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The Quality Improvement in Colonoscopy (QIC) Study:
Improving Adenoma Detection Rates and Reducing
Variation between Colonoscopists

Title: The Quality Improvement in Colonoscopy Study: Improving Adenoma Detection Rates and Reducing Variation between Colonoscopists by Introducing Evidence Based Changes into Clinical Practice

Author: Dr Praveen T Rajasekhar

Introduction

Adenoma detection rate (ADR) is an established quality marker in colonoscopy. Significant variability in ADR exists. Withdrawal time of ≥ 6 minutes; Buscopan use; position change and rectal retroflexion have been shown to improve lesion detection. We evaluated the feasibility and clinical outcome of implementing these measures, as a 'bundle', into routine practice to improve ADR. Factors influencing uptake were evaluated in a qualitative study.

Methodology

Twelve units participated. All nominated a lead colonoscopist and nurse. Implementation combined central training, local leadership, feedback and continuous central support. The 3 months prior to implementation was compared to a 9 month period after. Colonoscopists performing ≥ 25 procedures during the baseline period were ranked in quartiles by ADR. Buscopan use was used as a surrogate marker for uptake. Changes were evaluated using a corrected Chi Squared test. For the qualitative study, units and individuals were purposively sampled to ensure a range of units were included. Semi-structured interviews were conducted until saturation was reached. Data were evaluated using thematic analysis.

Results

Global and quartile analyses comprised data from 118 and 68 colonoscopists performing 17, 508 and 14,193 procedures respectively. There was a significant increase in Buscopan use globally (15.8% vs. 54.4%, $p < 0.001$) and in each quartile. The ADR also increased significantly globally (16.0% vs. 18.1%, $p = 0.002$), with a significant reduction in variation. Interviews were conducted with 8 lead and 3 non-lead colonoscopists and 1 lead nurse. Increased emphasis on examination time, awareness of ADR as a quality marker and empowerment of endoscopy nurses to encourage the use of quality measures were positive outcomes of the intervention. Challenges included difficulty in arranging set up meetings and engaging certain speciality groups.

Discussion

This evidence based educational intervention resulted in a significant change in behaviour, evidenced by increased Buscopan use. A significant increase in the global ADR and reduction in variation between quartiles was observed. Other positive outcomes included increased awareness of colonoscopy quality and empowerment of endoscopy nurses to promote quality measures. This study demonstrates that simple interventions can significantly change practice and improve quality. The timing of meetings and strategies to engage speciality groups are important.

The Quality Improvement in Colonoscopy (QIC) Study:

Improving Adenoma Detection Rates and Reducing

Variation between Colonoscopists by Introducing

Evidence Based Changes into Clinical Practice

Dissertation submitted towards the degree of Doctor

of Medicine by Dr Praveen Turuvekere Rajasekhar

Durham University School of Medicine, Pharmacy and

Health

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List of Abbreviations

ADR = adenoma detection rate

BCSP = bowel cancer screening programme

BR = Buscopan use rate

BSG = British Society of Gastroenterology

CIR = caecal intubation rate

FOBT = faecal occult blood testing

HR = hazard ratio

ICV = ileocaecal valve

IT = information technology

JAG = Joint Association for Gastrointestinal Endoscopy

QIC = Quality Improvement in Colonoscopy

TI = terminal ileum

TNM = tumour node metastases

UK = United Kingdom

USA = United States of America

Declaration and Statement of Copyright

I confirm that the work presented in this thesis is my own and the use of all materials from other sources has been properly and fully acknowledged with permission from the respective copyright holders. This thesis represents new material and has not previously been submitted for a degree at this or any other university.

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Introduction

Colorectal cancer is a major cause of premature death in the United Kingdom (UK) and is the second most common cause of cancer related death. The majority of sporadic colorectal cancers are thought to develop from benign colorectal adenomas. The detection and subsequent removal of colorectal adenomas has been shown to reduce the subsequent risk of developing colorectal cancers.

The starting point of this thesis is that the quality of colonoscopy across the UK is not uniform and that unacceptable variance exists between colonoscopists, as evidenced by a British Society of Gastroenterology (BSG) colonoscopy audit published in 2004. This clinical audit referred to caecal intubation rates (CIR) but there is also ample evidence that adenoma detection rates (ADR) also show unacceptable variation across the country and between individual colonoscopists.

Colonoscopy is considered the 'gold standard' investigation for the detection of colorectal adenomas and also allows their removal. Therefore, high quality colonoscopy has the potential to reduce the incidence of colorectal cancer and forms the backbone of colorectal cancer screening in most national programmes.

Maintaining and improving the quality of colonoscopy is vital to allow optimal detection of colorectal adenomas. A high quality colonoscopy must consist of both a complete and thorough examination of the colonic mucosa. The BSG

audit of colonoscopy practice published in 2004 demonstrated that completion rates were well below the nationally recommended standards. Following this report, significant investment was put into improving this aspect of colonoscopy through more thorough monitoring and improvements in training. These changes to colonoscopy training did not take into account the issue of training that may be required for independent colonoscopists who were underperforming.

The ADR, defined as the number of procedures in which one or more adenomas are detected, has been recommended as a surrogate marker for a thorough examination by many national societies. A recent study also demonstrated that patients undergoing colonoscopy by colonoscopists with a lower ADR were at higher risk of developing an interval cancer. This study further supports the use of ADR as a quality marker in colonoscopy. Several studies, both UK and international, have demonstrated that a variation in adenoma detection, and therefore colonoscopy quality, continues to exist. It is crucial that efforts are made to improve ADR in order to maximise the potential of colonoscopy to reduce colorectal cancer incidence.

Inspection of the colonic mucosa is performed primarily during the withdrawal phase of the colonoscopy. There are several measures that have been shown to improve adenoma detection by providing the optimal conditions for identifying such lesions. Whilst these measures are used by some colonoscopists, they are not used routinely by all. Therefore, it is possible that

the routine use of all these measures during colonoscopy withdrawal may improve adenoma detection and thereby the quality of colonoscopy.

Implementing evidence into clinical practice can be challenging and frequently involves changing long held behaviours and practices. There has been much work investigating how best to undertake this process including identifying barriers to uptake and mechanisms for implementation in varied settings. Peter Pronovost outlined a model for implementing a 'bundle' of interventions shown to reduce the number of catheter-related bloodstream infections in an intensive care setting. This combined central training, locally led implementation and ongoing central support. It is feasible that this model could be used to implement clinical evidence into colonoscopy practice.

The Quality Improvement in Colonoscopy (QIC) study was a region wide service improvement study that evaluated the feasibility of implementing a 'bundle' of evidenced based measures into routine colonoscopy practice with the aim of improving ADR.

Chapter one details the epidemiology of colorectal adenomas and colorectal cancer including early detection, prevention and the role of colonoscopy in achieving these aims. The importance of high quality colonoscopy and the metrics that are used to measure performance is further discussed.

Chapter two presents how current standards in the study region were evaluated and how these data provided a baseline against which the study intervention could subsequently be measured.

In chapter three, measures that have been shown to improve quality in colonoscopy, through improving lesion detection, will be reviewed and the evidence supporting each measure discussed. The potential problems of implementing evidence into clinical practice will also be reviewed, together with mechanisms that have been shown to overcome these issues in different clinical settings.

In chapter four, the model selected for this study is also discussed including how barriers were identified and solutions developed together. The results of implementation are presented along with how they compare to other implementation programmes.

Chapter five outlines how implementation of the 'bundle' affected ADR across the region as a whole as well as in relation to individual colonoscopists ranked in quartiles based on their baseline ADR and, importantly, the affect on variation.

The factors influencing uptake of the 'bundle' were studied in a qualitative study the outcomes of which are presented in chapter six, including how they can inform future service improvement initiatives.

The final chapter summarises this thesis, discusses the limitations of the work and the conclusions that can be drawn from this study. The further work that is required following the study is also outlined.

Chapter One: Colorectal Cancer - A preventable condition

Chapter One: Colorectal Cancer - A preventable condition

1.1. Introduction: Epidemiology of Colorectal Cancer

Colorectal cancer is a common disorder in the United Kingdom (UK). It is the third most common cancer overall with an annual incidence of 30 to 40,000 cases. It is the second most common cause of cancer related mortality resulting in approximately 16,000 deaths per year. (1) It affects men more commonly than women, the respective life-time risk being approximately 1 in 16 and 1 in 20 among men and women. It also occurs more frequently with increasing age with 80% of cases diagnosed in those aged 60 years and above. (1)

Colorectal cancer affects the left side of the colon more frequently with approximately 75% of cancers at or distal to the splenic flexure. (1) This may lead to bowel symptoms such as rectal bleeding, change in bowel habit and abdominal pain. (2) Cancers that occur proximal to the splenic flexure tend to cause fewer symptoms in the early stages and their presence may only be suspected following abnormal blood tests such as iron deficiency anaemia. (2) Currently, the majority of colorectal cancers come to the attention of medical services following the development of bowel symptoms or abnormal blood tests. (3) Unfortunately the presence and duration of such symptoms is associated with a more advanced cancer stage at presentation. (2) Individuals, especially those of advancing age, are therefore strongly encouraged to seek medical advice promptly following the development of new bowel symptoms.

1.2. Staging and Prognosis of Colorectal Cancer

Colorectal cancer is most commonly detected during colonoscopy. Following diagnosis, full staging must be performed in order to allow appropriate clinical decision making regarding treatment. The staging systems used for colorectal cancer staging include the tumour, node, metastases (TNM) staging system (4), which is also used in other cancers, and the Dukes staging system which is specific to colorectal cancer. The Dukes staging system was first described in 1932 and its modified version is still widely used. Both systems are based on extent of local tumour invasion, the presence of lymph node involvement and distant metastases. Table 1 describes each system and how they correlate with one another.

Table 1: Summary of TNM and Dukes staging systems

TNM		Modified Dukes stage
Stage 0	Carcinoma in situ	A
Stage I	No nodal involvement, no distant metastasis Tumour invades submucosa (T1, N0, M0) Tumour invades muscularis propria (T2, N0, M0)	
Stage II	No nodal involvement, no distant metastasis Tumour invades into subserosa (T3, N0, M0) Tumour invades into other organs (T4, N0, M0)	B
Stage III	Nodal involvement, no distant metastasis 1 to 3 regional lymph nodes involved (any T, N1, M0) 4 or more regional lymph nodes involved (Any T, N2, M0)	C
Stage IV	Distant metastasis (any T, any N, M1)	D

In addition to aiding clinical decision making, the cancer stage allows clinicians to estimate prognosis. As may be expected, the more advanced the cancer stage, the poorer the likely outcome.

Table 2 shows the approximate 5-year survival that can be expected for each Dukes stage. (5)

Table 2: Dukes stage and expected 5-year survival

Dukes Stage	5-year survival (%)
A	90
B	60
C	30
D	10

Table 3 summarises the Dukes stage at presentation for 28,112 patients from the UK 2011 National Bowel Cancer Audit Report. This highlights the relatively large proportion of individuals that continue to present with advanced (Dukes C and D) disease. (6)

Table 3: Dukes stage at diagnosis in symptomatic patients from the UK National Bowel Cancer Audit Report 2011 (6)

Dukes Stage	Proportion of patients (%) N = 28,112
A	12.4
B	23.8
C	20.4
D	18.6
Unknown	24.6

These data demonstrate that it is clearly preferable to detect cancers at an earlier stage. The National Bowel Cancer Screening Programme (BCSP) began to roll-out in England and Wales in 2006 with the primary aim of detecting colorectal cancers at an earlier stage. (7) Individuals aged between 60 to 74 years (age range extended from 69 years to 74 years from January 2010) are currently invited to take part in biennial postal faecal occult blood testing (FOBT) and those who test positive are considered for colonoscopy. Colonoscopists are eligible to become BCSP colonoscopists only if they have performed >1000 colonoscopies and perform colonoscopy safely and to a high technical standard. They must also undertake and pass a rigorous assessment process. Early published data has demonstrated that the BCSP has been successful in detecting cancer at an earlier stage when compared with the non-screening population. (8, 9)

In the years leading up to the introduction of the BCSP, colonoscopy performance in the UK was variable. This was highlighted by the first British Society of Gastroenterology (BSG) audit performed in 1999, the results of which were published in 2004. (10) This was of particular relevance as the then upcoming introduction of the BCSP could potentially affect the quality of colonoscopy in the symptomatic service both due to the increased demand and the more highly performing colonoscopists being potentially less able to perform diagnostic procedures due to BCSP commitments. This, in part, led to the government investing significantly in a programme of improvement in colonoscopy led by the Joint Advisory Group (JAG) for gastrointestinal endoscopy the outcome of which will be discussed below.

