

FULL/LONG TITLE OF THE STUDY

Identifying Procedure Adjusted Quality Indicators For Upper Gastrointestinal Endoscopy From Multivariable Analysis Of **Cohorts With Post Endoscopy Upper Gastrointestinal Cancer** (POUGIC) In The National Endoscopy Database (NED)

SHORT STUDY TITLE / ACRONYM

Identifying quality indicators for upper gastrointestinal endoscopy

PROTOCOL VERSION NUMBER AND DATE

Version 0.3 dated 14.12.20

Study Title: Identifying quality indicators for upper gastrointestinal endoscopy V 0.3 dated 14.12.20 IRAS Reference: 289695

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STUDY SUMMARY

Study Title	Identifying Procedure Adjusted Quality Indicators For Upper Gastrointestinal Endoscopy From Systematic Review And Multivariate Analysis Of Cohorts With Post Endoscopy Upper Gastrointestinal Cancer (POUGIC) In The National Endoscopy Database (NED)
Internal ref. no. (or short title)	Endoscopy Quality Indicators
Study Design	Population based case control study
Study Participants	No direct participants
Planned Size of Sample (if applicable)	NA
Follow up duration (if applicable)	NA
Planned Study Period	2 years
Research Question/Aim(s)	To identify indicators of high quality endoscopy of the oesophagus and stomach through analysis of patients with oesophagus and stomach cancer and who have an endoscopy that does not diagnose the cancer and analysis of a large database of all endoscopies in the UK to identify endoscopy quality indicators that vary between hospitals with low and high rates of not diagnosing cancer at endoscopy.

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Synopsis

In the UK, 16,800 people are diagnosed with upper gastrointestinal (GI) cancers each year, which

mainly include cancers in the oesophagus and stomach. Unfortunately, the outlook in people with

these two cancers is not good. One potentially important factor contributing to these poor outcomes

is how these cancers are diagnosed. Endoscopy (flexible telescopic examination of the oesophagus

and stomach) is the standard way to identify cancers in the oesophagus and stomach. In the UK, we

perform 1.2 million endoscopies each year. However, we do not know the current variation in the

quality of endoscopies. Previous research has shown that both around the world and specifically in

the UK, many people have an endoscopy that does not diagnose upper GI cancer but then they are

subsequently found to have upper GI cancer between 6 months and 3 years later. This occurs in

approximately 10% of all people diagnosed with upper GI cancers and is called post endoscopy upper

GI cancers (POUGIC).

We want to improve the quality of endoscopy for all patients in the UK by identifying potential quality

indicators for endoscopy and reduce the risk of POUGIC. We will use 10 years of information on

endoscopies from national coding records called Hospital Episode Statistics (HES) linked to National

Cancer Registration and Analysis Service (NCRAS) records of upper GI cancer to work out the variation

in POUGIC rates between NHS providers. This will later help us to compare the hospitals with the

lowest (best) POUGIC rates with the hospitals with the highest (worst) rates. We will use a large

dataset from the National Endoscopy Database (NED) to examine factors associated with the

diagnosis of upper GI cancer and examine established quality indicators. We will compare the

differences in these indicators between the 25% of hospitals with the lowest and highest rates of

POUGIC to see which factors differentiate between the two groups of hospitals.

These indicators will be then reviewed by a panel of medical experts and lay people, who will discuss

the practicability of these evidence-based measures. They will then be used in future in a randomised

controlled trial to intervene to improve endoscopy quality and reduce POUGIC rates.

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Quality indicators, Endoscopy, Oesophageal cancer, Gastric cancer

Background and rationale

Why is this research important?

Upper gastrointestinal (GI) cancer consists mainly of oesophageal and gastric cancer (and a smaller

proportion with duodenal cancer). In the UK 16,800 people are diagnosed with these two cancers

each year [1]. Unfortunately, the outlook in the UK for people with these two cancers is poor, with

only 16% surviving oesophageal cancer and 19% surviving gastric cancer for 5 years after diagnosis[2].

