anastomosis much like anastomotic technique is also a key factor in leak rate. There is evidence to suggest that cervical anastomoses are associated with an increased leak rate as compared to thoracic anastomoses (9, 10).

Management of leaks much like anastamotic techniques is a continued area of controversy with a very varied spectrum of practice. Early identification of an anastamotic leak can potentially speed clinical intervention and improve patient outcome. With the advent of newer conservative techniques such

as endo-luminal vacuum and some evidence not advocating stent usage, it will be important to identify potential trends in leak management that may improve patient outcome (11, 12).

An international multicentre audit will enable a larger number of patients' data to be obtained over a given time period. It will potentially obtain a greater overview of the variances in practice across units and countries. While such an audit will not provide true evidence of efficacy or the impact of a specific variable, it will provide data to narrow the spectrum of variables we can investigate to improve outcomes post oesophagectomy.

Access and anastomosis have been continued areas of disagreement amongst oesophago-gastric surgeons and their influence on mortality and morbidity has long been disputed. This audit seeks to provide up to date information in the international variances in practice.

For example:

1- Methods of access:
    a. Two-stage (Ivor Lewis)
    b. Three-stage (McKeown)
    c. Trans hiatal
    d. Thoraco-abdominal
2- Incision
    a. Open
    b. Minimally invasive oesophagectomy
    c. Hybrid
3- Technique of anastomosis
    a. Stapled
        i. Circular
        ii. Linear
    b. Sutured

4- Patient factors
    a. Haematological
    b. Biochemical
    c. Co-morbidity
5- Volume
    a. Surgeon
    b. Institutional

Aim

Primary Audit Question

1- Assess the variation in anastomotic leak rates

2- Assess which anastomotic technique is associated with optimal patient outcome

3- When anastomotic leak occurs what treatment options are associated with improved clinical outcomes

Audit Standard

1- Anastomotic leak rate should be less than 10%

2- Major post-operative morbidity should be less than 20%

3- 30 day mortality rate should be less than 5% and 90 day mortality rate should be less than 10%

Leak rates are very variable between surgeons, units and countries however current practices demonstrate a leak of from 1.8-18.2% (3, 10, 12-19). This accounts for all operative and anastomotic techniques to set a standard by which we can compare the observed standard in the collected population. The largest of the recent studies by Kassis et al identified 7,595 oesophagectomies with a leak rate of 10.6% and Ryan et al identified 7,167 oesophagectomies with a trans-thoracic oesophagectomy leak rate of 9.8% (54% of total oesophagectomies) and a trans-hiatal oesophagectomy leak rate of 12% (3,10). 30 day mortality has been shown to be similar across the globe. In US Kassis and Ryan demonstrated a 30 day mortality of 3.6% and 3.9% respectively (3,10). Of 2571 oesophagectomies analysed between 2011 and 2014 The Dutch Upper Gastrointestinal Cancer Audit (DUCA) group reported of a 30 day mortality of around 4% (2011- 4.1%, 2012- 4.0%, 2013- 4.6%,

2014- 3.5%)(26). In the UK the National Oesophago-Gastric Cancer Audit 2016 reported that 3031 oesophagectomies were performed between 2013 and 2015 and the 30 day mortality was 1.6% (2).

AUGIS has set forward in its guidance for the provision of services for upper GI surgery that the outcome standard for oesophagectomy leaks should be less than 10% (20). The guidance also advocates that major morbidity should be less than 20%, inpatient hospital mortality should be less than 5% and that 90 day mortality should be less than 10%.

The audit standard for oesophagectomy leak rate has therefore been adopted as 10% to enable direct comparison in the study. We will audit 30 day mortality rates against a figure of 5% and 90 day mortality rates of 10%. Major morbidity will also be audited against a standard of 20%.

Primary Objective

The audit will aim to identify trends in patient factors and operative technique differences that may influence outcome. This in turn will allow for the formulation of more detailed research.