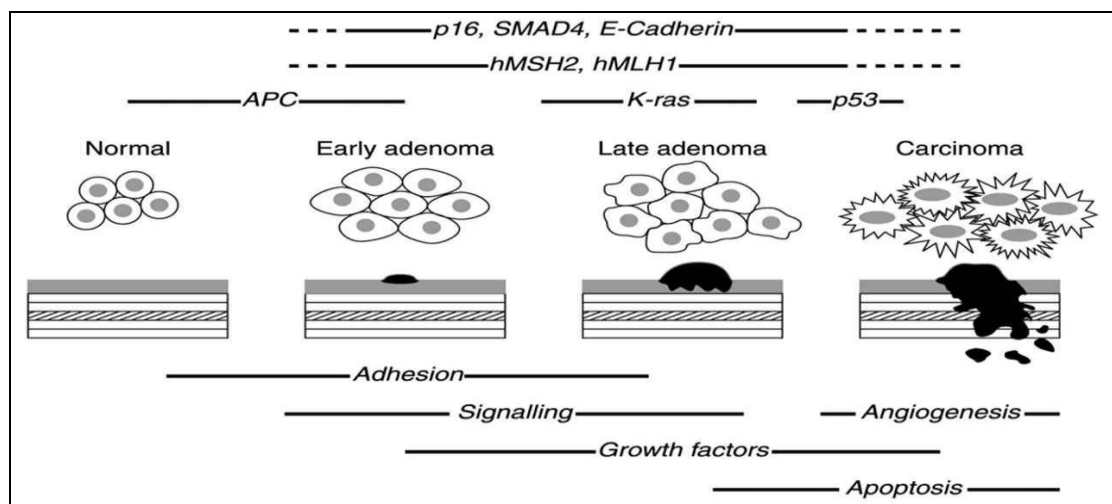
1.3. Colorectal adenomas and their management: the role of colonoscopy in cancer prevention

Whilst detecting colorectal cancer at an earlier stage has the potential to improve prognosis, its prevention would be preferable. It is widely accepted that colorectal cancers develop from colorectal adenomas. The progression of adenomas to cancer is known as the adenoma-carcinoma sequence.

Sporadic colorectal adenomas are thought to develop due to a combination of genetic and environmental factors. It is thought that multiple events are required to encourage progression along the adenoma-carcinoma sequence. This process is slow and amenable to intervention. (11)

Figure 1 summarises some of the genetic alterations thought to contribute at various stages of progression. (11)

Figure 1: Genetic changes at respective stages of the adenoma-carcinoma sequence (used with permission from Oxford Journals)



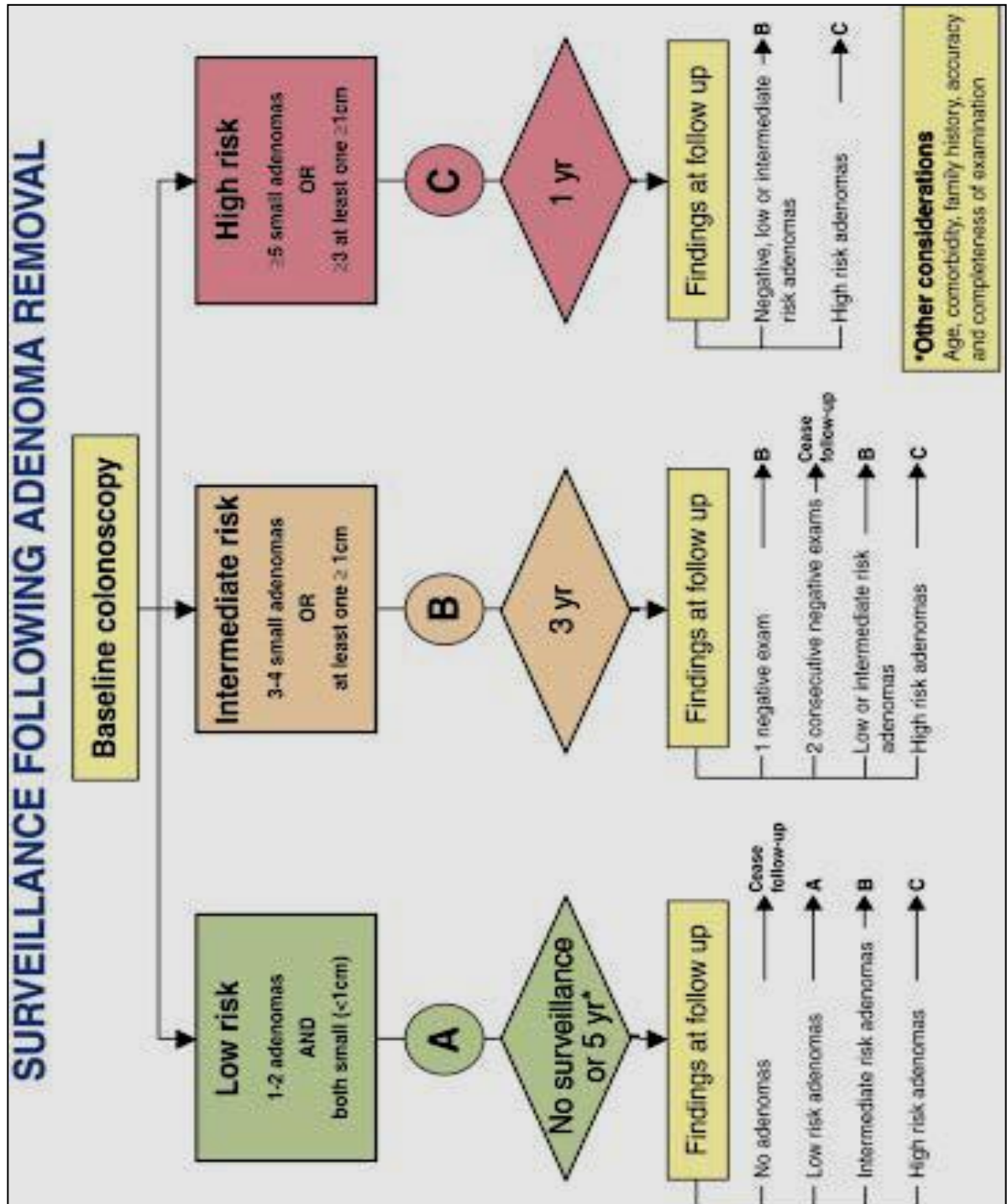
Factors associated with the probability of developing adenomas and colorectal cancers can be considered as modifiable and non-modifiable. Known non-modifiable factors include age, gender and family history (genetics). Several modifiable factors are recognised, including cigarette smoking, alcohol consumption, dietary intake and body mass index (BMI). (12-14) Co-existing medical disorders, such as inflammatory bowel disease, diabetes mellitus and acromegaly also influence the likelihood of developing colorectal adenomas and cancers. (13, 15, 16)

Whilst life style modification and optimal treatment of medical conditions is advisable to reduce the risk of colorectal adenoma formation, its efficacy has yet to be demonstrated. Currently, the most effective way preventing the progression of adenomas to cancer is their removal at colonoscopy and subsequent colonoscopic surveillance of “at risk” individuals, a strategy that is recommended by several national societies. (17, 18) There is a growing body of evidence demonstrating the effectiveness of this strategy with several studies showing the incidence of colorectal cancer amongst individuals undergoing complete colonoscopy and removal of detected adenomas was significantly lower than that in matched cohorts. (19, 20)

There has also been much work studying the association between the number and size of colorectal adenomas present and the risk of developing significant lesions in the future. These studies have demonstrated a clear association between both the number and size of the detected adenomas and the likelihood of individuals developing further clinically significant adenomas. (21)

In addition, it has been demonstrated that small adenomas in sufficient numbers are associated with the development of future adenomas and cancer. The BSG guidelines on colorectal adenoma surveillance incorporate this evidence and is summarised in Figure 2. (22) Individuals are classified into three risk groups depending on the number and size of the adenomas detected and future colonoscopic surveillance recommended based on the level of risk. The importance of detecting and removing colorectal adenomas both to reduce the risk of colorectal cancer and to plan future colonoscopic surveillance is highlighted by these guidelines with high quality colonoscopy an integral part of this process.

Figure 2: BSG guidance regarding adenoma surveillance (reproduced with permission from Gut) (22)



1.4. Colonoscopy: Room for Improvement

1.4.1. Quality Markers in Colonoscopy

Colonoscopy is currently the 'gold standard' investigation for the detection of colonic lesions. In addition to providing diagnostic information, colonoscopy allows sampling of colonic tissue and therapeutic procedures to be performed, including the removal of potentially premalignant colorectal adenomas.

When performing a colonoscopy it is vital to perform a complete examination. A colonoscopic examination is considered to be complete if the colonoscope is successfully passed into the caecum, known as caecal intubation, (17, 18) or terminal ileum (TI). All colonoscopists must record and report a complete examination of the colon and ideally support this with photographic documentation of caecal landmarks. The only reliable landmarks of completion are visualisation of the ileocaecal valve (ICV) or TI, although visualisation of the appendiceal orifice or tri-radiate folds is often accepted. The completion or caecal intubation rate (CIR) is considered a marker of quality in colonoscopy. Current UK guidelines from the Joint Advisory Group (JAG) for gastrointestinal endoscopy state that all colonoscopists should have a CIR of at least 90%. (17)

In addition to a complete examination, it is also vital that the colonic mucosa is examined thoroughly in order to maximise the detection of abnormalities. It is not currently possible to measure how thoroughly a colonoscopist visualises the mucosa directly. A surrogate marker for this is the frequency with which colorectal adenomas are detected. The most widely accepted measure is the

adenoma detection rate (ADR) defined as the number of procedures in which one or more adenomas are detected. (17, 18, 23) In the UK, the JAG states that a colonoscopist should have an ADR of at least 10%. (17)

There has been additional emphasis on quality in colonoscopy following the recent introduction of the BCSP. In order to practice as a BSCP colonoscopist, an individual must have performed at least 1000 colonoscopies and have a CIR of $\geq 90\%$ and ADR of $\geq 20\%$ in the preceding 12 months in the symptomatic services. Following accreditation, colonoscopists must maintain a CIR of $\geq 90\%$ and an ADR of $\geq 35\%$ in the BCSP population. (24) In the Netherlands, an ADR of at least 20% in the symptomatic services is also required for colonoscopists to be eligible for screening. (25) These criteria suggest that the minimum ADR of 10% required in the symptomatic services in the UK is too low and that colonoscopists should be aiming for a significantly higher figure. It also suggests that many colonoscopists fail to adequately visualise the entire colon to a satisfactory standard.

The use of ADR as a quality marker was further supported by a recently published study of data from the Polish bowel cancer screening programme. (26) This study examined the relationship between the CIR, ADR and interval colorectal cancers. Interval cancer was defined as colorectal cancers that were diagnosed between the time of screening colonoscopy and the scheduled time of surveillance colonoscopy, according to the recommendations of the U.S. Multi-society Task Force on Colorectal Cancer and the American Cancer Society. (27) Individuals were eligible for the

programme if they were 50 to 66 years of age and in good health and colorectal cancer was not suspected clinically. Individuals aged 40 to 49 were eligible if they had a family history of any type of cancer. The presence of any symptoms suggestive of cancer was grounds for exclusion from the programme. It was demonstrated that colonoscopists with an ADR less than 20% had a hazard ratio (HR) for interval cancer that was ten times higher than colonoscopists with an ADR of greater than 20%. The most likely explanation for this is that colonoscopists with a lower ADR may have missed significant lesions that subsequently developed into cancers. There was no association between CIR and interval cancers as the rates were globally high. The results of this work support the use of ADR as a surrogate marker of a thorough colonic examination. We must acknowledge that the study was performed within a screening population selected by age and increased risk due to a positive family history and so it is unclear whether the 20% figure is generalisable to an unselected symptomatic population. However, the findings do suggest that a higher minimum ADR should be aimed for, particularly in patients above the age of 50 years.

1.4.2. Variability in Colonoscopy Quality

Colonoscopy is widely available in the UK and demand for the procedure is increasing both in the diagnostic services, for which the majority are performed, and following the introduction of bowel cancer screening. (28) Until recently, there was considerable variation in the quality of colonoscopy in the UK. This was highlighted by Bowles et al who performed an audit of colonoscopy practice in 68 endoscopy units in 1999. (10) It was reported that

overall completion rate was as low as 76.9%. If only visualisation of the ICV or TI was considered acceptable for a colonoscopy to be considered complete, this fell to 56.9%. This is clearly well below recommended guidelines for acceptable completion rates. Polyps were detected in 22.5% of procedures however ADRs of the participating colonoscopists were not reported in this audit. This work prompted significant changes in colonoscopy training and monitoring of quality as mentioned above. The changes in training were centrally funded. This was approximately £497,000 over three years in the northern region alone. This led to the development of endoscopy teaching centres which ran programmes, including hands on training for those training in endoscopy initially, and training for those teaching endoscopy more recently. It must be borne in mind that the majority of current colonoscopists remain out with this change in training philosophy.

Several studies have demonstrated variability in polyp and adenoma detection between colonoscopists. One systematic review looked at six studies in which participants underwent two same-day (tandem) colonoscopies. (29) Polyps detected at the initial colonoscopy were removed. Miss rates were reported as the number of polyps seen only on the second colonoscopy expressed as a percentage of the total number of polyps detected. Results were given for polyps of all sizes and also for adenomas only of the following size groups: 1-5mm; 5-10mm; > 10mm. The miss rates for all polyps and all adenomas were 21% and 22% respectively. As may be expected larger lesions are missed less frequently, 2% for adenomas >10mm, with higher miss rates for smaller

adenomas, 13% for adenomas between 5-10mm and 26% for those between 1-5mm.