There are a number of potential reasons for these disappointing outcomes with oesophageal and

gastric cancer in the UK but one potentially important factor relates to how upper GI cancer is

diagnosed. Endoscopic examination of the oesophagus and stomach

oesophagogastroduodenoscopy (for simplicity, further in the text termed "endoscopy") is the method

of choice for investigating upper GI symptoms and diagnosing oesophageal or gastric cancer. Previous

research has shown that a number of people have an endoscopy that does not diagnose their cancer

but then they are subsequently found to have oesophageal or gastric cancer between 6 months and 3

years later [3][4]. This is termed post endoscopy upper GI cancer (POUGIC). A meta-analysis suggested

that 11% of upper GI cancers are not diagnosed at endoscopy up to 3 years previously[3].

Current variation in the quality of endoscopy is unknown

In the UK, we perform over 1.2 million endoscopies each year [5], however, the current variation in

endoscopy quality in the UK is not known. There is no requirement to locally audit endoscopy quality

beyond the crude measures of successful intubation of the oesophagus and duodenum and whether

gastric ulcers are followed up within 12 weeks. There has never been a national audit of endoscopy

performance, unlike bowel examination such as colonoscopy. Identifying endoscopy under

performance and intervening through support and education are therefore currently impossible.

How do we currently assess endoscopic quality?

In 2017, the available evidence on indicators for endoscopy quality was reviewed by a group of

experts in the UK[6]. It was recognised that the evidence base to guide any recommendations was

very limited but a number of potential quality measures were suggested, many of which are relevant

to oesophageal and gastric cancer and POUGIC, including:

photo-documentation of endoscopic landmarks and lesions detected

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adequate visualisation/cleansing of mucosa and reporting its quality

recording the inspection time for premalignant conditions such as Barrett's oesophagus

measuring and taking adequate biopsies of pre-malignant conditions such as Barrett's

oesophagus

taking adequate biopsies and organising appropriate endoscopic follow up for lesions known

to be associated with oesophageal or gastric cancer, such as oesophageal and gastric ulcers

auditing POUGIC at a hospital level

Individual patient factors such as age, sex and the indications, e.g. red flag or alarm features, for the

endoscopy, are all known to influence the prevalence of oesophageal and gastric cancers and pre-

malignant conditions relevant to oesophageal and gastric cancer such as Barrett's oesophagus [7,8].

These factors require adjustment for in the assessment of endoscopy quality measures.

Learning lessons from colonoscopy

Over the past 15 years, following the introduction of auditable measures, the quality of large bowel

examination or colonoscopy has significantly improved in the UK [9]. Colorectal cancer (CRC) arises

from bowel polyps and detection and removal of polyps at colonoscopy are crucial to preventing CRC.

Diagnosing CRC 6 months to 3 years after a colonoscopy that did not diagnose CRC is called post-

colonoscopy colorectal cancer (PCCRC). We know that doctors and nurses undertaking colonoscopy

with a low polyp detection rate, also have a higher risk of both PCCRC and death from CRC among

their patients[10–12]. Unfortunately, endoscopy does not currently have such quality indicators.

A recently published national analysis for PCCRC has revealed a four-fold variation in the adjusted

rates of PCCRC between NHS providers[13]. The lowest rates of PCCRC were seen within the bowel

cancer screening programme, which is recognised to have the highest quality indicator results for

colonoscopy in the UK, suggesting that high quality endoscopy would also be associated with lower

POUGIC rates.

The British Society of Gastroenterology endoscopy clinical research group was tasked with outlining

the top priorities for research in the field of endoscopy for the next 5 five years in 2018[14]. From the

top four priority areas for research, the second highest priority area was "How can we improve the

quality of upper GI endoscopy, using lessons learned from colonoscopy?"

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What are the main questions designed to answer?

For the first time, using linked Hospital Episode Statistics (HES) and National Cancer Registration and

Analysis Service datasets (NCRAS), we will examine the variation in POUGIC rates between hospitals

and risk factors for such events.

We will also analyse data of 200,000 endoscopies from the National Endoscopy Database (NED),

which is a novel registry that captures patient-level data automatically and in real-time from routine

clinical data entered into each hospital's electronic endoscopy reporting system by endoscopists. We

will explore the association between an endoscopic diagnosis of oesophageal, gastric and duodenal

cancer and patient, procedural, endoscopist and endoscopy unit factors, to identify the most relevant

factors to be potential endoscopy quality indicators. We will then compare these in hospitals with the

lowest 25% and highest 25% of POUGIC rates to establish optimised procedure-adjusted quality

measures for endoscopy.