Key outcomes will include:

- Leak rate

- 30-day mortality

- 90-day mortality

- 30-day complication rate as set out in the International Consensus on Standardization of Data Collection for Complications Associated With Esophagectomy as defined by the Esophagectomy Complications Consensus Group (ECCG) (1)

- Length of stay

- Readmission within 30 post-operative days

Methods

A global prospective audit of patients undergoing oesophagectomy over a 6 month period starting in April 2018. Patients will be followed up for 90 days.

Registered units must include all patients undergoing oesophagectomy during the study period.

A 2 month pilot of 4 centres within the UK will be undertaken to finalise the detailed investigation proforma. This will ensure that all relevant data is collected to achieve the goals of the audit.

Study Population

Inclusion Criteria

- All adult patients undergoing oesophagectomy for malignancy with an oesophagogastric anastomosis carried out during the study period.
- Any approach (e.g. Open, MIO, hybrid, 2 stage Ivor Lewis, 3 stage McKeown, thoracoabdominal, trans-hiatal)
- Malignant disease
- Elective (planned) resections.
- Thoracic and cervical anastomotic locations

Exclusion criteria

- Extended Total Gastrectomy
- Pharyngolaryngoesophagectomy
- Colonic interposition and small bowel jejunal interposition reconstructions
- Emergency resection
- Resections for benign disease

Patient identification

- Multidisciplinary team meetings
- Coordination with lead surgeon for oesophago-gastric cancer resections
- Coordination with Upper GI Cancer Specialist nursing services
- Review of theatre scheduling systems

Centre Eligibility

Any centre routinely performing elective oesophagectomies is eligible to join the audit. No restriction will be placed on global location or number of surgeons involved.

No restriction will be placed on the minimum number of oesophagectomies required to be enrolled in the audit.

Each unit will be required to register prior to the start date for data collection.

Each unit will be responsible for obtaining local hospital approval before commencement of the audit.

Each unit must ensure they have appropriate staff that will be able to ensure a >95% completeness of data entry before the closing date of the study.

Patient Follow Up

The study design aims to ensure that no additional patient follow up or intervention is required that would deviate from the normal patient journey.

For the purposes of accurate data entry follow up will require investigators to collate information from electronic and paper records. This will enable adequate analysis of the pre, intra and post-operative patient outcomes.

The data collection period will include 90 days after surgery to ensure good outcome data.

Data Completion and Organisation

Data input will be via a dedicated encrypted server through the Research Electronic Data Capture (REDCap) web application. No patient identifiable information will be inputted into the database. REDCap will provide an ID number for each patient entered. Locally held records containing corresponding REDCap ID numbers and local patient identifiers must be stored securely. This will

facilitate patient data entry at different time points by different team members and enable cross checking of data entry by different team members to ensure accuracy of data collection.

An electronic REDCap “App” will be available for smart phones to enable data collection. Data will be held securely on the “App” and information can be uploaded to the central database when internet access is available. Printable data collection proformas will be made available to enable participants to record data as required that can be uploaded to REDCap when a computer/device is available.

Patient data will be entered into case report forms (CRFs) which are designed not to deviate from safe patient care. CRFs will only record patient events and not instigate any form of intervention.

Each unit will be able to register a maximum of 5 members who will be granted access to input unit data. Each unit will be required to have a lead auditor of Consultant grade (or equivalent, country dependent). Units may apply on an individual basis if they require additional team member registration.

Intra-operative detail must be entered by a surgeon present at the time of the operation. However if a nominated member of the audit is not present at the operation he/she must take instruction from a surgeon who was present at the time of the operation. This will minimise error and ensure accurate operative data recording that may be absent in operation note records. All other data such as demographics or outcomes may be inputted by any member of the audit team.

Missing data may be entered any time during the study period. Units with >5% missing data will be excluded from the study.

The Birmingham Surgical Trials Consortium, University of Birmingham, will host the REDCap system. All data will be stored securely on encrypted and certified servers for a minimum of 5 years.