A further study which examined the association between mean withdrawal time (MWT) and adenoma detection demonstrated a 10 fold variation in the adenoma detection. (30) In this study, adenoma detection was expressed as ADR and the number of adenomas per subject screened which ranged from 0.10 to 1.05.

1.4.3. Colonoscopy withdrawal technique as a factor contributing to variable adenoma detection rates

The variability in adenoma detection, and therefore quality, has led to much work examining the factors that may contribute to this problem. Whilst there are likely to be many contributing factors, the colonoscopic technique used to view the colonic mucosa is undoubtedly a major one. The colon is examined primarily during the withdrawal phase of the procedure and there has been much work looking at the components of withdrawal technique and how this influences adenoma detection. The presence of variable technique and its influence on adenoma detection was demonstrated in a study performed by Rex et al. (31) In this study, two colonoscopists of similar experience with known different adenoma miss rates had ten colonoscopies video recorded. The withdrawal phase of the procedure was assessed by four experts with scores given for the following criteria: adequacy of time spent viewing; adequacy of luminal distension; cleaning and suctioning; examining the proximal sides of flexures, folds and valves. The colonoscopist with the higher

miss rate received consistently and significantly poorer scores for all four criteria. This suggests that improving colonoscopy withdrawal technique is one way of improving adenoma detection. Lee et al demonstrated similar findings in their study of 11 screening colonoscopists. (32) In addition to withdrawal technique, introducing measures to improve luminal distension and increase visible mucosal area also has the potential to improve mucosal examination as measured by adenoma detection during colonoscopy.

In summary, colorectal cancer continues to cause significant morbidity and mortality in the UK. The condition is potentially preventable by high quality colonoscopy aimed at detecting and removing colorectal adenomas. There is evidence that the quality of colonoscopy, including mucosal examination, is variable. Kaminski et al demonstrated the potential consequences of this variability in ADR, observing an increase in the risk of interval cancers among patients colonoscoped by endoscopists with a low ADR. The current standard of colonoscopy within the study region was evaluated to understand the variability in ADR prior to the study intervention and is presented in the next chapter.

Chapter Two: Evaluating colonoscopist performance within the study region and the use of funnel plots as a method of analysis

Chapter Two: Evaluating colonoscopist performance within the study region and the use of funnel plots as a method of analysis

This chapter details the quality of colonoscopy within the study region and how this affected subsequent analysis of study observations.

2.1. Introduction: Why the Northern Region Endoscopy Group?

The northern region is one of the largest health regions geographically in England covering an area stretching from the Scottish Borders to North Yorkshire and across to the western border of County Durham and northern Cumbria. Hospitals in the region serve a population of approximately 3.5 million people. The region has well developed endoscopy services and was at the forefront of developing and implementing the recent BSG and JAG led quality improvement initiative in endoscopy programme. This had improving colonoscopy completion rates, sedation practice and training among its primary aims. It was also the first region to have BCSP coverage across its entirety. (33) Research is actively encouraged in all units, however, most are too small to perform independent projects.

The northern region endoscopy group (NREG) is a collaborative research network formed in 2007 to allow high quality, region wide research, audit and service improvement work. (33) All 17 endoscopy units in the nine NHS Trusts within the region are members of NREG, representing all 300 endoscopists. There are approximately 100,000 endoscopic procedures performed in the region each year, comprising approximately 45,000 upper gastrointestinal

endoscopies, 28,000 colonoscopies, 18,000 flexible sigmoidoscopies and 3000 ERCPs (endoscopic retrograde cholangiopancreatography). Membership of NREG is open to all with an interest in endoscopic research. Each unit is asked to nominate a lead clinician to act as a representative and to disseminate information back to their unit. All units have equal voting rights within NREG. Meetings occur quarterly, coordinated by the chair, during which new research proposals are put forward and developed along with updates on projects that are underway. Each project has an individual steering group, overseen by the NREG committee.

The success and supportive infrastructure of NREG meant that it was an ideal setting in which to perform this quality improvement project. All member units were invited to participate and those who accepted were asked to nominate a lead colonoscopist (who could be different from their NREG link person) and a lead endoscopy nurse. Their role was to run and promote the study locally, in addition to being a point of contact for the central study team.

2.2. Methods

2.2.1. Data collection, transfer and storage

Twelve endoscopy units agreed to participate in the study. Prior to the collection of study data, the project was registered at all units through the appropriate departments. Caldicott approval was sought and gained for access to patient information and data collection including the transfer of data outside of the unit when required. Transferred data did not include patient identifiable information. Each colonoscopist was given a study code number

so that their name need not be used on transferred data. A data collection form was developed (Appendix A) onto which all data was transferred after appropriate cleaning. The data collected included:

- Endoscopy Unit
- Colonoscopist's code
- Colonoscopist Grade
- Total number of colonoscopies performed
- Total number of completed colonoscopies
- Caecal intubation rate
- Total number of procedures in which ≥ 1 polyp was detected
- Polyp detection rate
- Total number of procedures in which ≥ 1 adenoma was detected
- Adenoma detection rate
- Total number of patients in which Buscopan was used (discussed in chapter three)
- Total number of male patients
- Mean patient age

For the calculation of ADR, the histological diagnosis is required. The majority of individuals charged with colonoscopy performance quality assurance do not routinely collect these data. The polyp detection rate (PDR), proportion of procedures in which at least one polyp is detected expressed as a percentage, is often used as an alternative as its calculation is simpler. Consequently, data on histological type of all polyps was collected through

manual interrogation of the pathology systems at each respective unit. Thus the histology results of all lesions thought to be polyps by the colonoscopists, based on their endoscopic appearance, were retrieved.

Data on adverse events were also collected from each unit using their accepted reporting system. They were defined as those preventing completion of colonoscopy (excluding poor bowel preparation or technical failure) or resulting in unplanned hospital admission, prolongation of existing hospital stay, an unplanned interventional procedure or another medical consultation. (7)

Data were stored on a password protected computer at South Tyneside Foundation Trust in accordance with trust protocol and the terms under which data were allowed to be transferred from each of the other participating trusts.

2.2.2. Definitions

The caecal intubation rate (CIR) was defined as the proportion of all colonoscopies performed in which caecal intubation was achieved expressed as a percentage.

The adenoma detection rate (ADR) was defined as the proportion of procedures in which one or more adenomas were detected expressed as a percentage.

Buscopan use rate (BR) was defined as the proportion of procedures in which Buscopan was used expressed as a percentage.

2.2.3. Data cleaning

The monitoring of colonoscopy performance, including markers of colonoscopy performance and sedation practice, is mandatory. Each endoscopy unit must submit an annual report to the JAG regarding this and other areas of endoscopy performance. As a result, units have become reasonably accustomed to collecting this type of data. All of the units within NREG have electronic endoscopy reporting systems that can be used to extract colonoscopy related data. Whilst each unit had a mechanism for collecting performance data, they were different depending on the idiosyncrasies of the respective reporting system. The data extracted were also dependent of the quality of the reports entered by the colonoscopist. This was variable and has been shown in previous work. (34) The end result was that data was received in varying formats and quality requiring different degrees of cleaning. The systems in use were Endosoft in seven units, Unisoft in three units, Endoscribe in one unit and ADAM in one unit. The lead colonoscopist for each unit was approached regarding data collection although in some cases this was delegated to a more appropriate person responsible for this type of data collection. Unisoft, Endoscribe and ADAM allow clinicians to access the audit facility of the programme, however, only information technology (IT) personnel have access to the audit facility of Endosoft. Issues encountered included the following:

- Confirming colonoscopies had taken place
- Excluding incorrectly entered procedures e.g. gastroscopies and flexible sigmoidoscopies that had been entered as colonoscopies
- Ensuring no double counting of procedures
- Confirming polyp detection
- Confirming Buscopan use

After addressing these issues, histology results were retrieved and ADR and BR could be calculated.

2.2.4. Evaluating performance data: Funnel plots as a method of analysis

Quality assurance within the NHS is vital to ensure delivery of the best possible service. The monitoring and improvement of services can be challenging and requires a method that allows meaningful comparison between units and individuals that perform varying procedure numbers. Statistical process control (SPC) is one method used in many industrial processes to monitor the quality of their products. (35) In addition, SPC can identify processes that may be failing prior to the production of substandard goods. Recently, SPC methods have been used in a variety of clinical settings to monitor outcomes of their services including surgical procedures, percutaneous coronary angiograms and trauma care. (36, 37)

The use of funnel plots, as a graphical representation of performance data, is one such method. (35) In such graphs, the chosen performance measure is plotted (on the y axis) against case volume (on the x axis). Funnel plots

include upper and lower confidence limits, most commonly 95% +/- 99.8% limits, calculated relative to a reference standard or mean for the dataset. The confidence limits depict how much 'common cause variation' would be expected for a given case volume. Falling outside the confidence limits would indicate 'special cause variation' due to some other factor that may be internal or external to the process in question and may warrant further investigation. Therefore, this allows meaningful comparison of units and individuals that perform different procedure volumes, both with reference to established standards and to each other.

In order to allow analysis of the baseline data, idealized funnel plots with upper and lower 95% CIs were created for CIR and ADR relative to the current recommended national standards and for global mean for ADR for the dataset.

The colonoscopy data analysed included those from all colonoscopists performing procedures during a three month period (1st of October to 31st of December 2010) in the participating units. The prevalence of adenomas within the BCSP population has been shown to be higher than in the non-BCSP population. (38, 39) Therefore, the ADRs of colonoscopists that perform screening are higher than those who do not. It was not possible to reliably distinguish between procedures performed within the BCSP and those for the diagnosis of symptoms for each colonoscopist. As a result, performance data from colonoscopies performed by BCSP accredited colonoscopists were

included for the calculation of CIR (in order to more accurately reflect quality of this marker within the region) but were excluded from calculation of ADR.

2.3. Results

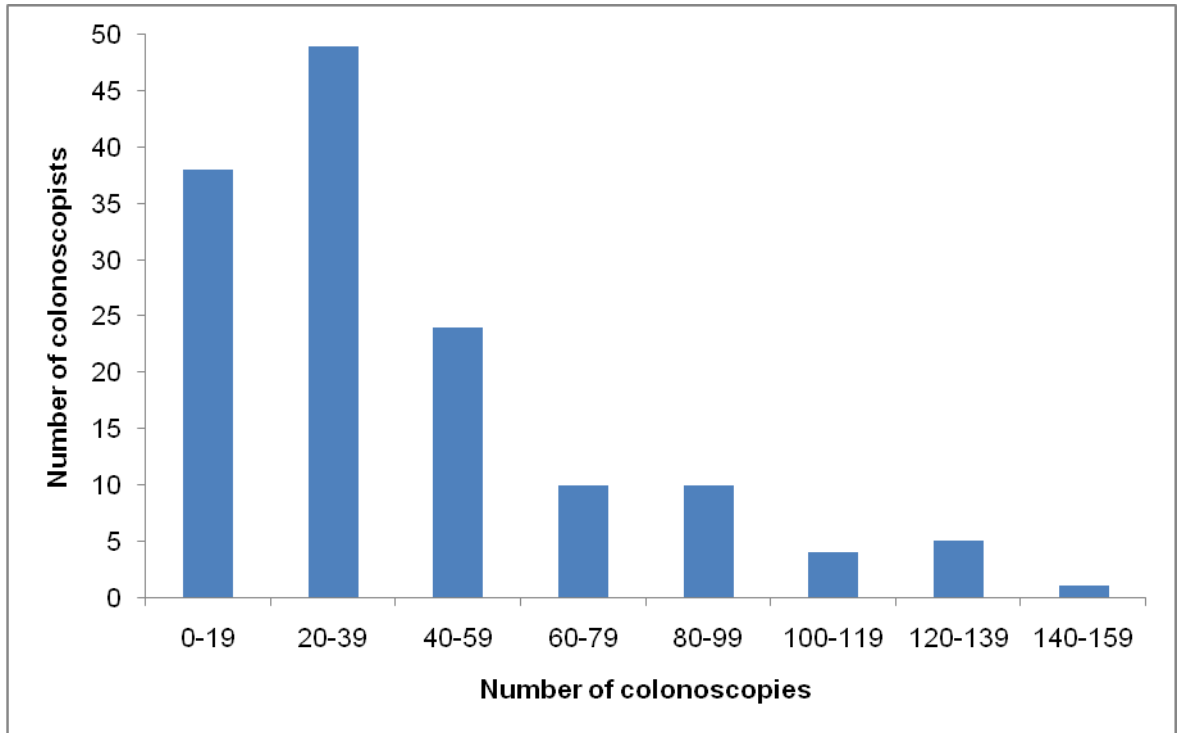
Overall, 129 colonoscopists were included for all stages of analysis including 47 (36.4%) consultant gastroenterologists, 42 (32.6%) consultant surgeons, 15 (11.6%) nurse endoscopists, 6 (4.7%) non-consultant grade staff, 18 (14.0%) trainees and 1 (0.8%) geriatrician. The mean patient age was 60 years (range of mean ages per colonoscopist 48 to 70 years) and 49% were male.