What new information will the research provide?

Our study will establish, for the first time, trust level POUGIC data and evidence-based quality

indicators for endoscopy. Through leading efforts to improve endoscopy quality and reduce

unwarranted variation, as has been seen through similar efforts in colonoscopy, we anticipate that we

will diagnose many cases of oesophageal and gastric cancer earlier and save lives from these cancers.

What do we intend to produce from our research?

We subsequently plan to seek funding to undertake a randomised controlled trial based on the

National Endoscopy Database APRIQOT (Automated Performance Reports to Improve Quality

Outcomes Trial) model, involving a complex behavioural intervention with endoscopists and

endoscopy units receiving automated feedback on National Endoscopy Database generated individual

and endoscopy unit level procedure adjusted quality indicators for endoscopy, to assess whether this

can improve endoscopy quality, and reduce variation in endoscopy quality indicators and POUGIC

rates.

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Patient and public involvement

Mimi McCord, Chair of Heartburn Cancer UK, expressed the critical importance of the issue of POUGIC

and endoscopy quality from a patient's and their relative's perspective:

"Many thanks for sending through the protocol, which I have gone through with both interest and

dismay – (for) patients to be let down dramatically by the endoscopist is insupportable. As head of a

charity raising awareness of the link between heartburn, Barrett's oesophagus and OAC (Oesophageal

Adenocarcinoma), to hopefully enable an early diagnosis of the disease, for there to be this delay in

diagnosis is totally unacceptable. I had not expected patients would be let down and remain

undiagnosed for a period of time which is likely to give them a death sentence. The protocol makes

perfect sense to me and would, from my lay perspective, dramatically improve the quality of upper GI

endoscopy reducing missed upper GI cancers and therefore reducing the number of deaths resulting

in these cancers. The burden on an already overstretched health system would be reduced as a

result."

We presented the project to the Upper GI Blues, a charity that provides support to patients and their

families with oesophageal and gastric cancer, and 17 out of 17 patients and their relatives thought

this was a very important study to undertake and that it would make a difference for future patients

with cancer. They asked us to focus on the issue of sedation during endoscopy, as they thought this

was likely to be a major factor in POUGIC from their own experiences.

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Methodology

Post endoscopy upper GI cancer

Following approval of the Office for Data Release (ODR) data request from Public Health England and

a data sharing agreement, population level data will be provided through collaboration with

University Hospitals Birmingham NHS Foundation Trust (UHBFT) and Public Health England's National

Cancer Registration and Analysis Service (NCRAS). All individuals who developed oesophageal,

stomach and duodenal cancers in the UK from 1st January 2009 to 31st December 2018 will be

identified from NCRAS.

This data will be linked to Hospital Episode Statistics (HES) records, which will allow identification of

patients who have undergone an endoscopy in the English NHS between 1st January 2006 and the

31st December 2018 and subsequently developed oesophageal, gastric and duodenal cancer

(International Classification of Diseases V.10 (ICD10) code C15–17), within 3 years of endoscopy.

A cut of directly de-identified linked NCRAS and HES patient level data will be then exported into and

analysed within a secure area at UHBFT, which is compliant with the Data Security and Protection

toolkit.

Authorised Informatics Analysts from UHBFT will access the secure area to analyse the characteristics

associated with POUGIC, risk factors for POUGIC and trust variation in POUGIC rates.

Data Flow A:

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NCRAS

- Approval of ODR data request form and data sharing agreement between NCRAS, UHB NHSFT and SWB NHST
- •All individuals who were diagnosed with oesophageal, gastric and duodenal cancer in the UK from 1st January 2009 to 31st December 2018 will be identified

HES

- •NCRAS data will be linked to HES records to identify the individuals who had endoscopies in the English NHS between 1st January 2006 and the 31st December 2018
- Data will be deidentified

UHB NHSFT

- Linked HES and NCRAS data will be exported to a Data Security and Protection toolkit compliant secure area at UHB NHSFT
- Analysis of data will be completed within secure area by authorised information analysts

