Post Endoscopy Upper Gastrointestinal Cancer (PEUGIC) root cause analysis project

Chief investigator

Nigel Trudgill

Sandwell and West Birmingham NHS Trust

Sandwell General Hospital

Lyndon, West Bromwich B71 4HJ

nigel.trudgill@nhs.net

Co-investigators

Amar Srinivasa

Sandwell and West Birmingham NHS Trust

Sandwell General Hospital

Lyndon, West Bromwich B71 4HJ

amarsrinivasa@nhs.net

Dr Matthew Banks
Consultant Gastroenterologist
University College London
University College London University College London Hospitals
matthew.banks2@nhs.net

Dr Chris Healey
Consultant Gastroenterologist
Airedale General Hospital
Skipton Road Steeton Keighley BD20 6TD
chris.healey@anhst.nhs.uk

Mr Dip Mukherjee
Consultant General Surgeon
Barking, Havering and Redbridge University Hospitals NHS Trust
Queens Hospital Romford Rom Valley Way Romford RM7 0AG
dipankar.mukherjee@nhs.net

Prof Pradeep Bhandari
Consultant Gastroenterologist
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital Cosham, Portsmouth
PO6 3LY pradeep.bhandari@porthosp.nhs.uk

Dr Nicholas Burr
Consultant Gastroenterologist
Leeds Teaching Hospital NHS trust
Great George St, Leeds LS1 3EX

N.E.Burr@leeds.ac.uk

Mrs Mimi McCord
Chair of Heartburn Cancer UK
Heartburn Cancer Awareness and Support
Grove House, Lutyens Close, Chineham Court
Basingstoke RG24 8AG
mccord@mimimccord.co.uk

Dr Roland Valori
Consultant Gastroenterologist
Employer Gloucestershire Hospitals NHS Foundation Trust
Gloucester Royal Hospital
Great Western Rd
Gloucester GL1 3NN
roland.valori@nhs.net

Prof Eva Morris
Post Professor of health data epidemiology
University of Oxford
Big Data Institute and the Nuffield Department of Population Health.
Old Road Campus OX3 7LF
eva.morris@ndph.ox.ac.uk

Title

Reducing the rate of missed diagnoses of oesophageal and gastric cancers during endoscopy through endoscopy provider root cause analysis of potentially missed cancers

Keywords

PEUGIC, Quality improvement, Upper GI endoscopy, missed cancer

Background

The PEUGIC root cause analysis project is funded by the NIHR RfPB. The project has near identical aims and methods to the PCCRC audit, but for upper GI cancers diagnosed by endoscopies (instead of colorectal cancers diagnosed by colonoscopy). In summary, the project is to develop a portal for trusts to enter additional information on endoscopies which were negative for cancer, but the patient was later diagnosed with upper GI cancer, hence labelled a post endoscopy upper GI cancer. The purpose of the project is to identify improvements that can be made in the endoscopy process to reduce the rate of PEUGICs. The specific cohort for the portal is endoscopies carried out 3-36 months (within the NHS) prior to the cancer diagnosis. Due to the complexity, private providers will be treated by a separate project carried out by HDI.

Study design

We propose a large database analysis project of the output of the national PEUGIC route cause analysis tool which we have created. Given the size of the cohort we will be able to identify risk factors for missed cancer at endoscopy.

Primary objectives

The aims and objectives of this project are to:

1. Prospectively identify all missed upper gastrointestinal cancer (PEUGIC) within the English NHS and tell each endoscopy provider/NHS Trust about the missed cancer associated with their endoscopies.

2. Enable local detailed review and root cause analysis of why each missed cancer occurred, based on the World Endoscopy Organisation algorithm for post-colonoscopy colorectal cancer adapted for PEUGIC, to understand how many might be preventable.

3. Act on the pooled findings and introduce interventions, in partnership with endoscopy regulators, including quality improvement efforts to reduce the occurrence of missed cancers.

Secondary objectives

Patient, procedural and institutional risk factors for endoscopy that does not diagnose cancer in patients later diagnosed with cancer or post endoscopy upper gastrointestinal cancers (PEUGIC)

Plan

The project will be composed of five interlinked work packages. These are:

1.Identification of all PEUGIC in the English NHS

Following appropriate ethics and information governance approvals with NHS Digital, including producing a data protection impact assessment to support data flows, the research team will adapt a previously developed algorithm to identify post colonoscopy colorectal cancer using routine cancer and endoscopy data across the NHS (Burr 2019). This will be adapted to identify PEUGIC cases prospectively. Essentially, linkage of almost real-time Hospital Episode Statistics (for endoscopy) and National Cancer Registration and Analysis Service (NCRAS) databases every quarter will enable identification of patients with oesophageal and stomach cancer who have had an endoscopy in the previous 3~~6~~-36 months, where that cancer was not detected at the endoscopy and will be classed as a PEUGIC. The service in which the endoscopy was performed will be responsible for capturing details of the cancer and other relevant factors about the PEUGIC and transferring them to the root cause analysis tool described in work package 2.