Excluding BCSP colonoscopist data, 4748 colonoscopies were performed during the three month baseline period. The number of colonoscopies performed by each colonoscopist ranged from 1 to 143, the spread of which is shown in Figure 3.

Caecal Intubation Rate (CIR)

The global CIR including BCSP colonoscopists was 92.5% (CI 91.2-92.6). The CIR excluding BCSP colonoscopists was 91.5% (CI 90.5-92.5). The figures from BCSP colonoscopists are excluded from all subsequent results. Results per unit are shown in Table 4. A funnel plot showing each unit's CIR with respect to the national standard is shown in Figure 4. All units were above the lower 95% confidence limit. Three units achieved CIR's that were above the upper limit.

Figure 3: Summary of the number of colonoscopies performed per colonoscopist during the three month period



A funnel plot for each colonoscopists CIR relative to the national standard is shown in Figure 5. The majority were grouped around the national standard. Seventeen (13.2%) colonoscopists were above the upper limit and 1 (0.8%) below the lower limit. Thirty nine (30.2%) were below the national standard but above the lower limit.

Adenoma Detection Rate (ADR)

The global ADR was 15.9% (CI 14.9-17.0). ADRs per unit are summarised in Table 5. Funnel plots showing each unit's ADR with respect to the national standard and the global mean were plotted and are shown in Figure 6 and Figure 7 respectively. All units met the national standard with 10 units

achieving ADRs above the upper limit. With respect to the global mean ADR, all but 1 unit were above the lower 95% limit.

Funnel plots of each colonoscopist's ADR with respect to the national standards and the global mean are shown in Figure 8 and Figure 9 respectively. The majority of colonoscopists were above the national standard and within the 95% confidence limits. Ninety nine (76.7%) of colonoscopists were above the national standard. Twenty three (17.8%) colonoscopists were outliers of whom 16 (12.4%) were above the upper limit and 7 (5.4%) below the lower limit. Twenty three (17.8%) were below the national standard but above the lower limit. Using the global mean for ADR, the majority of colonoscopists were again within the confidence limits. Eighteen (14.0%) were outliers, 5 (3.9%) being above the upper limit and 13 (10.1%) below the lower limits.

Table 4: Summary of CIR per unit

Unit	Number of colonoscopists	N° of procedures performed	CIR (%) (95% CI)
A	3	120	90.0 (83.0-94.5)
B	10	303	91.2 (89.0-94.5)
C	8	325	92.9 (89.5-95.4)
D	6	257	91.8 (87.2-94.4)
E	15	556	89.0 (86.1-91.4)
F	16	829	93.7 (91.8-95.2)
G	9	342	93.9 (90.7-96.1)
H	13	563	93.4 (91.0-95.3)
I	14	379	91.8 (88.5-94.3)
J	14	247	91.1 (86.7-94.2)
K	9	373	90.0 (87.4-93.5)
L	12	454	90.5 (87.4-93.0)
Total	129	4748	91.9 (91.1-92.7)

Figure 4: Funnel plot showing each unit's CIR with respect to the national standard

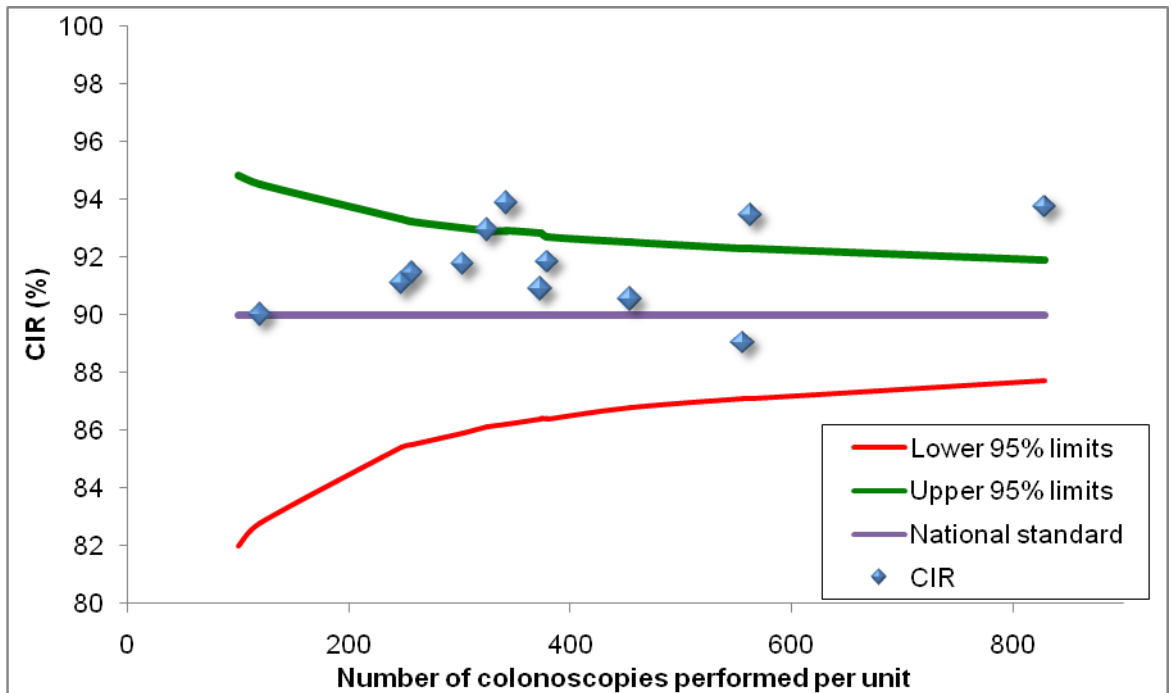


Figure 5: Funnel plot of each colonoscopist's CIR relative to the national standard

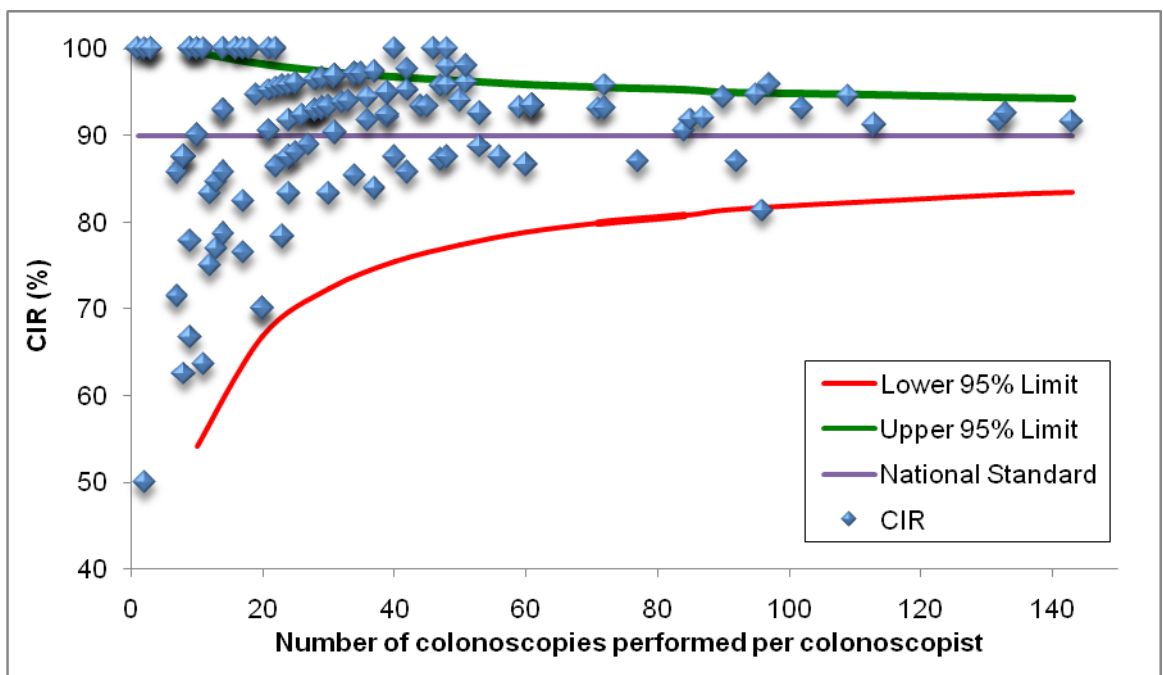


Table 5: Summary of ADRs per unit

Unit	Number of colonoscopists	N^o. of procedures performed	ADR (%) (95% CI)
A	3	120	17.5 (11.4-25.7)
B	10	303	13.5 (10.0-18.0)
C	8	325	14.5 (10.9-18.9)
D	6	257	10.1 (6.8-14.6)
E	15	556	18.3 (15.3-21.9)
F	16	829	16.4 (14.0-19.1)
G	9	342	15.8 (12.2-20.2)
H	13	563	17.2 (14.3-20.7)
I	14	379	15.3 (11.9-19.4)
J	14	247	17.8 (13.4-23.3)
K	9	373	14.2 (10.9-18.3)
L	12	454	17.2 (13.9-21.0)
Total	129	4748	15.9 (14.9-17.0)