SWB NHST

- •Fully anonymous, analysis report will be received by CI and research fellow at SWB NHST
- •Data on trust POUGIC rates will be utilised for analysis of NED data

NCRAS: National Cancer and Research Analysis Service, ODR: Office for Data Release, PHE: Public Health England, HES: Hospital Episode Statistics, UHB NHSFT: University Hospital Birmingham NHS Foundation Trust, SWB NHST: Sandwell and West Birmingham NHS Trust, POUGIC: Post endoscopy Upper GI Cancer, CI: Chief Investigator

Endoscopies will be categorised into positive and negative tests depending on whether oesophageal, gastric or duodenal cancer was diagnosed within 6 months of the test. True positive tests were those where a cancer was diagnosed within the first 6 months after an endoscopy. False negative tests where a cancer was diagnosed between 6 and 36 months after an endoscopy.

Cancers diagnosed beyond 36 months after an endoscopy will not be included. Cancers will be defined as detected cancers if they were preceded by a true positive endoscopy and as a POUGIC if preceded by a false negative endoscopy.

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Where patients have undergone multiple endoscopies, only the closest true positive and false

negative endoscopy to diagnosis will be included.

The hospital provider delivering each endoscopy will be identified from unique 5-digit codes in HES.

Organisations change over time (for example hospital mergers) and in instances where this has

happened, historical organisations will be mapped to current providers. Hospitals providers will then

be divided into quartiles to allow comparison of those with the lowest and highest POUGIC rates

Patient level data available to investigate relevant factors that might increase the risk of POUGIC

includes:

age at both diagnosis and endoscopy stratified into quintiles

sex

socioeconomic status (based on quintiles of the income domain of the Index of Multiple

Deprivation 2007) and

a Charlson comorbidity score based on diagnostic Hospital Episode Statistics codes in the year

prior to diagnosis of the cancer and categorised as 0, 1, 2 and \geq 3.

Ethnicity

Route to diagnosis (e.g. emergency presentation)

In addition, all individuals with a prior HES coded diagnosis of the conditions with a potential

higher risk of being diagnosed with upper GI cancer (e.g Barrett's oesophagus, oesophageal ulcer,

oesophageal stricture, gastric ulcer and gastric atrophy) will be noted for sub-analysis, as will

those with a previous diagnosis of oesophageal or gastric cancer.

Following tumour characteristics and cancer outcomes will be compared between POUGIC and

detected cancers (i.e. diagnosed with in 6 months of endoscopy):

site of cancer

stage of cancer

grade of cancer

treatment received (surgery, chemotherapy, radiotherapy or no active treatment)

duration between diagnosis of cancer and death

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Development of endoscopy quality indicators in data from the National Endoscopy

Database

National Endoscopy Database (NED) is a novel national registry in the UK, overseen by the Joint

Advisory Group on GI endoscopy (JAG), that captures patient-level data automatically and in real-time

from routine clinical data entered into each hospital's electronic endoscopy reporting system by

endoscopists. Second iteration of NED is expected to be launched from January' 2021. It will expand

upon first iteration and provide more detailed and better quality data.

Following permission from the JAG research committee and a data sharing agreement, under the

instruction of the sponsor, for the sole purpose of the research, University of Birmingham will request

data for 200,000 endoscopies recorded in NED from JAG. Data will be exported to the Institute of

Applied Health Research (IAHR) at University of Birmingham for analysis.

The research team in the IAHR (Dr Umair Kamran and Dr Nicola Adderley) will examine associations

between an endoscopic diagnosis of oesophageal, gastric and duodenal cancer and patient,

procedural, endoscopist and endoscopy unit factors that are potential quality indicators or require

adjustment for, if not related to endoscopy quality.

Data Flow B

Study Title: Identifying quality indicators for upper gastrointestinal endoscopy

JAG

- •JAG research committee approval and data sharing agreement between JAG, UOB and SWB NHST
- •Fully anonymysed data on 200,000 endoscopies' peformed in England and recorded in NED.

