NED: APRIQOT study of performance feedback emailed to endoscopists and endoscopy unit lead clinicians through the National Endoscopy Database (NED) on the endoscopists' detection of polyps

| Submission date | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|------------------------------|---|--------------------------------|--|--|
| 09/09/2019 | | ☐ Protocol | | |
| Registration date 27/09/2019 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 20/05/2024 | Digestive System | | | |

Plain English summary of protocol

Background and study aims

Around 41,000 people are diagnosed with bowel cancer each year. Bowel cancer develops from polyps, which grow slowly on the lining of the bowel. Colonoscopy is the best test to find and remove polyps, before they change into cancer. Polyps are missed for many reasons, including how the endoscopist does the test. Patients of endoscopists who find fewer polyps, are more likely to develop bowel cancer after the test. It is not known how often we should find polyps in the UK, or if feedback of performance will improve how many polyps are found. The researchers hope to improve colonoscopies for all patients in the UK by finding more polyps to prevent bowel cancers. The study will use the National Endoscopy Database (NED) to assess how often doctor and nurse endoscopists currently find pre-cancerous growths in the bowel (polyps) when performing camera tests through the bottom (colonoscopies). They will give feedback to endoscopists and the units they work in about how successful they are at finding polyps compared to others nationally. They want to find out if this makes them better at finding polyps.

Who can participate?

Colonoscopists at participating NHS endoscopy units in the UK

What does the study involve?

NED collects data from every colonoscopy in the UK including if polyps were found and removed. The researchers will look at over 100,000 colonoscopies to work out how often polyps should be found by endoscopists. Participating colonoscopy units are randomly allocated to either receive regular feedback on their colonoscopy performance or to not receive feedback. After a year the researchers will see if receiving feedback improved how many polyps they found. Before and after the study they will interview endoscopists to explore what kind of feedback is most likely to help them, how feedback and behaviour are influenced in endoscopy, and how they can improve feedback further.

What are the possible benefits and risks of participating?

The results will help guide the use of performance data from NED, to improve quality of colonoscopy and performance feedback, benefiting all endoscopists. If colonoscopists are allocated to the feedback group they will receive information, educational material and feedback aiming to improve their own practice. The researchers think this will be incentivising and rewarding as an endoscopist. They do not envisage any risks - this study involves providing colonoscopists with performance data, which will only be shared with the colonoscopist and the endoscopy unit lead (the lead already has access to local performance data). This feedback should only be used as a guide by endoscopy leads, and not for formal competency review.

Where is the study run from?
The Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? April 2019 to November 2022

Who is funding the study? Health Foundation (UK)

Who is the main contact? Simon Sinclair simon.sinclair1@nhs.net

Study website

https://www.health.org.uk/programmes/insight-2017/projects/ned-apriqot-%

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS: 41104

Study information

Scientific Title

Automated Performance Reports to Improve Quality Outcomes Trial (APRIQOT) Using the National Endoscopy Database (NED) to evaluate endoscopy performance and reduce unwarranted variation in quality

Acronym

NED: APRIQOT

Study objectives

To assess, by means on an RCT, whether regular automated feedback of endoscopist- and endoscopy unit-level colonoscopy performance data reduces unwarranted variation in colonoscopy quality.

Ethics approval required

Old ethics approval format

Ethics approval(s)

As per HRA approval; REC approval is not required for this study

Study design

Randomised; Both; Design type: Diagnosis, Process of Care, Psychological & Behavioural, Active Monitoring, Other, Qualitative

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Bowel polyps

Interventions

Trial design: Cluster randomised control trial, 1:1 randomisation

Intervention group: monthly automated email including KPI data report to individual endoscopists and to the endoscopy unit leads. The precise content will be determined in the initial stage of the NED-APRIQOT project. Guidance and consensus from the Advisory Group, many members of which have considerable expertise in QA, will be sought regarding content and structure of the KPI reports. In addition, the proposed qualitative work, detailed above, will inform the structure and content of the KPI reports.

KPI data reports will be provided for endoscopy leads, and formatted using the above qualitative work. This will include pooled data for the unit, from all independent endoscopists. This summary statistic will be calculated may include data from colonoscopists who have not consented to partake in the NED APRIQOT study. The endoscopy lead's report will include detailed KPI reports for all individual endoscopists who are consented into the study, including any action plans. Unit leads will be given information about dealing with underperformance in endoscopy which is their clinical responsibility, based on international expert guidance (Rees et al., 2018) with a link to further resources.