Figure 6: Funnel plot showing unit ADR with respect to the national standard

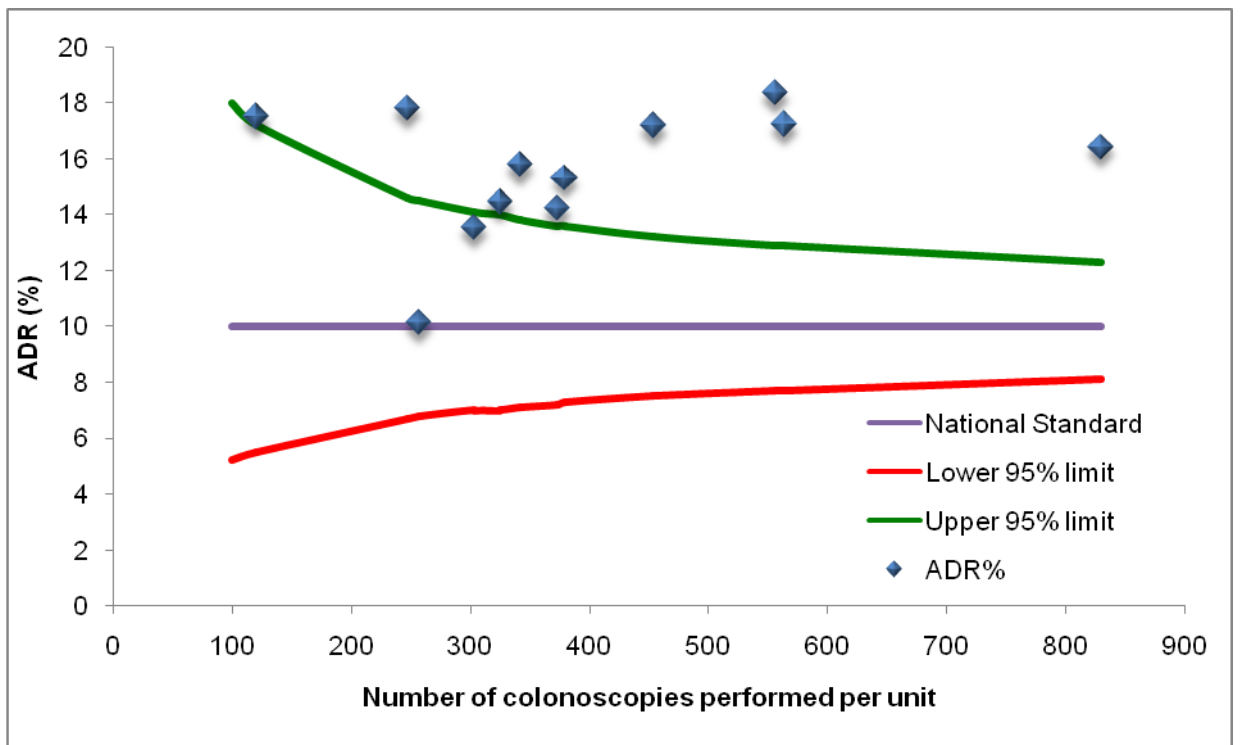


Figure 7: Funnel plot showing unit ADR with respect to the global mean

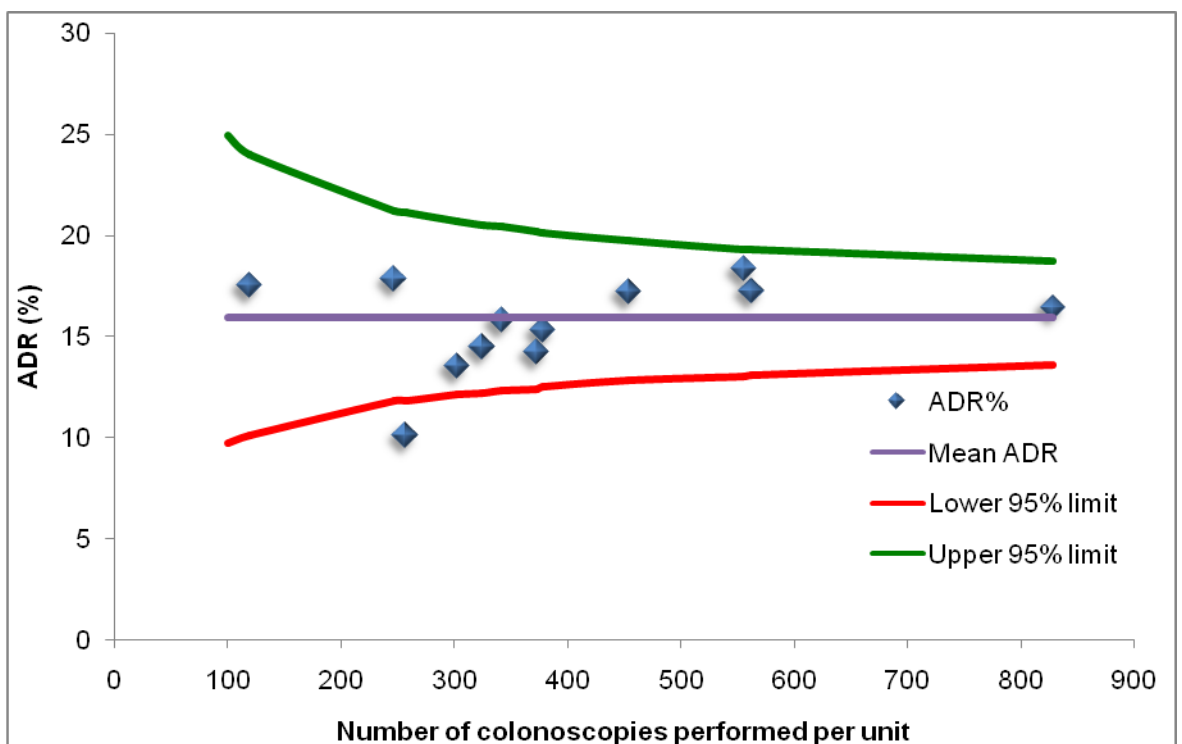


Figure 8: Funnel plot showing each colonoscopists ADR with respect to the national standard

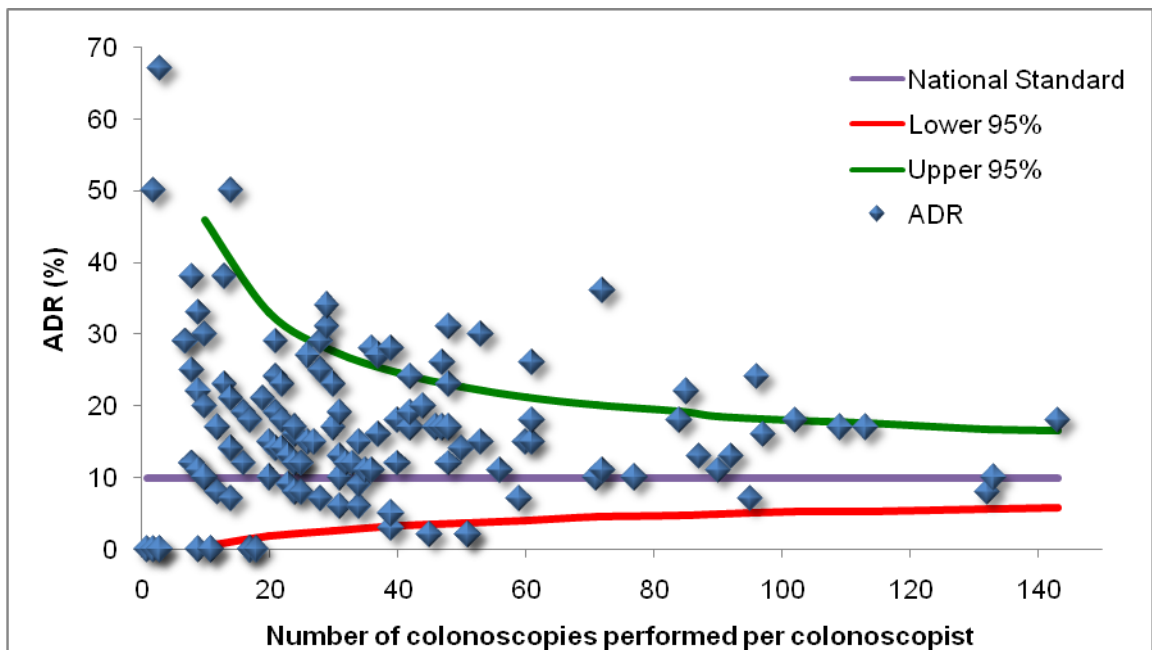
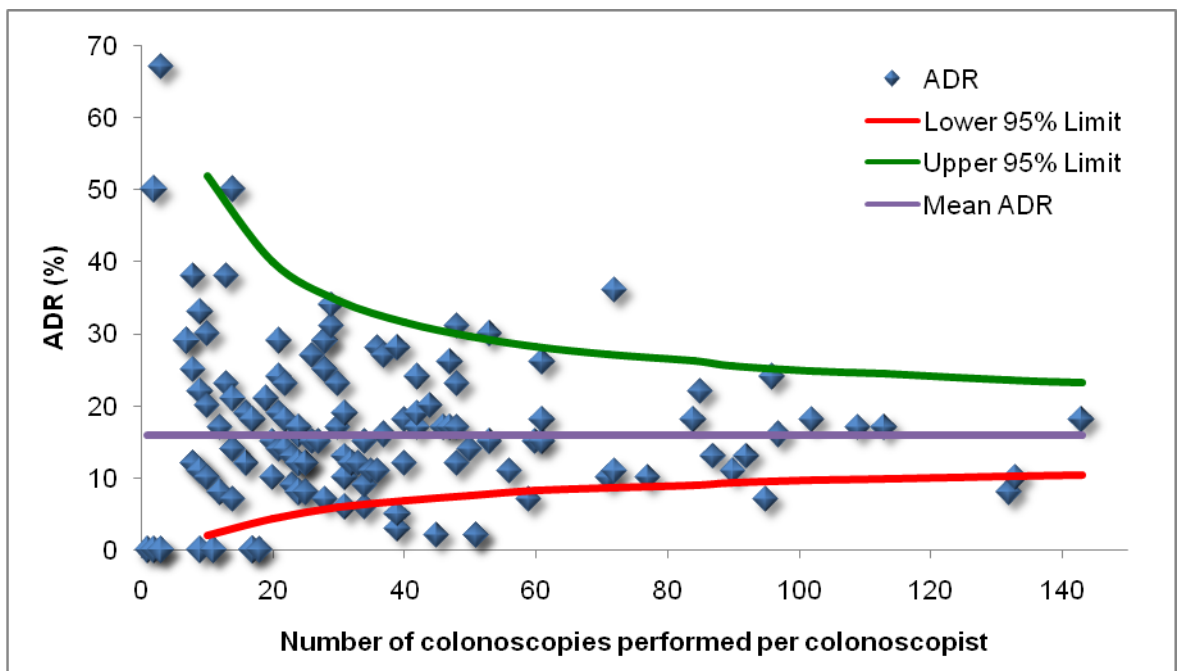


Figure 9: Funnel plot showing each colonoscopists ADR with respect to the global mean



Adverse Events

All colonoscopy related adverse events during the baseline period were collected and summarised in Table 6. There was one death within 30 days of colonoscopy in which the procedure was abandoned in the rectum due to poor preparation. The patient later suffered a cardiac arrest and died due to acute left ventricular failure. It was felt that bowel preparation may have contributed to death.

Table 6: Summary of adverse events during baseline period

	Number	Incidence (% , n=4,748)
Bleeding		
Minor	4	0.08
Intermediate	1	0.02
Major	0	0
Fatal	0	
Perforation		
Major	1	0.02
Fatal	0	0
Other unplanned event		
Minor	5	0.10
Intermediate	0	0
Major	0	0
Fatal	1	0.02

2.4. Discussion

It was important to understand the performance levels within the study region prior to any intervention. The analysis of the data from a three month period from the participating 12 units provided an appropriate representation of colonoscopy practice within the region.

It can be difficult to compare performance of individual colonoscopists and endoscopy units, particularly as the number of procedures performed are likely to be variable. The use of funnel plots takes into account 'common cause variation'. This type of variation is greater when a sample size is small. Furthermore, representing data graphically allows a thorough, rapid and meaningful analysis to be performed.

The funnel plot in which all the colonoscopists CIR is summarised shows that, whilst there was variation between endoscopy units, all were within the 95% confidence limits. For individual colonoscopists, all but one (0.8%) were above the lower limit of the funnel. Furthermore, the majority were grouped around the 90% national standard suggesting that this standard remains appropriate. The global mean of 92.5% (CI 91.2-92.6) highlights that CIR within the units studied is in line with national recommendations and significantly better than the BSG audit published in 2004.

It is evident analysing the funnel plots summarising the ADR data created relative to the current national standard of 10%, that all units are within the funnel, with 10 units above the upper 95% limit. When each colonoscopist's

ADR is plotted, there is wide dispersion with the overwhelming majority lying above the current national standard and 12.4% above the upper confidence limit. This calls into serious question whether the national standard of 10%, set in 2006, is too low. Using the global mean of 15.9%, a more even distribution is seen at both a unit and colonoscopist level, as would be expected. This study data provides powerful evidence that the national standard for ADR should be reviewed and that 15%, at the very least, is a more appropriate standard. Both plots for ADR reveal the wider variation that exists for this quality marker. Using the global mean for ADR also results in 1 unit falling below the lower 95% confidence limit and increases in the number of colonoscopists below the lower limit (10.1% vs. 5.4%).

Complications were few with post-polypectomy bleeding and perforation rate similar to that reported in other published series. (40-42) The bowel preparation related death does highlight the importance of adequate patient assessment prior to prescribing.

The benefit of using funnel plots to evaluate performance is avoidance of unnecessary investigation of those falling below expected standards simply due to 'common cause variation' rather than true under performance. This tool has been shown to aid health service decision making. (43) Whilst not traditionally presented on funnel plots, it is important to consider that each data point has its own error (i.e. 95% CI) which may cross the limits of the plot and is more likely for individuals or units performing lower procedure numbers where the CI will be wider. Therefore, it is important to interpret plots with care

when individuals have performed a small number of procedures and reassessment may be required when larger numbers can be included. The funnel plots for CIR also draws attention to the procedure numbers that need to be performed to ensure that an individual colonoscopists CIR is truly above national standards considering the error for the sample size evaluated i.e. that the lower limit for the individual is above the lower limit for the plot. This is an issue that has been highlighted previously and has implications for demonstration of ongoing competence and performance, particularly for trainees. (44)

Funnel plots are often used to evaluate performance data as a 'snap-shot'. Maintaining quality, however, is a continuous process and early identification of deteriorating performance prior to falling below lower confidence limits is preferable. Funnel plots using cumulative data or using change in performance at two time points may be useful methods of monitoring for this purpose. (45)

In summary, funnel plots are a powerful tool with which to rapidly analyse performance data and highlight both good and poor performance. The CIR within the participating units comfortably meets current requirements but is not, on its own, a complete quality measure. Whilst ongoing monitoring is required to ensure standards are maintained, the results will not be presented in this thesis. Adverse events were also in keeping with other large published series confirming that safety within the region is acceptable. Analyses of ADRs in this period strongly indicate that the current standard of 10% is too

low. This is supported by another study from a single UK endoscopy unit that included 10,026 procedures reported a global ADR of 19.2%. (46) The baseline mean of 15.9% is a good marker of the standard of colonoscopy within the study region. Therefore, this was considered a more appropriate reference standard against which to measure changes in performance observed in this study. The variation in the ADR was also a significant finding which highlighted the need for further improvement across all units.

Chapter Three: Improving Adenoma Detection

Chapter Three: Improving Adenoma Detection

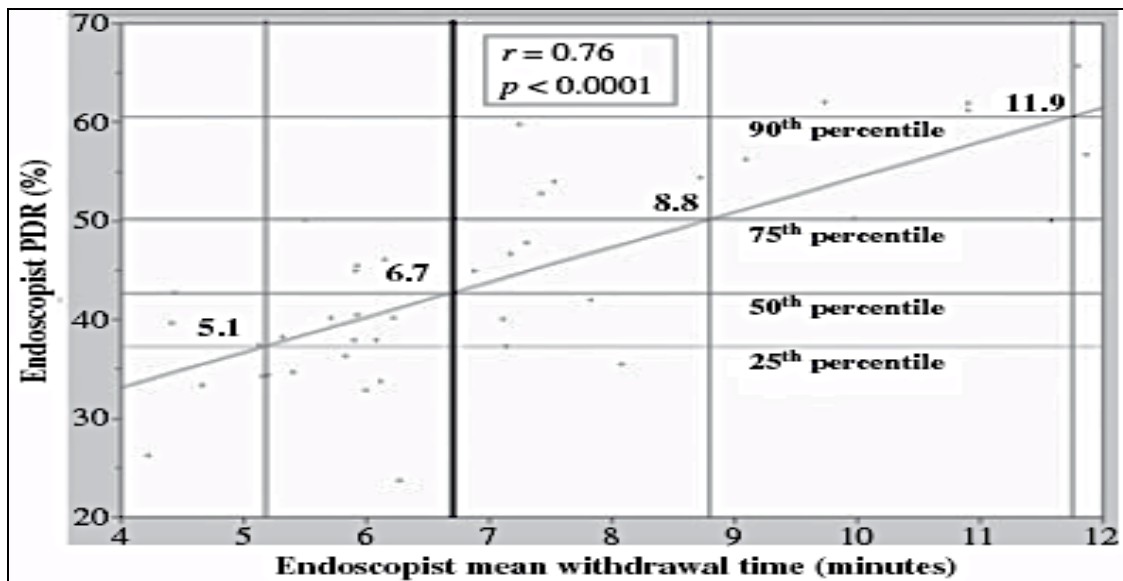
3.1. Introduction: methods of improving adenoma detection

The previous chapter highlights the six to ten fold variations that exist in ADR in the participating units within the northern region. Service improvement interventions aim to improve standards of care, although it is often not possible to improve standards amongst those performing well. Interventions are primarily aimed at individuals whose performance is below average, with the effect of reducing variation and improving the overall quality of the services delivered to patients. Certain measures used during colonoscopy withdrawal, in addition to good colonoscopy technique, have been shown to improve lesion detection.