UOB

- Research fellow and senior lecturer in IAHR will analyse anonymysed NED data and output on trust POUGIC rates
- Informatics tools will be developed

SWB NHST

Fully Anonymous report will be received by CI at SWB NHST

JAG: Joint Advisory Group on GI endoscopy, NED: National Endoscopy Database, UOB: University Of Birmingham, IAHR: Institute of Applied Health Research, SWB NHST: Sandwell and West Birmingham NHS Trust, POUGIC: Post endoscopy Upper GI Cancer, CI: Chief Investigator

Quality indicators in hospitals with the lowest 25% and highest 25% of POUGIC rates will then be compared through multivariable analysis.

Using data from 200,000 endoscopies, we will develop informatics tools to investigate variation in procedure adjusted quality measures for endoscopy between endoscopists and endoscopy units. We will examine the variation in such measures due to patient, procedural, endoscopist and endoscopy unit factors.

Two-thirds of the endoscopies from NED will be used for model development, while the remaining third will serve as independent data to validate the performance of the models.

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Statistical analyses

The proportion of oesophageal, gastric and duodenal cancers undergoing true positive (cancer

diagnosed within the subsequent six months) and false negative (cancer diagnosed over six months

later but less than three years later) endoscopies will be calculated to give the POUGIC rate for the

whole cohort.

Multivariable logistic regression models of all covariates will be used to determine factors associated

with the occurrence of POUGIC and p-values of <0.01 will be considered statistically significant.

The dependent variable will be the occurrence of POUGIC and the exploratory variables will include

year of endoscopy, age at endoscopy, sex, socioeconomic status (quintiles), comorbidity score,

ethnicity, route to diagnosis, prior Hospital Episode Statistics coded diagnosis of Barrett's oesophagus,

oesophageal ulcer, oesophageal stricture, gastric ulcer, gastric atrophy and prior oesophageal, gastric

and duodenal cancer diagnosis and prior endoscopy.

These models will be used to build funnel plots[15] to investigate variation in POUGIC rates between

English endoscopy providers.

Potential differences in cancer characteristics and outcomes between POUGIC cases and detected

cancers will be compared by univariable and multivariable logistic regression analysis for: site of

cancer, grade of cancer, stage of cancer, treatment received (surgery, chemotherapy, radiotherapy)

and mortality.

Logistic regression models, including random effects as appropriate, will be employed to the data

obtained from NED to develop adjusted quality indicators at endoscopist and endoscopy unit level for

an endoscopic diagnosis of oesophageal and gastric cancer.

Forward stepwise selection will be used in two-thirds of the endoscopies to identify predictive

variables for oesophageal, gastric cancer and POUGIC rates and procedure adjusted quality indicators,

and the remaining third will serve as independent data to investigate the performance of the

methods[16]. p-values of <0.2 will be considered statistically significant for variable selection. Missing

data will be addressed using multiple imputation using chained equations with predictive mean

matching.

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We will use this data to establish an appropriate endoscopy quality indicator minimum and target

standards based on control limits from funnel plots. We will then analyse the various candidates for

procedure adjusted quality indicators and look for correlations between them, to establish which

might be most fit-for-purpose for application, with pros and cons established for each.

Inclusion criteria

• All patients 18 years of age and over at diagnosis, who are diagnosed with oesophageal, gastric

and duodenal cancers from 1st January 2009 to 31st December 2018, identified in National Cancer

Registration and Analysis Service (NCRAS).

•All endoscopies performed and recorded in Hospital Episode Statistics (HES) in the England

between 1st January 2006 to 31st December 2018 in patients identified with oesophageal, gastric

and duodenal cancer from NCRAS data.

•200,000 upper gastrointestinal endoscopies performed in the UK and recorded in National

Endoscopy Database (NED)

Exclusion criteria

Paediatric population (<18 years)

Residents outside England

Consent

NCRAS has legal permission to collect patient level data and use it for research to protect the health

of the population under Section 251 of the NHS Act 2006. The risk to patient data is minimal as only

de-identified data will be handled outside NCRAS. The NED database only captures non identifiable

information. The volume of data being analysed and the fact that many of the patients might have

died from cancer would make it impossible to seek consent from each individual.