Provisionally, the KPI data report will report on a rolling monthly period, to balance the reports reflection of contemporary practice with its statistical power.

Recipients will be provided with contact details of their endoscopy lead to flag concerns about their performance, and local investigators and the central research team to flag any perceived discrepancy in the accuracy of the feedback data. Local investigators will have local access to assess potential mismatch between NED data and local ERS data.

This can then be fed-back to problem-solve any IT accuracy issues with the research and Weblogik © team. If accuracy is challenged, local units may be asked to provide numerator and denominator data for the period in question which can be checked and compared centrally.

Comparator group: No KPI report; access to NED website available, but optimal detection KPI not displayed. This is the current feedback available to all endoscopists nationally, and reflects current endoscopic practice.

Intervention Type

Behavioural

Primary outcome measure

Mean value of optimal detection KPI in the 2 study arms, measured at 12 months

Secondary outcome measures

Measured at 9 months in both arms:

- 1. Percentage of endoscopists above minimum standard for optimal detection KPI
- 2. Percentage of endoscopists above target standard for optimal detection KPI
- 3. mean value of optimal proximal detection KPI
- 4. Percentage of endoscopists above minimum standard for optimal proximal detection KPI
- 5. Percentage of endoscopists above target standard for optimal proximal detection KPI
- 6. Change over time in optimal detection KPI during the 9-month trial
- 7. Change over time in optimal proximal detection KPI during the 9-month trial
- 8. Subgroup analysis of endoscopists in the intervention group who access learning resource materials on the NED website during the trial

- 9. Subgroup analysis of endoscopists in the control group who access the basic NED website during the trial
- 10. Mean value in other colonoscopic KPIs (caecal intubation rate, terminal ileal intubation rate, rectal retroversion rate, colonoscopy withdrawal time, polyp retrieval success, patient comfort, bowel preparation quality)

We shall also perform a nested study to correlate the opadKPI with both adenoma detection rate (ADR) and serrated polyp detection rate (SDR). This will be performed by asked each trial centre to review polyp histology from all independent colonoscopies within a specific 3-day period of the trial. We estimate that this will amount to 20-40 procedures per centre, totaling approximately 1500 procedures.

Overall study start date

08/04/2019

Completion date

30/11/2022

Eligibility

Key inclusion criteria

- 1. Endoscopy units: NHS endoscopy units in the UK that perform at least 600 colonoscopies per annum
- 2. Endoscopists: All consenting independently-practising colonoscopists within a trial endoscopy unit
- 3. Colonoscopy data): All colonoscopy data from trust-employed independent endoscopists at participating endoscopy units

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 480; UK Sample Size: 480

Total final enrolment

546

Key exclusion criteria

- 1. Endoscopy units:
- 1.1. Independent sector and private sector endoscopy units
- 1.2. Endoscopy units performing fewer than 600 colonoscopies per annum
- 1.3. Endoscopy units without express support for the RCT from the endoscopy lead
- 1.4. Endoscopy units without express support for the RCT from the trust's R&D team
- 1.5. Those units not participating in valid accurate data-uploading to NED

- 2. Endoscopists:
- 2.1. Non-consenting colonoscopists
- 2.2. Colonoscopists in non-independent (supervised) training (NB trainees who are performing colonoscopies independently can participate)
- 3. Colonoscopy data:
- 3.1. Procedures performed by trainee endoscopists in non-independent (supervised) training
- 3.2. Procedures where an independent endoscopist was acting as a trainer
- 3.3. Procedures performed by endoscopists who are not employed by that trust
- 3.4. Procedures performed by endoscopists who are not anticipated to remain in the trust for the duration of the RCT

Date of first enrolment

21/11/2019

Date of final enrolment

30/11/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Aintree University Hospital

Lower Lane Liverpool United Kingdom L9 7AL

Study participating centre Airedale NHS Foundation Trust

Airdale Hospital Skipton Rd Steeton Keighley United Kingdom Keighley

Study participating centre Ashford & St Peter's NHS Trust

Ashford Hospital London Road Ashford Surrey Ashford United Kingdom TW15 3AA

Study participating centre Barts Health

The Royal London Hospital Whitechapel Rd Whitechapel London United Kingdom E1 1BB