3.1.1. Colonoscopy withdrawal time

The time spent viewing the colonic mucosa has been raised as a potential factor that could influence lesion detection. The relationship between an endoscopist's withdrawal time and polyp detection rate (PDR) was studied by Simmons et al. (47) Data were retrieved from the computerised database at the Mayo clinic in the United States (US). Colonoscopies performed for routine indications were selected for analysis. The mean withdrawal time (MWT) was calculated using normal colonoscopies only to more accurately reflect mucosal viewing time as opposed to time spent performing therapeutic procedures. A total of 10,955 colonoscopies performed by 43 colonoscopists were studied. A longer MWT was associated with a higher PDR. The median PDR correlated with a withdrawal time of 6.7 minutes. The results are summarised in Figure 10.

Figure 10: Relationship between mean withdrawal time and PDR (reproduced with permission from Alimentary, Pharmacology and Therapeutics) (47)



These data were supported by a prospective study performed by Barclay et al assessing the correlation between adenoma detection and colonoscopy withdrawal time in screening colonoscopies. (30) The MWT was again calculated using normal colonoscopies only. Adenoma detection was given both as ADR and mean number of adenomas per subject screened. In addition, the association with advanced adenomas (defined as adenomas >10mm, villous histology, high grade dysplasia or cancer) detection was studied. Two thousand and fifty three colonoscopies were performed by 12 colonoscopists. A longer MWT was again associated with higher adenoma detection. Furthermore, colonoscopists with a MWT greater than 6 minutes had significantly higher adenoma detection for all adenoma and advanced adenomas as shown in Table 7.

Table 7: The association between MWT and adenoma detection (reproduced with permission from the New England Journal of Medicine) (30)

Table 4. Rates of Detection of Lesions According to Mean Withdrawal Time for Procedures in Which No Polyps Were Removed.*				
Variable	All Physicians (N=12)	Less Than 6 Minutes (N=3)	6 Minutes or Longer (N=9)	P Value†
Subjects with adenomas (%)	24.2±8.3	11.8±2.2	28.3±4.0	<0.001
Adenomas per subject screened (no.)	0.50±0.26	0.17±0.07	0.61±0.20	0.006
Subjects with advanced neoplasia (%)	5.5±2.3	2.6±1.1	6.4±1.7	0.005
Advanced neoplastic lesions per subject screened (no.)	0.06±0.03	0.03±0.01	0.07±0.02	0.005
Cancers per subject screened (no.)	0.005±0.005	0.002±0.004	0.006±0.005	0.30
Subjects with hyperplasia (%)	22.6±12.1	10.2±4.2	26.8±10.9	0.03

These studies support the use a withdrawal time of at least 6 minutes that, in addition, is recommended by several guidelines. (18, 23) Despite this many colonoscopists take less than 6 minutes to withdraw the scope. It must also be emphasised that colonic mucosa must be carefully inspected during this time with careful examination of folds and flexures and adequate suctioning and aspiration of fluid pools. (31)

3.1.2. Antispasmodic use during colonoscopy withdrawal

Factors that can hinder mucosal inspection are the presence of folds and colonic spasm. Whilst the tip of the colonoscope can and should be used to depress and view behind folds, it can be difficult. The use of antispasmodic agents can relax colonic smooth muscle thereby reducing spasm and the prominence of folds. The most commonly used agent is hyosine N-butylbromide (Buscopan) although glucagon and peppermint oil (given topically via the colonoscope) are used. Bowles et al reported that

antispasmodics were used in approximately 20% of the colonoscopies studied in their audit. (10)

A prospective randomised placebo controlled trial of the effect of Buscopan on polyp detection was performed by Lee et al. (48) The principal outcome measures for the study were change in colonic spasm score and number of polyps detected. A statistically significant reduction in spasm score was seen in the Buscopan group. More polyps were detected in patients with moderate to severe spasm receiving Buscopan compared to placebo, however, this didn't quite reach statistical significance ($p=0.06$).

Regarding evidence to support antispasmodic use to improve the visualised colonic surface available for inspection, one study examined the effect of Buscopan on colonic surface area visualised at computed tomography (CT) colonography. CT colonography is a radiological test used for colonic assessment when colonoscopy is felt to be unsafe or is refused by the patient. Images are taken both in the supine and prone position in order to shift luminal fluids and contents and maximise mucosal views. The computer software also calculates the colonic surface visualised. This study revealed that significantly more colonic surface was visualised in both the supine and prone positions with Buscopan use compared with when no antispasmodics were used. (49)

In addition to the above studies, expert colonoscopists recommend the use of Buscopan, particularly for lesions that may be difficult to detect or resect. (50)

Together there is sufficient evidence, albeit at lower levels, to suggest that the routine use of Buscopan for the withdrawal phase of colonoscopy may improve mucosal visualisation and adenoma detection.

3.1.3. Dynamic position change during colonoscopy withdrawal

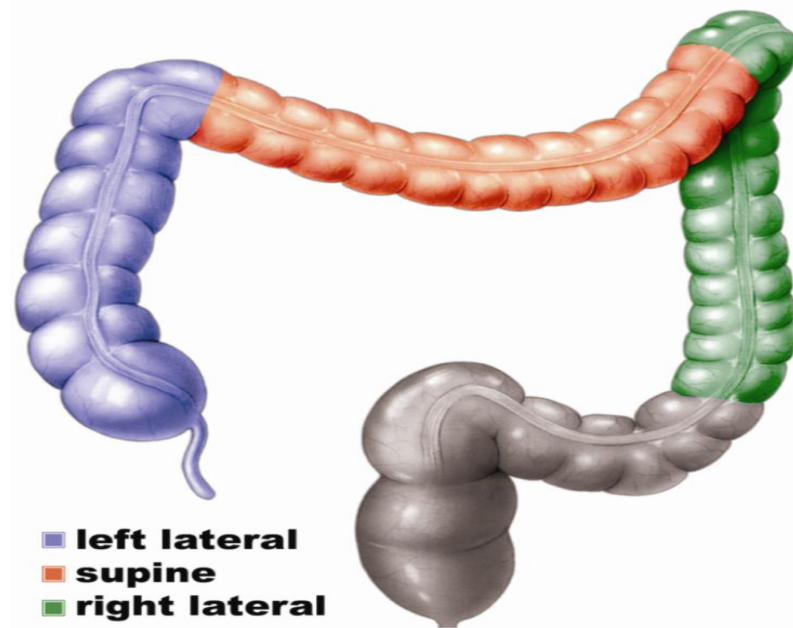
Colonoscopy has traditionally been performed with the patient lying on their left side (left lateral position) with the knees drawn up so that the thighs are at approximately 90 degrees to the torso. The anatomy of the colon dictates that this is often not the ideal position for passage of the colonoscope along its entirety as certain segments have a tendency to be collapsed making insertion and mucosal inspection difficult. The concept of changing the position of the patient has been used for some time in radiological assessments of the colon, initially barium enema studies and more recently CT colonography. (51) The objective of position change is to allow luminal gas to rise and fluid to drain away from the colonic segment of interest. The positions that allow optimal luminal distension and mucosal visualisation for a given colonic segment were taken from the experience of these radiological tests and have been used with increasing frequency in recent years to aid colonoscope insertion and withdrawal.

The potential benefits of dynamic position change on luminal distension and adenoma detection were studied by East et al who performed a randomised, crossover trial comparing examination of the colon in the left lateral position and with dynamic position changes. (52) Consecutive patients presenting for routine colonoscopy were invited to participate in the study. Patients with

known colitis, polyposis syndromes or musculoskeletal problems precluding position changes were excluded. Following caecal intubation, the colonoscope was withdrawn to the rectum with the patients either in the left lateral position or with dynamic position change (as shown in Figure 11) as dictated by the randomisation process. The colonoscope was subsequently re-inserted to the caecum and withdrawn using the alternative technique to the original. Polyps were only removed after the second withdrawal. The number of adenomas per segment and degree of luminal distension were recorded. The study demonstrated an increase in the number of adenomas detected in the segments where the optimal position for examination differs from the left lateral position. This was statistically significant for examination of the transverse colon ($p=0.02$). Luminal distension was also significantly better with the use of position change and this was positively correlated with the increase in adenoma detection.

The most significant limitation of the study was that it was a single operator study. It does, however, support the proof of concept that adenoma detection can be increased with position change, in particular the use of the supine position for examination of the transverse colon which can be achieved simply during colonoscopy withdrawal.

Figure 11: Optimal patient position to examine each colonic segment (reproduced with permissions from Gastrointestinal Endoscopy) (52)



3.1.4. Retroflexion within the rectum

Detection of lesions low in the rectum can sometimes be difficult with the colonoscope in the forward viewing position. Better views of the distal rectum can be achieved by retroflexing the colonoscope in the rectum. This also provides a better position to sample or remove lesions. Whilst retroflexion within the rectum is a simple and safe technique, it is not performed routinely by all colonoscopists.

One study looked polyp detection among patients in whom examination of the distal rectum was performed initially in the forward viewing position and subsequently in the retroflexed position. (53) In this study, 12 polyps (2.5% of all) were seen only in the retroflexed position, of which 4 were adenomas.

There were no adverse events associated with retroflexion. The simplicity and safety of retroflexion and the potential to increase adenoma detection suggest that its routine incorporation into withdrawal technique would be of use.

The Quality in Colonoscopy (QIC) Study

An opportunity arose for me to participate in a study evaluating the process of implementing evidence into routine colonoscopy practice in a large scale service improvement initiative. This involved evaluating both the feasibility and clinical effect of integrating an evidence-based 'bundle' of measures into routine colonoscopy practice. The measures described above shown to improve adenoma detection are simple, safe and feasible to perform routinely in clinical practice and, if used in combination as a 'bundle', could significantly improve ADR. Therefore, the QIC study 'bundle' consisted of:

1. A minimum withdrawal time from the caecum to anus of 6 minutes in all individuals with an intact colon.
2. Antispasmodic use for withdrawal where no contra-indication exists.
3. Examination of the transverse colon with the patient in the supine position.
4. Examination of the distal rectum in the retroflexed position (in addition to the forward viewing position) where no contra-indication exists.

The measures above are used by some colonoscopists but not by all and not routinely. The hypothesis being tested in this thesis is that incorporation of the 'bundle' into routine colonoscopy practice, in combination with good

colonoscopy technique during withdrawal, is feasible and could improve mucosal visualisation and consequently improve the ADR.

3.2. Changing Behaviour in Healthcare Professionals: the challenges of introducing evidence into clinical practice

The use of a standardised or protocol based care approach within the NHS has long been thought of as a useful method of delivering a high quality service that provides the most up to date evidence-based care. (54) The incorporation of this approach into clinical practice involves changing behaviour and attitudes in healthcare professionals, a process which can be challenging. (55, 56) Resistance can be encountered to even simple changes, such as completion of forms to document time of intravenous catheter insertion, and changes may not be uniform or consistent. Various studies have investigated how well evidence-based practice (EBP) and national guidelines are adhered to across the world and have been shown to be variable. (57) In the US and Holland, it has shown that between 30% and 40% of patients receive clinical care that is not in keeping with the latest scientific evidence. (58)

Achieving changes in behaviour has become increasingly important in recent years due to the importance of EBP and the increasing number of clinical guidelines. Much work has been performed studying how we can improve engagement with current evidence and guidelines. (57, 59-61) This type of work is known as implementation research.

3.2.1. Awareness of and identifying barriers to change

There are many potential factors that may influence willingness to change clinical practice and it is vital to be aware of these barriers and understand how they can be identified prior to developing a method of implementation.