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Ethical and regulatory considerations

There is no direct involvement of patients in our study. National Cancer Registration and Analysis

Service (NCRAS) captures patient identifiable data. National Cancer Registration and Analysis Service

(NCRAS) (hosted by Public Health England) is responsible for population cancer registration of all

patients diagnosed or treated in England with an invasive malignancy or specific pre-malignant

conditions (C00-97, D00-48). NCRAS has been permitted by the Secretary of State to process patient

identifiable data without consent in accordance for the processing purposes outlined in Regulation 2,

Health Services (Control of Patient Information) Regulations 2002 and this exemption to common law

is reviewed annually by the Confidentiality Advisory Group per Regulation 7 requirements. Access to

patient identifiable data within the organisational boundary of PHE is controlled through appropriate

organisational and technical measures; including CLSPs and system-specific controls that adopt

privacy by design by default (i.e. replacement of NHS numbers in the Cancer Analysis System with a

patient ID to limit access to direct identifiers to a need to know basis). For the purpose of this study,

PHE will act as a data intermediary to identify and then share clinical data about patients who have

been registered by NCRAS as having a diagnosis of oesophageal, gastric and duodenal cancer from the

1st January 2009. All processing of patient confidential data will be conducted under the permissions

granted to PHE under the COPI regulations and the data disclosed by PHE will be effectively de-

personalised to the standard outlined in the ICO Anonymisation Code of Practice. This will include the

use of project specific pseudonyms to replace persistent identifiers within the registry data (such as

the patient ID and tumour ID). This data will then be exported into a Data Security and Protection

toolkit compliant secure area at University Hospitals Birmingham NHS Foundation Trust for analysis by

authorised analysts.

Health care providers will be defined as outliers if their performance (i.e POUGIC rate) is more than

two standard deviations away from expected performance (which will be decided based on detailed

analysis of national data). We will follow guidance published by Department of Health (England, DH)

and the National Advisory Group on Clinical Audit and Enquiries (NAGCAE) on the detection and

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management of outliers [17]. We will contact potential outliers after data analysis and inform them of the work and their results. We will offer them the opportunity to engage in detailed discussion before publication of results and address their concerns which include running additional analysis if indicated.

Our study proposal has been peer reviewed as part of our application to the Research for Patient Benefit Programme and approved for funding.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
Research for Patient Benefit (RfPB) Programme:	£245,622.00
National Institute of Health Research	
Central Commissioning Facility	
Contact No. 02088438089	
Francesco.sciammarella@nihr.ac.uk	

ROLE OF STUDY SPONSOR AND FUNDER

Sandwell and West Birmingham NHS Trust, as Sponsor, will take legal responsibility for the design, management and conduct of this study.

SWB NHST will act as Data Controller.

SWB NHST will collaborate with all participating organisations including University Hospitals
Birmingham NHS Foundation Trust, the University of Birmingham, the Joint Advisory Group on
Endoscopy and the National Cancer Registration and Analysis Service to ensure data sharing and
storage is compliant with information governance and GDPR requirements.

SWB NHST Research and Development department will take responsibility for monitoring and auditing the management and conduct of this research.

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NIHR will monitor progress of study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES, GROUPS &

INDIVIDUALS

The steering committee will hold monthly meetings to monitor the progress of the project.

-Dr Nigel Trudgill, chief investigator will supervise the research team throughout the study period.

-Professor Matthew Brookes will provide mentorship through regular meetings to assist in the co-

leadership of this project.

-Professor Eva Morris will help in establishment of hospital level post endoscopy upper

gastrointestinal cancer rates. Professor Morris has led an identical study of post-colonoscopy

colorectal cancer.

-Professor Matt Rutter is the Chair of the National Endoscopy Database working group, and will be

involved in analysis of post endoscopy upper gastrointestinal cancer in hospital episode statistics and

National Endoscopy Database.

-Dr Nicola Adderley will be assisting with the steering committee and analysis of data from the

National Endoscopy Database.

-Mrs Mimi McCord will be the lay member of the steering committee.

-Dr Umair Kamran is a research fellow who will be involved in all phases of the project.

-A representative from the sponsor (head of research and development SWB NHST) will provide

administrative support.

We will update NIHR on regular basis about our progress.

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Research Ethics Committee (REC) and other Regulatory review & reports

Approved by HRA and REC (IRAS Reference No. 289695)

Regulatory Review & Compliance

Data sharing agreements have been signed between all participating organisations

Peer review

Our project has been extensively peer reviewed as part of the funding application which has been

approved by Research for Patient Benefit Programme.