Local Approvals

All data collected will measure current practice, with no changes made to normal treatment. As such, this study should be registered as an audit of current practice at each participating centre. It is the responsibility of the local team at each site to ensure that local audit approval (or equivalent) is completed for their centre. For example, surgeons and teams from other countries will have to abide by their local hospital / country approval process. Participating centres will be asked to confirm that they have gained formal approval at their site.

Authorship

A maximum of five investigators from each individual unit will be incorporated in this study as co-investigators. Investigators will be PubMed searchable and citable. The output form the study will be published under a single corporate authorship “Oesophageal Anastomosis Investigators” (OAI).

Pilot

A 2month pilot held across 4 UK hospitals will be undertaken prior to the commencement of the full global audit. This will allow for potential adjustments to the investigation proforma for a more comprehensive study.

Data Publication and Governance

Data will be published as pooled data. It is important to emphasise that no surgeon or unit specific data will be published. Local units may request their own specific data at the end of the study.

The “Oesophageal Anastomosis Investigators” welcome the use of the data for further research. All requests will be assessed on an individual basis with a strong emphasis on safeguarding of data.

All subsequent publications using the dataset must recognise OAI and be published under the principals of shared authorship with a single corporate author.

Funding

There is currently no external funding for the Oesophageal Anastomosis Investigation.

Cohort size

We have estimated the number of eligible operations performed across Europe. Hospital Episode Statistics (HES) is a data warehouse containing details of all admissions at NHS hospitals in England. A HES database publication showed that over a ten year period between 2000 – 2010, an average of 1657 oesophagectomies were performed per year in England[EG1] (27). The population of England is approximately 53 million. The population of Europe is approximately 739.2 million. Therefore if we accept the same rate ((1657/53,000,000) x 739,200,000) there will be around 23,110 operations performed across Europe per year.

This prospective study will only pick-up a proportion of these cases, and this depends upon three factors: Penetration - the proportion of hospitals who sign up to recruit patients to the study across Europe; Pick-up - the proportion of the eligible patients at each centre are entered into the study; Study duration.

The following projection models have been estimated using various combinations of these three factors:

5% penetration; 80% pick-up 6 month recruitment = 924 cases

8% penetration; 90% pick-up 6 months recruitment = 1663 cases

10% penetration; 80% pick-up 6 month recruitment = 1848 cases

10% penetration; 90% pick-up 6 months recruitment = 2079 cases

20% penetration; 90% pick-up 6 month recruitment = 4159 cases

Caveats to these calculations include the variation in rates of oesophageal cancer and oesophagectomy in Europe and our hope that international centres will also contribute to the study

Statistical analysis

The report of this study will be prepared in accordance to guidelines set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational studies[EG2] (28)[RE3]. Data will be collected and analysed in clinically relevant categories, and the Chi squared tests used to detect differences between groups. Missing data for predictor values will be replaced using the multiple imputation method to create five imputed datasets; all predictor and outcome variables will be entered into the predictive models for imputation.

Binary logistic regression modelling will be used. Multivariable models will be built to produce odds ratios (OR) to account for the impact of predictive variables when assessing outcomes (anastomotic leak). Variable selection will be based upon those which are statistically significant at univariable analysis, and those which are clinically significant but not statistically. Fixed, forced entry will be used to adjust the main outcome measure. The effect of interaction, and sequential removal of non-significant variables will be assessed using changes in Akaike information criterion for multilevel models, and p-values for multiply imputed fixed models. Finally, risk adjusted funnel plots will be produced to test the performance of individual (anonymised) centres for rates of anastomotic leak and other factors.