Commented [as1]: This is primarily because we should be diagnosing cancer withing 3 months if the initial endoscopy is abnormal. ^ months is likely too long.

2.Development of a secure web-based root cause analysis tool

Based on the national root cause analysis tool for post colonoscopy colorectal cancer, a proforma will be developed that captures the data items required to undertake a comprehensive root cause analysis of a PEUGIC involving the following areas: 1) Patient – Demographic details 2) Endoscopy – Details of the procedure itself Full Set of Project Data IRAS Version 6.3.5 9 DRAFT 3) Cancer – Nature of the missed cancer treatment 4) Management – plan following the endoscopy 5) Summary – PEUGIC classification, potential to be avoidable, duty of candour. We have learned from our current work on post colonoscopy colorectal cancer root cause analysis that it is particularly important to focus on:

1.Patients at risk of PEUGIC for biological or other reasons (e.g. poor tolerance of procedure)

2. Adequate protocols for follow up, either repeat procedures or surveillance, and whether adhered to or not

3. Clinician decision-making, including documentation

4. Booking processes

5. The quality of endoscopy procedures: protocols; care; equipment

6. Patient choice and co-morbidity

7. Action taken when patients fail to attend for procedures

A secure web-based portal with be developed by a developer working for Health Data Insight. This will involve: producing a specification based on the existing portal for the post colonoscopy colorectal cancer root cause analysis project; agreeing data entry screen design and creating a data entry screen; testing a mock up portal and getting feedback; undertaking any portal changes; and finalising the specification and pushing the PEUGIC pages to the live portal. The portal will then be piloted in two trusts with data entry on PEUGIC cases for those trusts. Feedback will be sought on the data entry screens and portal changes made as needed. A second pilot phase will then be undertaken in 10 trusts with data entry on the portal for PEUGIC cases in those trusts. Further portal changes will be made following meetings with feedback on the data entry screens and any portal changes needed. Contingency will be allowed for additional changes, checking, and preparation for the portal go live.

3.National rollout of secure web-based root cause analysis tool.

The process for account registration and validation will follow that of the post colonoscopy colorectal cancer root cause analysis project via an account verification Standard Operating Procedure. User guides will be created for the portal and other relevant user documents (duty of candour guidance, information governance information, information for other endoscopists, etc.). We will advertise the launch of the PEUGIC root cause analysis portal through partner organisations (BSG, AUGIS, JAG) and PPI partners via social media and their websites. We will also ask Cancer Alliances, the National Oesophago-gastric Cancer Audit network, endoscopy training academies, the National Nurse Endoscopist Group, gastroenterology trainee networks and regional gastroenterology associations (e.g. Midland Gastroenterological Society) to promote the launch of and involvement in the project. Lead endoscopists at each trust who will undertake data collection for PEUGIC cases via the portal will be identified from trusts. We will have regular follow up meetings with lead endoscopists to ensure there are no data entry issues. We will run weekly data completeness reports to monitor data completeness. We will update data on the portal each quarter and remind trusts there will be a data refresh and further PEUGIC cases to root cause analyse.

4.Quantifying the reasons why PEUGIC occur

The portal will enable each endoscopy provider not only to be informed of each PEUGIC and the need for a root cause analysis but also facilitate this by providing a structured method to report the results of the root cause analysis that can be captured centrally and enable analysis of the reasons for PEUGIC at a national level. Once the results of root cause analysis data have been collated at pilot and rollout stages of the root cause analysis tool, pseudonymised record level~~anonymised aggregated~~ data release will be organised with NHS digital to enable analysis by Nigel Trudgill and Amar Srinivasa~~, Nick Burr, Eva Morris and Roland Valori~~ supported by a research fellow to assess common factors and generate population level information as to why PEUGIC occur. This will be by

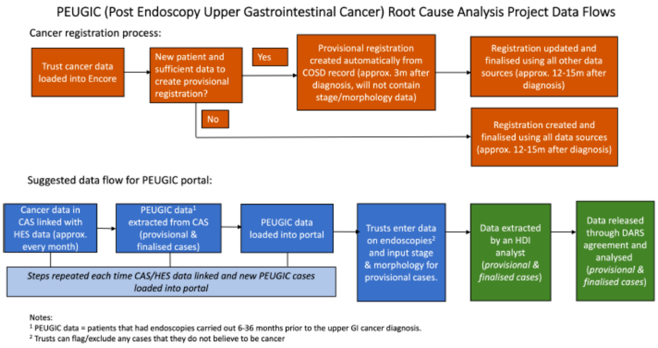
Commented [as2]: Data requested to NCRAS will be for pseudonymised data as cases will be allocated an ID. However researcher will not be able to identify patients. Furthermore it is not aggregated data

Commented [as3]: Because of the data sharing agreement it will only be available to the CI's trust far the largest cohort of PEUGIC studied in such detail and enable us to identify e.g. high and low risk groups or endoscopy practices. The intelligence generated will then be used to inform effective interventions to tackle the incidence of PEUGIC through local and national quality improvement efforts.