Study participating centre Basildon & Thurrock University Hospitals NHS Foundation Trust

Basildon University Hospital Nethermayne Basildon United Kingdom SS16 5NL

Study participating centre Bedford Hospital NHS Trust

Bedford Hospital Kemston Rd Bedford United Kingdom MK42 9DJ

Study participating centre Bradford Teaching Hospitals NHS Foundation Trust

Bradford Royal Infirmary Duckworth Lane Bradford United Kingdom BD9 6RJ

Study participating centre Brighton & Sussex University Hospitals NHS Trust

The Royal Sussex County Hospital

Barry Building Eastern Rd Brighton United Kingdom BN2 5BE

Study participating centre Cambridge University Hospitals

Addenbrooke's Hospital Hills Rd Cambridge United Kingdom CB2 0QQ

Study participating centre County Durham & Darlington Hospitals

Bishop Auckland Hospital Cockton Hill Rd Bishop Auckland United Kingdom DL14 6AD

Study participating centre Dorset County Foundation

Dorset County Hospital Williams Ave Dorchester United Kingdom DT1 2JY

Study participating centre East & North Herts NHS Trust

Lister Hospital Coreys Mill Lane Stevenage United Kingdom SG1 4AB

Study participating centre East Kent University Hospitals Trust Queen Elizabeth the Queen Mother Hospital

St Peter's Rd Margate United Kingdom CT9 4AN

Study participating centre East Sussex Healthcare NHS Trust

Eastbourne District General Hospital Kings Dr Eastbourne United Kingdom BN21 2UD

Study participating centre Frimley Park Hospital

Portsmouth Rd Frimley United Kingdom GU16 7UJ

Study participating centre Gloucestershire Hospitals NHS Foundation Trust

Cheltenham General Hospital Sandford Rd Cheltenham United Kingdom GL53 7AN

Study participating centre Guy's and St Thomas' NHS Foundation Trust

St Thomas' Hospital Westminster Bridge Rd London United Kingdom SE1 7EH

Study participating centre University Hospitals Birmingham NHS Foundation Trust

Good Hope Hospital Rectory Rd Sutton Coldfield, United Kingdom B75 7RS

Study participating centre Hampshire Hospitals NHS Foundation Trust

Royal South Hants Hospital Brintons Terr Southampton United Kingdom SO14 0YG

Study participating centre Isle of Wight NHS Primary Care Trust

St Mary's Hospital Parkhurst Rd Newport United Kingdom PO30 5TG

Study participating centre James Paget University Hospital

Lowestoft Rd Gorleston Great Yarmouth United Kingdom NR31 6LA

Study participating centre Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Lancashire Teaching Hospitals NHS Trust

Royal Blackburn Teaching Hospital Haslingden Rd Blackburn United Kingdom BB2 3HH

Study participating centre London North West / St Mark's

St Mark's Hospital Watford Rd Harrow United Kingdom HA1 3UJ

Study participating centre Maidstone Hospital & Tunbridge Wells Hospital

Maidstone Hospital Hermitage Lane Maidstone United Kingdom ME16 9QQ

Study participating centre North Bristol NHS Trust

Southmead Hospital Southmead Rd Westbury-on-Trym Bristol United Kingdom BS10 5NB

Study participating centre North Cumbria NHS Foundation Trust

Cumberland Infirmary Newton Rd Carlisle United Kingdom CA2 7HY

Study participating centre North Tees & Hartlepool NHS Trust

University Hospital of North Tees Hardwick Stockton on Tees United Kingdom TS19 8PE

Study participating centre Sheffield Teaching Hospital NHS Foundation Trust

Northern General Hospital Herries Rd Sheffield United Kingdom S5 7AU

Study participating centre Northumbria Healthcare NHS Foundation Trust

North Tyneside General Hospital Rake Ln North Shields United Kingdom NE29 8NH

Study participating centre Nottingham University Hospitals NHS Trust

Queen's Medical Centre Derby Rd Nottingham United Kingdom NG7 2UH

Study participating centre Pennine Acute Hospitals NHS Trust

The Royal Oldham Hospital Rochdale Rd Oldham United Kingdom OL1 2JH

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Rd

Reading United Kingdom RG1 5AN

Study participating centre Royal Devon and Exeter Hospital - Tiverton and Axminster Hospitals