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Pre-Operative Data Collection

Anonymised Patient Code	
Country	
Gender	Male / Female
Age (in Years)	
ASA	1/2/3/4
Comorbidity (21-22) Ischaemic Heart Disease Cerebrovascular Disease Peripheral Vascular disease Diabetes Renal Disease Chronic Lung Disease Liver Disease	 Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No
Smoking History	Never, Current, ex >6/52, ex <6/52
Height (cm) **Weight** (kg)	Automatic BMI Calculation
Pre-op bloods at start of surgery (or last recorded level, within previous 2 weeks) Albumin Haemoglobin eGFR (estimated Glomerular filtration rate)	 _____ g/L **or** mmol/L Absolute value in g/L to one decimal place [with pop-up converter to change from g/dL to mmol/L]
Malignancy details Tumour type Location of tumour Neo-adjuvant therapy Overall Pre-operative staging (Appendix 4, 23-24) If Radiotherapy give pre-op	 Adeno / SCC / Other Upper / Mid/ Siewert 1 / 2 / 3 None/Chemotherapy/Chemoradiotherapy TNM 7th Total Gy _____ Did the radiotherapy field include the gastric fundus – yes / no
Pre-operative nutritional support	None Oral Supplements Enteral Nutrition via NJ/NG/PEG/Jej etc TPN

Pre-operative gastric ischaemic preconditioning performed *	Yes / No

* This is when laparoscopy and division of the left gastric vessels +- short gastric vessels are performed prior to oesophagectomy under a separate anaesthetic

Intra Operative Data Collection

Training operation Trainee performed abdominal phase Trainee performed chest dissection Trainee performed anastomosis	Yes / No Yes / No Yes / No Yes / No
Abdominal phase	Lap / Open / Lap Converted to open / Robotic
Thoracic phase	Thorascopic / Open Right Chest / Open Left chest or thoracoabdominal / Thorascopic converted to open / Trans-hiatal / Robotic
Lympadenectomy	Abdominal only Abdominal and Thoracic (2 field) Abdominal / Thoracic / Neck (3 field)
Gastric Tube	Whole Stomach, Wide Gastric Tube > 5cm, Thin Gastric Tube < 5cm
Anastomosis level	Neck / Chest above Azygous / At Azygous / Below Azygous / Anastomosis not performed
Anastomotic configuration	End to End Side to End Side to Side
Anastomosis technique Handsewn Circular stapler Orringer style anastomosis (linear stapled and sutured)	 Single layer / Two layer Interrupted / Continuous Type- CEA / CDH / other- please specify Head diameter (mm)- please specify OrVil (25mm) Yes / No
Was the anastomosis securely covered in omentum	Yes / No
Was the anastomosis buried in pleura	Yes / No
Was the anastomosis tested for integrity	Not performed / NG Air Leak Test / Intra-op Endoscopy / Methylene Blue / Indigocyanine green (IGC) assessment / Other method
Nutritional Feeding Access	None / Feeding Jejunostomy / Nasojejunal tube
Procedures on the Pylorus	None/ Pyloromyotomy / Pyloroplasty / Botox / Dilatation / other
Intra-op complications	Yes / No

	Please specify
Operative duration (mins)	

Anaesthetic Data Collection

Single Lung Ventilation	Yes / No If Yes – Double Lumen Tube or Bronchial Blocker If Yes - Duration of One Lung Ventilation (mins)
Intra-operative vasopressor support required (Noradrenaline or Metaraminol etc)	Yes / No If yes Noradrenaline infusion Total mg infused during surgery Metaraminol infusion or bolus Total mg infused during surgery
Total IV Fluid (mls) given intra-operatively	_____mls crystalloid _____mls colloid
Intra-operative blood transfusion	Yes / No If Yes - Number of units transfused
Analgesia technique	Epidural Thoracic paravertebral block Spinal Morphine Patient Controlled Analgesia (PCA) Ketamine Abdominal pain catheter
Lactate Level immediately postoperative	_____mmol/L
Was the patient extubated the same day as resectional surgery?	Yes / No