The National Institute for Health and Clinical Excellence (NICE) provide literature on how to understand, identify and overcome barriers to change and highlight several important areas. (56) Knowledge of the most up to date evidence or guidance is one potential barrier. It is difficult to remain aware of the increasing number of guidelines and scientific papers that are produced and also how they are best integrated into current practice. The acceptance of guidelines or evidence is also a potential barrier if they conflict with a practitioner's own views on a topic or alternative guidance. Motivation is also crucial to bringing about change. This may be provided by external factors, such as rewards or penalties for non-engagement. Internal factors, such as an individual's drive to improve, are also very important. The presence of the appropriate skill set to bring about change must also be considered and training may be required before the implementation process can begin. The practicalities of implementing a standardised care approach are, of course, an important consideration including a lack of resource or personnel, or the lack of infrastructure within an organisation to allow a particular change. Finally, there may be barriers, such as financial or political factors, that are beyond the immediate control of a particular organisation that may limit the implementation of guidelines.

There are many ways that the possible barriers to change can be identified, each of which has advantages and disadvantages. The chosen method should be selected in accordance with the information required and feasibility in a given setting. Use of questionnaires is one method of identifying barriers. This has the advantage of allowing relatively large amounts of information to be collected quickly and at low cost. Limitations include poor response rates and self-reporting bias which can affect the quality and type of information collected. Running a focus group of individuals involved in the respective care team can be useful, however, this can be difficult both to organise and analyse. Other useful methods are the use of brainstorming sessions, observation of clinical practice and talking to key individuals in the organisation to assess the feasibility of the proposed intervention. Once the potential barriers to change have been identified, it is important to develop a structured approach to implement the required changes.

3.2.2. How should we implement a standardised care approach?

When deciding how best to implement changes in practice, it is vital to consider all the barriers discussed in the previous section in order to achieve the best outcome. One method was proposed by Pawson and Tilley. (62) They suggest the following equation:

$$\text{Context (C) + Mechanism (M) = Outcome (O)}$$

In addition to helping us focus on the factors to be considered, this also highlights the potential problems that can be faced when attempting to bring

about change in large organisations. The often complex nature of these organisations can result in a different 'context' depending on the member of the team being addressed. As a result, a single 'mechanism' may not be adequate. The practicalities of developing several mechanisms of implementation across one organisation or system often dictates that comprises are required. When considering an endoscopy unit, potential barriers posed by colonoscopists are likely to differ from those posed by endoscopy nurses. Therefore, it is important to consider both and, where feasible, develop a model or mechanism that addresses the majority of potential issues.

Rycroft-Malone et al studied in detail how standardised care approaches, such as the use of protocols and guidelines, worked in a variety of clinical settings. (63) They set out to answer the questions 'what works, for whom, why and in what circumstances?' Importantly, they also studied how different 'mechanisms' were developed and how this influenced their acceptance. This detailed study yielded many interesting results. When developing the 'mechanism' of delivery, the authors made the following propositions:

A clear understanding about the purpose and nature of protocol-based care by potential users will determine the extent to which standard care approaches are routinely used in practice.

1. Standardised care approaches that are developed through a systematic, inclusive, and transparent process may be more readily used in practice.

2. Standardised care approaches that are based on a clear and robust evidence base are more likely to impact positively on outcomes.
3. Locally developed standardised care approaches may be more acceptable to practitioners and consequently more likely to be used in practice.
4. More senior and experienced clinical staff will be less positive than junior and/or inexperienced staff about using standardised care approaches.
5. Interactive and participatory approaches and strategies to implement standardised approaches to care may influence whether or not they are used in practice.
6. The support of a project lead may increase the likelihood of the ongoing use of standardised care approaches.
7. Some contexts will be more conducive to using standardised care approaches than others, but it is unclear what might work in what circumstances and how.

The study also reported many useful results regarding the reasons that some 'mechanisms' were more effective than others. Factors that were positively associated with uptake included:

1. Location and visibility: protocols were more likely to be used if they were highly visible.
2. Incentives: protocols linked to financial incentives were more closely adhered to.
3. Buy-in and ownership: when the whole multi-disciplinary team has been actively involved in protocol development it was more likely to be used.

4. Making a difference: when a protocol was perceived as making a difference to their practice and patient care.
5. Embedding into systems: when protocols were integrated into documentation or IT systems.
6. Ongoing project lead: the presence of a clear leader encouraged use of protocols and allowed for ongoing monitoring.

The development and implementation of standardised care mechanisms is a complex area that we are yet to understand completely. However, some of the principles discussed here can be utilised to aid the process.

3.3. An Intervention to Decrease Catheter-Related Bloodstream

Infections in the ICU: An example of successful implementation of an intervention 'bundle'

The concept of using an evidence-based intervention 'bundle' in order to improve the quality and safety of clinical practice was tested by Pronovost et al. (64) The problem identified by this group was the high number of catheter related blood stream infections that were occurring in the intensive care unit (ICU) in the US, together with the resulting morbidity, mortality and cost issues. Previous small studies had demonstrated that good education regarding central line management could successfully reduce catheter related infections. Pronovost et al aimed to study the extent to which such infections could be reduced by implementing a similar intervention in a state-wide safety initiative regarding patients in ICU.

All hospitals within the state with an adult ICU were invited to participate in the study. Units that agreed were asked to nominate at least one physician and one nurse as team leaders. The team leaders were instructed in the science of safety and the interventions and then disseminated the information to colleagues in their respective units. The ongoing support consisted of fortnightly conference calls, coaching by research staff and state-wide meetings twice a year. Supporting information on each component of the intervention, suggestions for implementation and instructions regarding data collection were also provided. Team leaders were partnered with their local infection control practitioners to aid implementation and assist with data collection. The intervention consisted of the following measures that were to be performed during all central catheter insertion and subsequent management:

- Hand washing.
- Use of full barrier precautions during catheter insertion.
- Use of chlorhexidine to disinfect the skin prior to catheter insertion.
- Avoiding the femoral site (where possible).
- Prompt removal of unnecessary catheters.

Locally team leaders educated colleagues regarding practices to control infection and harm due to central catheter-related infections. A central-line cart with necessary equipment was created and a check-list provided. Providers were stopped (in non-emergency situations) if practices were not being adhered to. Finally, removal of catheters was discussed at daily ward

rounds. Teams also received feedback regarding the number and rates of catheter-related infections at monthly and quarterly meetings. All units were asked to provide data on the number of catheter-related infections (expressed as number of infections per 1000 catheter-days) for the three month period before implementation and used as a baseline measure for each unit. The change in rate of catheter-related infections after implementation of the 'bundle' was recorded for the eighteen months following implementation.

A total of 103 ICUs from 67 hospitals provided complete datasets and were therefore included for analysis. A significant reduction in bloodstream infections related to central catheters was demonstrated at both 3 months, indicating efficacy of the intervention, and at 18 months demonstrating its durability. Results are summarised in Table 8.

Table 8: Summary of reduction in catheter-related bloodstream infections

(reproduced with permission from the New England Journal of Medicine) (64)

Table 3. Rates of Catheter-Related Bloodstream Infection from Baseline (before Implementation of the Study Intervention) to 18 Months of Follow-up.*						
Study Period	No. of ICUs	No. of Bloodstream Infections per 1000 Catheter-Days				
		Overall	Teaching Hospital	Nonteaching Hospital	<200 Beds	≥200 Beds
<i>median (interquartile range)</i>						
Baseline	55	2.7 (0.6–4.8)	2.7 (1.3–4.7)	2.6 (0–4.9)	2.1 (0–3.0)	2.7 (1.3–4.8)
During implementation	96	1.6 (0–4.4)†	1.7 (0–4.5)	0 (0–3.5)	0 (0–5.8)	1.7 (0–4.3)†
After implementation						
0–3 mo	96	0 (0–3.0)‡	1.3 (0–3.1)†	0 (0–1.6)†	0 (0–2.7)	1.1 (0–3.1)‡
4–6 mo	96	0 (0–2.7)‡	1.1 (0–3.6)†	0 (0–0)‡	0 (0–0)†	0 (0–3.2)‡
7–9 mo	95	0 (0–2.1)‡	0.8 (0–2.4)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.2)‡
10–12 mo	90	0 (0–1.9)‡	0 (0–2.3)‡	0 (0–1.5)‡	0 (0–0)†	0.2 (0–2.3)‡
13–15 mo	85	0 (0–1.6)‡	0 (0–2.2)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.0)‡
16–18 mo	70	0 (0–2.4)‡	0 (0–2.7)‡	0 (0–1.2)†	0 (0–0)†	0 (0–2.6)‡

In addition to this initial work, further data has been published by the group showing that the reductions in catheter-related bloodstream infections brought about by this intervention were sustained four years after implementation. (65)

In line with existing evidence on methods of improving organisational and individual performance, Pronovost et al confirmed that the following strategies can be used to successfully implement evidence into practice:

- A standardised care pathway based on good quality clinical evidence.
- Identification of enthusiastic team leaders to initiate and support implementation.
- Training on how to perform each component of the 'bundle' provided to leaders.
- Resource provision i.e. providing all equipment in a trolley including provision of a checklist.
- Penalties for non-compliance i.e. individual stopped performing procedure
- Embedding the 'bundle' into unit infection control systems.
- Regular feedback of results to units and individuals.
- On-going central support.

On current evidence, it would seem reasonable that an evidence-based intervention 'bundle' could be successfully be integrated into routine clinical practice and yield long-lasting results when the appropriate mechanism for introducing change is used. The next chapter outlines how the evidence discussed on implementation of clinical evidence into practice and the

measures shown to improve adenoma detection were combined to develop an implementation process and educational package for the current study.

Chapter Four: Did the intervention successfully change practice?

Chapter Four: Did the intervention successfully change practice?

4.1. Introduction

The factors discussed in chapter 3 were carefully considered when designing the intervention 'bundle' and selecting the process of implementation in this study. In the setting of a busy endoscopy unit, it was felt that the most important factors regarding the 'bundle' were that it should be:

- based on good quality evidence
- safe
- simple (including no need for additional training)
- time efficient
- inexpensive
- reproducible

The measures in the study 'bundle' certainly meet these criteria and can be performed without adversely affecting the number of procedures on any endoscopy list. Therefore, incorporating these measures into an evidence-based intervention 'bundle' for routine use during the withdrawal phase of colonoscopy should be feasible and could improve the standard of the colonoscopy without adversely affecting procedure volume or adding significant cost.

Ethical Approval

The QIC study was a service improvement initiative in which all participating units were to receive the intervention. The study was reviewed by the chairman of the Sunderland Research Ethics Committee (REC) who felt that,

as a service improvement project, formal ethical review was not required and issued a waiver stating this (Appendix B).

4.2. Methods

4.2.1. The Implementation Process

As with development of the 'bundle', the model of implementation must also take into account the setting into which it is to be introduced. The process of implementation utilised by Provonost et al included many features that would also be useful in an endoscopy setting. Therefore, this model was used as a base from which to design the implementation process used in this study.

A de novo, multifaceted implementation model was developed that included a single central training session for leads and local training sessions at each site led by the study team. Information was provided detailing the evidence on which the 'bundle' was based both in written form and by way of a DVD. A follow up visit a minimum of four months after implementation was planned at which preliminary results would be presented. The study leads were also charged with continuous local study promotion. The programme was consensus based and peer led (including peer participation) which are proven powerful education tools. (66-68) It utilised standard endoscopy teaching practices to ensure it would be familiar those working in this environment. The programme was reviewed and endorsed by the NREG committee. Roll out was incremental with the first units acting as a pilot to identify and solve any unidentified problems.

4.2.1.1. Central Training

A central training day was organised at which all lead colonoscopists and lead endoscopy nurses from the participating units were required to attend. Members of the central study team led the session. The team consisted Dr Colin Rees (CR), Dr Brian Saunders (BS), Dr James East (JE), Dr Matt Rutter (MR) and Professor Mike Bramble (MB). Team members were selected as they were considered to be leaders in the field of colonoscopy and due to their expertise in colonoscopy training and in management within the NHS. All sessions were interactive. The outline for the training day is shown in Table 9.

Table 9: Summary of central training day

Section Title	Summary of content	Session lead
Introduction		MR
Overview of the Quality Improvement in Colonoscopy (QIC) Study	Current variability in colonoscopy. Quality markers in colonoscopy Factors influencing ADR An example of a successfully implemented 'bundle' The QIC 'bundle'	JE
NREG and the QIC study	Summary of NREG How NREG can help with the QIC study	CR
Academic detailing and educating doctors	How to change behaviour Who can influence/encourage colonoscopists to change practice? Feedback and changing practice	MB
Live video-linked demonstration of the QIC 'bundle'	Demonstration of the QIC 'bundle'.	BS
Feedback	Identification of local barriers Suggestions to aid local implementation	CR

The minutes of the meeting, including a breakdown of the questions raised and answered and suggestions to aid implementation, is provided in Appendix C.

C. The key suggestions and points of discussion were as follows:

1. Local training sessions were to be led by myself (PTR), to aid consistency, supported by the local leads. Sessions must be a maximum of 45 minutes long so they can be efficiently delivered in a busy clinical setting. Discussion took place regarding whether a more senior member of the study team should lead local training sessions and also whether a surgeon should present to surgical colonoscopists, who might be more difficult to engage. However, it was felt that this would be logistically more difficult, in addition to adding variability to training.
2. Assessment of compliance to be performed by endoscopy nurses to evaluate uptake of the 'bundle'. Endoscopists should be aware that assessments will be performed but blinded as to when the assessments were taking place.
3. Engage all endoscopy nurses as they could potentially influence colonoscopists uptake of the 'bundle'.
4. Posters to act as a reminder in all endoscopy rooms.
5. Letter to all medical directors at participating units to inform them about the study and gain their support to encourage uptake.

