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

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.

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 Mr Simon Sinclair

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

BN21 2UD

Study participating centre East Sussex Healthcare NHS Trust Eastbourne District General Hospital Kings Dr Eastbourne United Kingdom

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 nonpublically 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?
<u>Results article</u>		15/05/2024	20/05/2024	Yes	No