Post Operative Data Collection

Re-intubated	Yes / No
Return to ICU	Yes / No
Return to theatre	Yes / No
Was assessment of anastomosis performed in the post op period? Endoscopy Plain Film Contrast Swallow CT Contrast Swallow Other	 Yes / No Yes / No Yes / No Please specify What day post operatively did this occur
Post Operative Complications Anastomotic leak No. of days after surgery leak was diagnosed Conduit Necrosis No. of days after surgery conduit necrosis was diagnosed Chyle Leak Pneumonia Diaphragmatic hernia Feeding jejunostomy complication Cardiac complication DVT or PE Other significant complication	 Yes / No / Grade 1 / 2 / 3 No days _____ Yes / No / Grade 1 / 2 / 3 No days _____ Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No Details _____
Primary Treatment of leak/conduit necrosis Post-operative day of start of treatment _____ Primary treatment successful – Yes / No	Non-operative management – Yes / No Radiological drainage – Yes / No Oesophageal stenting – Yes / No If Stent – Covered Plastic / Covered Metal Successful / Unsucessful

	Complications from Stent – Displacement / Erosion / Failure to Occlude Leak / Other Re-stented Total no of stents used Endoluminal VAC therapy – Yes / No Total no of EndoSponge changes Re-operation: Opening of Neck Wound Minimal Access or Open Thoracotomy Washout only / Anastomotic Repair / Reformation of the Anastomosis / T-Tube / Intercostal or muscle flap repair / Disconnection and cervical oesophagostomy
Secondary Leak Treatment of leak/conduit necrosis Post-operative day of start of treatment _____ Secondary treatment successful – Yes / No	Non-operative management – Yes / No Radiological drainage – Yes / No Oesophageal stenting – Yes / No If Stent – Covered Plastic / Covered Metal Successful / Unsucessful Complications from Stent – Displacement / Erosion / Failure to Occlude Leak / Other Re-stented Total no of stents used Endoluminal VAC therapy – Yes / No Total no of EndoSponge changes Re-operation: Opening of Neck Wound Minimal Access or Open Thoracotomy Washout only / Anastomotic Repair / Reformation of the Anastomosis / T-Tube / Intercostal or muscle flap repair / Disconnection and cervical oesophagostomy
Total Length of stay of hospital stay (Days)	
Total length of ICU and HDU stay (Days)	
Was the patient discharged from hospital eating and drinking?	Yes / No
Final Histology (23-24)	

T stage No Nodes examined No Nodes positive for malignancy Surgical Margins M stage	Complete path response / HGD / 1 / 2 / 3 / 4 No nodes_____ No nodes_____ Proximal – clear / involved (<1mm) Distal – clear / involved (<1mm) CRM – clear / involved (<1mm) 0/1
In hospital post-operative death Within 30 days of surgery? Within 90 days of surgery?	Yes / No Yes / No Yes / No
Out of hospital post-operative death Within 30 days of surgery? Within 90 days of surgery?	Yes / No Yes / No Yes / No
30 day readmission	Yes / No

Unit Questionnaire

Number of consultant surgeons performing oesophagectomy	Total No.
Number of oesophagectomies performed between Jan 2015 and Dec 2016	
Speciality of Surgeons	Thoracic / Oesophagogastric / General Surgeon / Surgical Oncologist
Size of institution	Total number of beds Total number of ICU beds
24 hour on call rota for oesophageal emergencies	24hour / 9-5 / none
24 hour on call availability for interventional radiology	24hour / 9-5 / none
24 hour access to emergency theatre	24hour / 9-5 / none
Where do oesophagectomy patients routinely go post-operatively	Ward HDU ICU Dedicated GI HDU
ERAS protocol for oesophagectomy patients ERAS nurse Physio input	Yes / No Yes / No Nil dedicated / Daily / Twice daily
Does your unit perform gastric ischaemic preconditioning?	Yes – Routinely Yes – Selectively No If Yes – how many days prior to surgery
Does your unit have an agreed approach to oesophagectomy for lower 1/3 adenocarcinoma?	No Yes Open Right Transthoracic Oesophagectomy Open Left thoracoabdominal oesophagectomy Open Transhiatal Oesophagectomy Hybrid Transthoracic Oesophagectomy (Lap abdominal mobilisation) 2 stage Minimal Access Oesophagectomy 3 stage Minimal Access Oesophagectomy Robotic Oesophagectomy Other
Does you unit have an agreed technique to perform intra-thoracic anastomosis?	No Yes Handsew Circular Stapled OrVil