5.Interventions to reduce the occurrence of PEUGIC and impact

For an individual endoscopy provider, a PEUGIC will be an infrequent event (we estimate 10 to 20 per year depending on the size of their service) and even less frequent for individual endoscopists (10-15 in a lifetime practice depending Full Set of Project Data IRAS Version 6.3.5 10 DRAFT on their volume of endoscopy activity). It would therefore take time for a service to identify all the potentially avoidable factors. Furthermore, experience with post-colonoscopy colorectal cancer suggests that up to 20% of missed cancers are diagnosed in a different provider from the index endoscopy (Burr 2019). Consequently, the endoscopy provider would be unaware of these PEUGIC without this project.

Data Flows


PEUGIC (Post Endoscopy Upper Gastrointestinal Cancer) Root Cause Analysis Project Data Flows

Notes:
[1] PEUGIC data = patients that had endoscopies carried out 6-36 months prior to the upper GI cancer diagnosis.
[2] Trusts can flag/exclude any cases that they do not believe to be cancer

Timeline

- Decide on data cohort to populate the PEUGIC root cause analysis tool (October to December 2022)
- Adapt the PCCRC algorithm for identifying PEUGICs in the cancer registry database (CAS) (provisional and finalised) and Hospital Episode Statistics (HES) data (October to December 2022)
- Decide on the data item questions and answer options for PEUGIC root cause analysis tool based on the PCCRC audit portal (October to December 2022)
- Develop the root cause analysis tool (January to March 2023)
- Create necessary documentation for engaging with Trusts (March to September 2023)
- Extract agreed data from CAS and HES and populate the PEUGIC root cause analysis tool (March to April 2023)
- Pilot the national PEUGIC root cause analysis tool (May to July 2023)
  - Sandwell & West Birmingham NHST (**NT**)
  - Mid Yorkshire Hospitals NHST (**NB**)
  - Gloucestershire Hospitals NHST **(Roland Valori)**
  - Nottingham University Hospitals NHST **(Dr Frank Phillips)**

- Airedale NHS Foundation Trust **(Chris Healey)**
- Barking, Havering and Redbridge University Hospitals NHS Trust **(Dip Mukherjee)**
- University College London Hospitals NHS Foundation Trust **(Matt Banks)**
- Portsmouth NHS Trust **(Pradeep Bhandari)**

At this point research phase of the project begins (End of July 2023)
Data request sent to NCRAS for pseudonymised ~~anonymised~~ data from the audit for analysis at SWB NHS trust and optimisation of online platform

- National roll out of the national PEUGIC root cause analysis tool following optimisation (October to December 2023) **(Trusts)**
- Capture root cause analysis data on all PEUGICs that occur in the English NHS (December 2023 onwards) **(Trusts) this will occur over 12 months.**

A further data request will be sent to NCRAS for pseudonymised ~~anonymised~~ data from the national audit for analysis at SWB NHS trust after 12 months of data collection.

End point

Will occur following 12 months of data collection from the national PEUGIC root cause analysis portal expected to be between September and December 2024.

Analyse of the PEUGIC root cause analysis data from the previous 12 months and disseminate results including publications in peer-review journals (January 2025).

This cohort will allow for identification of risk factors for missing cancer on endoscopy.

Project Deliverables/Outputs

1. A system to identify all PEUGICs occurring within 3-36 months of an endoscopy (that has not identified cancer) (based on the PCCRC algorithm)
2. Providing the endoscopy unit where the original endoscopy was done with Patient Identifiable Data via a secure online platform (root cause analysis tool) that will enable the service to identify cases for review
3. A root cause analysis tool that enables classification and determination of the 'most plausible explanation' of each PEUGIC (local factors that lead to PEUGIC)
4. Publication of aggregated analysed data inserted into the portal by individual trusts for a more complete picture of why PEUGICs occur that can be shared across the NHS to enable endoscopy services to address causes of PEUGIC that have not yet occurred in their service
5. Providing the Joint Advisory Group on GI Endoscopy (JAG) with the root cause analysis tool once it is fully developed and has been rolled out nationally. This reporting tool can become part of the ongoing quality improvement step in the accreditation process for participating services.
6. A dedicated website for the project. This will be used to host background information about the project and also to promote the project outputs. It is hoped that this will be referenced and linked to by potential sponsors, Public Patient Involvement (PPI) partners, or publishers of the scientific output.
7. A dedicated twitter account for the project with regular updates, outputs and related educational topics for healthcare professionals and members of the public or patient community. This will include links to any sponsor and related society or charity.

Dissemination

Results of the study will be published in peer reviewed journals as well as presented at conferences, from January 2024 onwards initially the pilot data followed by the results of the national audit.

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Research and Development Department
Sandwell & West Birmingham NHS Trust
Clinical Research Facility, Sandwell General Hospital, West Bromwich, B71 4HJ

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