Wondford Hospital Barrack Rd Exeter United Kingdom EX2 5DW

Study participating centre Royal United Hospital Bath

Combe Park Bath United Kingdom BA1 3NG

Study participating centre Salford Royal NHS Foundation Trust

Salford Royal Hospital Stott Ln Salford United Kingdom M6 8HD

Study participating centre Sherwood Forest Hospitals NHS Foundation Trust

King's Mill Hospital Mansfield Rd Sutton-in-Ashfield United Kingdom NG17 4JL

Study participating centre Shrewsbury & Telford Hospital NHS Trust

Royal Shrewsbury Hospital Mytton Oak Rd Shrewsbury United Kingdom SY3 8XQ

Study participating centre South Devon Healthcare NHS Foundation Trust

Torbay Hospital Newton Rd Torquay United Kingdom TQ2 7AA

Study participating centre South Warwickshire General Hospitals NHS Trust

Warwick Hospital Lakin Rd Warwick United Kingdom CV34 5BW

Study participating centre

St George's University Hospitals NHS Foundation Trust

St Georges Hospital Blackshaw Rd Tooting London United Kingdom SW17 0QT

Study participating centre St Helens & Knowsley Teaching Hospitals

St Helen's Hospital Marshalls Cross Road St. Helens United Kingdom WA9 3DA

Study participating centre Taunton and Somerset NHS Trust

Musgrove Park Hospital, , Somerset, TA1 5DA Taunton United Kingdom TA1 5DA

Study participating centre The Dudley NHS Foundation Trust

Russells Hall Hospital Pensnett Rd Dudley United Kingdom DY1 2HQ

Study participating centre The Princess Alexandra Hospital

Hamstel Rd Harlow United Kingdom CM20 1QX

Study participating centre The Rotherham NHS Foundation Trust

Rotherham General Hospital Moorgate Road Rotherham United Kingdom S60 2UD

Study participating centre

The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust

Royal Bournemouth Hospital Castle Lane East, , Bournemouth United Kingdom BH7 7DW

Study participating centre The Royal Liverpool & Broadgreen Trust

The Royal Liverpool Hospital
Prescot St
Liverpool
United Kingdom
L7 8XP

Study participating centre The Royal Wolverhampton NHS Trust

New Cross Hospital
Wolverhampton Rd
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2GW

Study participating centre University Hospitals Coventry & Warwickshire

University Hospital Coventry Clifford Bridge Road Coventry United Kingdom CV2 2DX

Study participating centre West Herts Hospital NHS Trust

Watford General Hospital Vicarage Rd Watford United Kingdom WD18 0HB

Study participating centre West Sussex Hospital

Spitalfield Lane Chichester United Kingdom PO19 6SE

Study participating centre Wye Valley Trust - Hereford and Ross

Hereford County Hospital Union Walk Hereford United Kingdom HR1 2ER

Study participating centre Yeovil District Hospital NHS Foundation Trust

Yeovil District Hospital Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre York Teaching Hospital

The York Hospital Wigginton Road York United Kingdom YO31 8HE

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

c/o Aaron Jackson
Newcastle Joint Research Office
Level 1 Regent Point
Newcastle-Upon-Tyne
England
United Kingdom
NE3 3HD
+44 (0)1912825789
aaron.jackson@nuth.nhs.uk

Sponsor type

Hospital/treatment centre

Website

http://www.newcastle-hospitals.org.uk/

ROR

https://ror.org/05p40t847

Funder(s)

Funder type

Charity

Funder Name

Health Foundation; Grant Codes: 695428

Results and Publications

Publication and dissemination plan

- 1. Peer reviewed scientific journals
- 2. Internal report
- 3. Conference presentation
- 4. Publication on website

Intention to publish date

31/03/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The study utilises the National Endoscopy Database [NED] data set which is overseen by JAG/RCP London (https://www.thejag.org.uk/ or https://www.rcplondon.ac.uk]. This dataset does not contain any patient identifiable data. For the NED: APRIQOT trial; a data download from NED is being provided to the research team lead by Newcastle University (the sponsor) as per data sharing agreement. The participants (endoscopists and clinical endoscopy leads) are consenting to the data sharing as part of the informed consent process.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 15/05/2024 | 20/05/2024 | Yes | No |