	Stapled side to side with suturing (Orringer style) Other
Does your unit have access to Indigo-Cynanine Green assessment of the anastomosis or gastric conduit?	Yes / No
Does your unit have a policy of performing routine post-operative assessment of the anastomosis?	No Yes – Barium or Water Solulble Contrast Swallow Yes – Endoscopy Yes – CT If your unit routinely assess the anastomosis in the post-operative period, what day is this generally performed? Postop Day_____
Does your unit have access to following for the treatment of oesophageal anastomotic leak?	TPN – Yes / No Endoscopic Clips – Yes / No Endoscopic or radiologically placed covered oesophageal stents – Yes / No EndoVAC / Endosponge therapy – Yes / No Interventional guided drainage of abdominal or thoracic collections – Yes / No

Appendix 1- How to register this audit

Every hospital has an audit department which should be able to advise on the information required to register the project. Please contact them well in advance to ensure all the paper work is correct (we would recommend at least one month prior to the study commencing).

At Trust level:

1. Identify a PI (Primary Investigator) at each trust – this is a Consultant who agrees to support the study.

2. Create a team of Consultants/ surgical registrars.

3. Contact your hospital's Clinical Audit Department preferably by email

    a. They will provide you with a standard audit form to complete, via email or from the intranet

    b. You can copy and paste from this protocol

    c. Ensure that the audit department know that this is part of a larger project and that you will send anonymised data for central collation via secure nhs.net email addresses. This will involve gaining permission from the Trust's Caldicott Guardian if based in the UK.

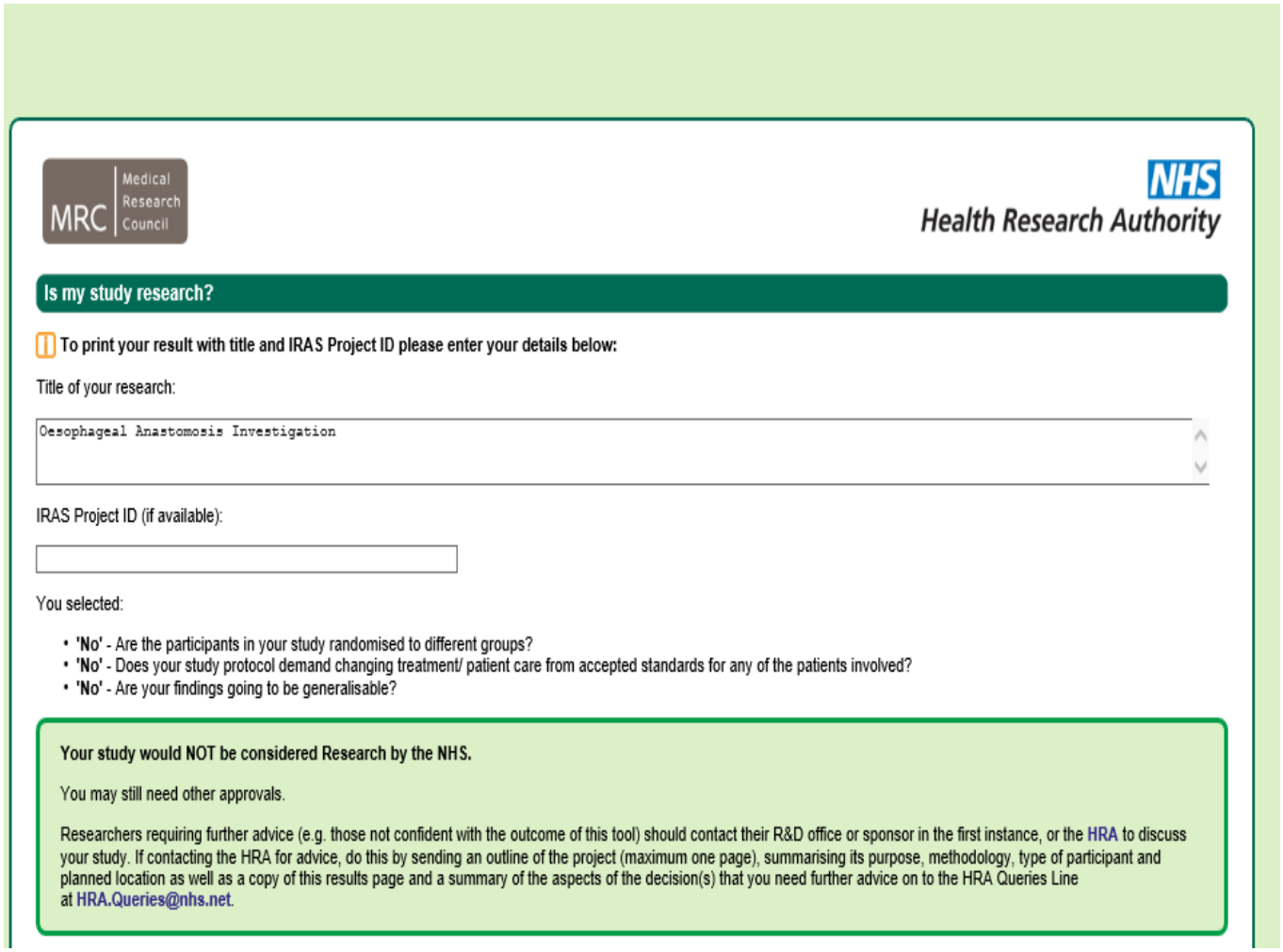
4. Once the form is completed, you may need to ask your supervising consultant to sign it.