Patient & Public Involvement

As described above (Page 11)

Protocol compliance

We are not expecting deviation from protocol as our study mainly involves analysis of the data

already recorded in NCRAS, HES and NED.

Data protection and patient confidentiality

Only non-identifiable data will be accessed by the research team. NCRAS (National Cancer

Registration and Analysis Service) will export deidentified data to a secure area (Data Security and

Protection toolkit compliant) at University Hospitals Birmingham NHS Trust where this will be

analysed by the informatics team.

National Endoscopy Database (NED) captures only non-identifiable information, which will be used by

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the IAHR team at the University of Birmingham for analysis.

Indemnity

The NHS Indemnity scheme will be applied.

Access to the final study dataset

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No patient identifiable data will be the accessed by the research team. Data analysts (Health informatics at UHBFT and IAHR at University of Birmingham) will access this anonymised information for analysis.

DISSEMINIATION POLICY

Dissemination policy

Results from our study will be presented in conferences and published as peer reviewed papers.

Authorship eligibility guidelines and any intended use of professional writers

Steering committee members will share authorship.

IRAS Reference: 289695

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Annex

OPSC-4 Codes for endoscopy:

- G12.1 Fibreoptic endoscopic mucosal resection of lesion of oesophagus
- G12.8 Other specified other fibreoptic endoscopic extirpation of lesion of oesophagus
- G14.1 Fibreoptic endoscopic snare resection of lesion of oesophagus
- G14.2 Fibreoptic endoscopic laser destruction of lesion of oesophagus
- G14.3 Fibreoptic endoscopic cauterisation of lesion of oesophagus
- G14.4 Fibreoptic endoscopic injection sclerotherapy to varices of oesophagus
- G14.5 Fibreoptic endoscopic destruction of lesion of oesophagus NEC
- G14.6 Fibreoptic endoscopic submucosal resection of lesion of oesophagus
- G14.7 Fibreoptic endoscopic photodynamic therapy of lesion of oesophagus
- G14.8 Other specified fibreoptic endoscopic extirpation of lesion of oesophagus
- G14.9 Unspecified fibreoptic endoscopic extirpation of lesion of oesophagus
- G15.1 Fibreoptic endoscopic removal of foreign body from oesophagus
- G15.2 Fibreoptic endoscopic balloon dilation of oesophagus
- G15.3 Fibreoptic endoscopic dilation of oesophagus NEC
- G15.4 Fibreoptic endoscopic insertion of tubal prosthesis into oesophagus
- G15.5 Fibreoptic endoscopic dilation of web of oesophagus
- G15.6 Fibreoptic endoscopic insertion of expanding metal stent into oesophagus NEC
- G15.7 Fibreoptic endoscopic insertion of expanding covered metal stent into oesophagus
- G15.8 Other specified other therapeutic fibreoptic endoscopic operations on oesophagus
- G15.9 Unspecified other therapeutic fibreoptic endoscopic operations on oesophagus
- G16.1 Diagnostic fibreoptic endoscopic examination of oesophagus and biopsy of lesion of oesophagus
- G16.8 Other specified diagnostic fibreoptic endoscopic examination of oesophagus
- G16.9 Unspecified diagnostic fibreoptic endoscopic examination of oesophagus
- G20 Therapeutic fibreoptic endoscopic operations on oesophagus
- G20.1 Fibreoptic endoscopic coagulation of bleeding lesion of oesophagus
- G20.8 Other specified therapeutic fibreoptic endoscopic operations on oesophagus
- G20.9 Unspecified therapeutic fibreoptic endoscopic operations on oesophagus
- G21.5 Insertion of stent into oesophagus NEC
- G42.0 Other fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract
- G42.1 Fibreoptic endoscopic submucosal resection of lesion of upper gastrointestinal tract
- G42.2 Fibreoptic endoscopic photodynamic therapy of lesion of upper gastrointestinal tract