5. Form submission

a. Submit the form and protocol to the Audit Department as soon as possible.

6. Email form to OGanastomosisaudit@gmail.com to register your interest.

Appendix 2- Health Research Authority Tool UK



MRC Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Oesophageal Anastomosis Investigation

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net.

Appendix 3- Grading Oesophageal Complications

Anastomotic Leak

Defined as: Full thickness GI defect involving oesophagus, anastomosis, staple line, or conduit irrespective of presentation or method of identification

Type I: Local defect requiring no change in therapy or treated medically or with dietary modification

Type II: Localized defect requiring interventional but not surgical therapy, for example, interventional radiology drain, stent or bedside opening, and packing of incision

Type III: Localized defect requiring surgical therapy

Conduit Necrosis

Type I: Conduit necrosis focal Identified endoscopically

Treatment — Additional monitoring or non-surgical therapy

Type II: Conduit necrosis focal Identified endoscopically and not associated with free anastomotic or conduit leak

Treatment — Surgical therapy not involving esophageal diversion

Type III: Conduit necrosis extensive

Treatment — Treated with conduit resection with diversion

Low, Donald E., et al. "International consensus on standardization of data collection for complications associated with esophagectomy: Esophagectomy Complications Consensus Group (ECCG)." *Annals of surgery* 262.2 (2015): 286-294

Appendix 4 – TNM Staging (7th Edition, 23-24)

Primary Tumour (T)

TX Primary tumour cannot be assessed

T0 No evidence of primary tumour

Tis High-grade dysplasia

T1 Tumour invades lamina propria, muscularis mucosae, or submucosa

T1a Tumour invades lamina propria or muscularis mucosae

T1b Tumour invades submucosa

T2 Tumour invades muscularis propria

T3 Tumour invades adventitia

T4 Tumour invades adjacent structures

T4a Resectable tumour invading pleura, pericardium, or diaphragm

T4b Unresectable tumour invading other adjacent structures, such as the aorta, vertebral body, and trachea

Regional lymph nodes (N)

NX Regional lymph node(s) cannot be assessed

N0 No regional lymph node metastasis

N1 Metastasis in 1-2 regional lymph nodes

N2 Metastasis in 3-6 regional lymph nodes

N3 Metastasis in 7 or more regional lymph nodes

Distant metastasis (M)

M0 No distant metastasis

M1 Distant metastasis