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G42.3 Fibreoptic endoscopic mucosal resection of lesion of upper gastrointestinal tract
G42.8 Other specified other fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract
G42.9 Unspecified other fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract
G43.1 Fibreoptic endoscopic snare resection of lesion of upper gastrointestinal tract
G43.2 Fibreoptic endoscopic laser destruction of lesion of upper gastrointestinal tract
G43.3 Fibreoptic endoscopic cauterisation of lesion of upper gastrointestinal tract
G43.4 Fibreoptic endoscopic sclerotherapy to lesion of upper gastrointestinal tract
G43.5 Fibreoptic endoscopic destruction of lesion of upper gastrointestinal tract NEC
G43.6 Fibreoptic endoscopic injection therapy to lesion of upper gastrointestinal tract NEC
G43.7 Fibreoptic endoscopic rubber band ligation of upper gastrointestinal tract varices
G43.8 Other specified fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract
G43.9 Unspecified fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract
G44 Other therapeutic fibreoptic endoscopic operations on upper gastrointestinal tract
G44.1 Fibreoptic endoscopic insertion of prosthesis into upper gastrointestinal tract
G44.2 Fibreoptic endoscopic removal of foreign body from upper gastrointestinal tract
G44.3 Fibreoptic endoscopic dilation of upper gastrointestinal tract NEC
G44.5 Fibreoptic endoscopic percutaneous insertion of gastrostomy
G44.6 Fibreoptic endoscopic pressure controlled balloon dilation of lower oesophageal sphincter
G44.7 Fibreoptic endoscopic removal of gastrostomy tube
G44.8 Other specified other therapeutic fibreoptic endoscopic operations on upper gastrointestinal tract
G44.9 Unspecified other therapeutic fibreoptic endoscopic operations on upper gastrointestinal tract
${\sf G45.1\ Fibreoptic\ endoscopic\ examination\ of\ upper\ gastrointestinal\ tract\ and\ biopsy\ of\ lesion\ of\ upper\ gastrointestinal\ tract}$
G45.4 Fibreoptic endoscopic examination of upper gastrointestinal tract and staining of gastric mucosa
G45.8 Other specified diagnostic fibreoptic endoscopic examination of upper gastrointestinal tract
G45.9 Unspecified diagnostic fibreoptic endoscopic examination of upper gastrointestinal tract
G46.2 Fibreoptic endoscopic coagulation of bleeding lesion - upper gastrointestinal tract
G46.8 Other specified therapeutic fibreoptic endoscopic operations on upper gastrointestinal tract
G46.9 Unspecified therapeutic fibreoptic endoscopic operations on upper gastrointestinal tract
G54.1 Endoscopic extirpation of lesion of duodenum
G54.2 Endoscopic dilation of duodenum

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G54.3 Endoscopic insertion of tubal prosthesis into duodenum

 ${\sf G54.8~Other~specified~therapeutic~endoscopic~operations~on~duodenum}$

G54.9 Unspecified therapeutic endoscopic operations on duodenum

G55.1 Diagnostic endoscopic examination of duodenum and biopsy of lesion of duodenum

G55.8 Other specified diagnostic endoscopic examination of duodenum

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G55.9 Unspecified diagnostic endoscopic examination of duodenum

ICD-10 Codes

C15x: Malignant neoplasm of esophagus

C16x: Malignant neoplasm of stomach

C17x: Malignant neoplasm of duodenum

K20.9: Esophagitis, unspecified

K21.0: Gastro-esophageal reflux disease with esophagitis

K22.1: Oesophageal ulcer

K22.2: Oesophageal stricture

K22.7: Barrett's oesophagus

K25x: Gastric ulcer

K25.0 Acute gastric ulcer with hemorrhage

K25.1 Acute gastric ulcer with perforation

K25.2 Acute gastric ulcer with both hemorrhage and perforation

K25.3 Acute gastric ulcer without hemorrhage or perforation

K25.4 Chronic or unspecified gastric ulcer with hemorrhage

K25.5 Chronic or unspecified gastric ulcer with perforation

K25.6 Chronic or unspecified gastric ulcer with both hemorrhage and perforation

K25.7 Chronic gastric ulcer without hemorrhage or perforation

K25.9 Gastric ulcer, unspecified as acute or chronic, without hemorrhage or perforation

K29.4 Gastric atrophy

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