Following the central training day, the implementation model was modified to include separate sessions for the endoscopy nurses in order to engage and empower their involvement in the study. A study poster was also designed for all endoscopy units (Appendix D).

4.2.1.2. Local Training

The session consisted of a 30-45 minute interactive training session (Appendix E) and a study information pack which contained both written information regarding the study (Appendix F) and a DVD demonstrating the components of the 'bundle' (Appendix G) followed by time for questions. An A2 poster was provided for each of the endoscopy rooms in the participating units.

The leads invited all colonoscopists in their respective units to take part in the study. Local training sessions, led by myself, were organised at times that would allow for maximal attendance. Multiple visits were required for some units if feasible and the initial attendance was particularly low. Registers were kept for all sessions. Colonoscopists who were not able to attend these sessions were provided with the study information pack and were contacted by the lead colonoscopist for the respective unit who gave a brief outline of the study and answered any questions. Colonoscopists were informed that endoscopy nurses would perform compliance assessments in order to monitor whether or not the 'bundle' was being used, but that they would not be made aware when the assessments were taking place.

Colonoscopists were also asked to complete a short questionnaire regarding how frequently they used the measures comprising the 'bundle' in their practice prior to the study (Appendix H). Lead colonoscopists distributed and collected the questionnaires for those who could not attend the training.

At the central training day, it was identified that the nursing staff working in each endoscopy unit could play a significant role in bringing about and maintaining change in practice among the participating colonoscopists. Therefore, we considered enlisting and encouraging the participation of the nurses as an important element of the implementation process. A separate session was arranged for the nurses that worked in each endoscopy unit organised by the lead endoscopy nurse. The session included a similar (albeit shorter) version of the talk given to the endoscopists, including an outline of the study and the components of the 'bundle'. The nurses were also informed that they would be asked to complete a brief compliance assessment form for a proportion of the colonoscopies performed by each colonoscopist. The assessment form (Appendix I) was presented and discussed and all questions answered. There were no immediate issues that arose as a result of the discussions regarding the assessment form. Furthermore, nurses were empowered and encouraged to promote the study including reminding all colonoscopists about the bundle and referring to the poster.

4.2.1.3. Follow-up Sessions

Following completion of local training at all participating units, there was regular contact with the lead colonoscopist and lead nurse at each unit. This consisted of a monthly e-mail, in which updates as to the progress of roll out were provided as well as reminders regarding the importance of the study promotion.

An update session was provided at all participating units between 4 and 6 months of study commencement. During these sessions, preliminary results from all units were presented and discussed to act as a form of ongoing encouragement. An A4 size poster of these results was also provided to each unit and it was requested that this be placed alongside the study poster (Appendix J). Registers were kept at all update sessions. The lead colonoscopists were also provided with an e-mail consisting of a brief presentation and discussion of the preliminary results, which could be forwarded to all colonoscopists within the unit (Appendix K).

4.2.2. Data Analysis

It was important to understand whether our intervention was successful in bringing about a change in practice amongst the participating colonoscopists. Due to the logistics of delivering the educational package across all participating units, data from the first quarter of the year (1st January to 31st March 2011 inclusive) included a mix of data from both the pre and post-intervention periods. Therefore, this data was excluded from the analysis. Valid comparisons were for procedures undertaken between 1st October to 31st December 2010 and 1st April to 31st December 2011 in order to best evaluate whether the intervention to change practice had been successful. To be included in the analysis, colonoscopists must have performed procedures in both periods. The process used to collect and clean the data has been described in chapter two and was also used to collect the post intervention data.

To better understand how the bundle affected colonoscopists at different performance levels, quartiles were created after ranking colonoscopists according to their baseline ADR. To be included in these analyses, colonoscopists must have performed a minimum of 25 colonoscopies during the baseline period.

Assessing compliance with the intervention bundle through observation proved more challenging than originally expected. Lack of robust data and relatively small number of compliance assessment forms meant that the most reliable marker of uptake was Buscopan use. Thus, the change in Buscopan use rate (BR), defined as the proportion of procedures in which Buscopan was used expressed as a percentage, was used as a surrogate marker of compliance with our educational package.

Comparisons were made at the level of the colonoscopist, unit, globally (inclusive of data from all 12 units) and between quartiles. The unit, quartile and global level data included sufficiently large sample numbers that the normal distribution approximation is valid. For the data at the level of the colonoscopist where numbers are smaller, an exact test was used.

Whilst the data analysed is paired at the level of the colonoscopist, there are many other variables for which it is not possible to appropriately correct. These include patient factors such as age, gender, co-morbidities, quality of bowel preparation and tolerance of the procedure, as well as organisational factors that may influence uptake of the 'bundle' and adenoma detection. The

main limitation was the difficulty in collecting reliable data regarding several of these factors due to variable documentation. In addition, the number of procedures that each colonoscopist performed also varied. Taking these factors into consideration, the most appropriate statistical analyses were to calculate the ratio of two binomial proportions together with its 95% confidence interval. The presence of a significant change was evaluated using a corrected Chi Squared and Fishers Exact test respectively.

4.3. Results

4.3.1. Attendance at training and follow-up sessions

The QIC study began with a central training day held at University Hospital North Tees. Lead colonoscopists from all 12 units attended the session. Five non-lead colonoscopists from four units also chose to attend. Seven endoscopy nurse leads were able to attend the central training session, although, one subsequently handed over the role as lead to another nurse in the unit. A summary of attendance is shown in Table 10.

Following the central training day, a local training session was arranged at each of the participating units to implement the 'bundle'. The attendance at these sessions was variable with some units requiring multiple sessions (when logistically feasible) to capture as many colonoscopists as possible. The percentage attendance ranged from 38.5% to 83.3%. The dates, number of sessions and attendance figures are summarised in Table 11. The timing and the set-up of the session, either study specific or added to another meeting, is summarised in Table 12.

The attendances by grade of those included in the analyses were as follows: consultant gastroenterologist 58.5% (24/41), consultant surgeon 31.6% (12/38), nurse endoscopist 66.7% (10/15), trainee in gastroenterology 61.5% (8/13). There was one general practitioner whose data were included in the analysis who attended and also one geriatrician and one trainee in surgery, whose data were included but who did not attend a training session.

In addition to the training sessions for colonoscopists, a separate session was held for the endoscopy nurses to discuss the study and encourage them to promote use of the 'bundle'. In one unit (unit H), the lead nurse felt the most pragmatic way to circulate the required information was to meet with her and another of the senior sisters who would subsequently disseminate the information. In all other units, as many endoscopy nurses as possible attended the sessions and subsequently circulated the information to the remainder.

Table 10: Summary of attendance to central training day

Unit	Lead Colonoscopist	Lead Nurse	Non-lead colonoscopist
A	Y	Y	N
B	Y	Y	Y
C	Y	Y*	N
D	Y	N	N
E	Y	Y	N
F	Y	N	Y
G	Y	N	Y
H	Y	Y	N
I	Y	N	N
J	Y	Y	N
K	Y	Y	N
L	Y	N	Y

*Did not continue as lead nurse for the unit

Table 11: Summary of initial training session, date and attendance

Unit	Number of sessions	Date(s)	Total number of colonoscopists*	Number of attendees* (%)
A	1	4/2/11	2	1 (50.0)
B	1	28/2/11	9	5 (55.6)
C	1	4/2/11	6	2 (33.3)
D	2	21/1/11 + 27/1/11	6	5 (83.3)
E	1	7/1/11	15	7 (46.7)
F	2	14/1/11 + 27/1/11	15	7 (46.7)
G	2	18/2/11+ 25/3/11	9	4 (44.4)
H	2	27/1/11	11	4 (36.4)
I	1	13/1/11	14	7 (50.0)
J	1	21/1/11	12	5 (41.7)
K	1	10/1/11	7	5 (71.4)
L	2	18/2/11 + 25/3/11	12	8 (66.7)

*Numbers include only colonoscopists whose data were included in analysis.

Table 12: Summary of timing and set-up of training sessions

Unit	Timing of session	Session set-up
A	Afternoon	Study specific
B	After hours	Study specific
C	Afternoon	Study specific
D	Afternoon	Study specific
E	Afternoon	Study specific
F	Afternoon	Study specific + Before lower GI MDT
G	Afternoon	Endoscopy users meeting + Endoscopy training session
H	Morning	Study specific
I	Afternoon	Before joint gastro-surgery meeting
J	Afternoon	Prior to general surgery meeting
K	Afternoon	After lower GI MDT
L	Afternoon	Study specific + Endoscopy training session

Following the initial training sessions, I (PTR) attended each unit for a follow up visit at between four and six months during which the preliminary results were presented to encourage engagement with the bundle.

4.3.2. Self-reported use of the ‘bundle’ measures prior to intervention

During the training sessions, colonoscopists were asked to complete a short questionnaire regarding their use of the measures comprising our bundle in their routine practice prior to the study. A total of 80 questionnaires were returned, of which 59 (50%) were from colonoscopists that were included in

our post intervention analyses (see below). The results are summarised in Table 13.

Table 13: Summary of how often each measure was used routinely

	Always/nearly always (%)	Often (%)	Rarely (%)	Never (%)
Withdrawal time*	26 (44.1)	23 (39.0)	9 (15.3)	1 (1.7)
Buscopan use *	7 (11.9)	14 (23.7)	23 (39.0)	15 (25.4)
Position Change*	19 (32.2)	23 (39.0)	13 (22.0)	13 (6.8)
Retroflexion*	38 (64.4)	16 (27.1)	5 (8.5)	0 (0.0)

*Numbers from colonoscopists whose data were included in analysis only.

4.3.3. Change in Practice: compliance assessment forms and Buscopan use

To be included in the comparative analyses, colonoscopists must have performed procedures in both periods. After applying this criterion, 118 colonoscopists remained of whom there were 41 consultant gastroenterologists (34.7%), 39 consultant surgeons (33.1%), 15 nurse endoscopists (12.7%), 13 gastroenterology trainees (11.0%), 5 non-consultant grade staff (4.2%), and 1 general practitioner, (0.8%), 1 consultant geriatrician (0.8%), and 3 surgical trainees (2.5%).

The 118 colonoscopists listed above performed a total of 4,351 colonoscopies during the baseline period included in the statistical analysis. The number of procedures performed per colonoscopist ranged from 1 to 143. A total of 13,157 colonoscopies were performed during the period following the intervention excluding performance data from the first quarter (implementation

period). The number of procedures performed per colonoscopist ranged from 1 to 464. Graphs summarising the spread of the number of colonoscopies performed is shown in Figure 12 and Figure 13 respectively.

Figure 12: Summary of the number of procedures performed per colonoscopist during period before implementation of the ‘bundle’

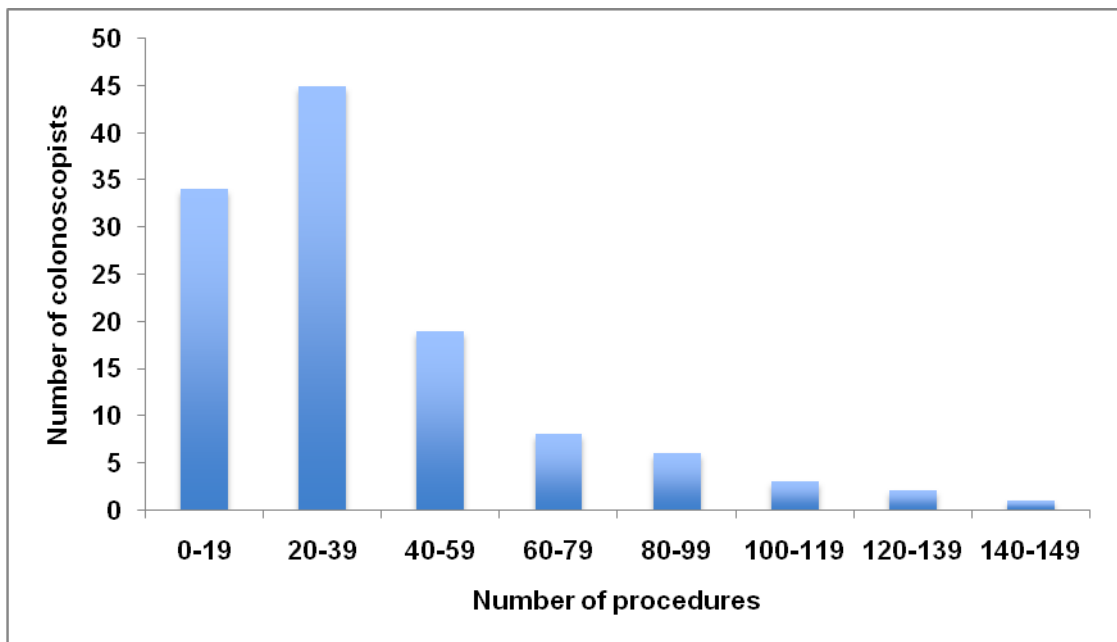
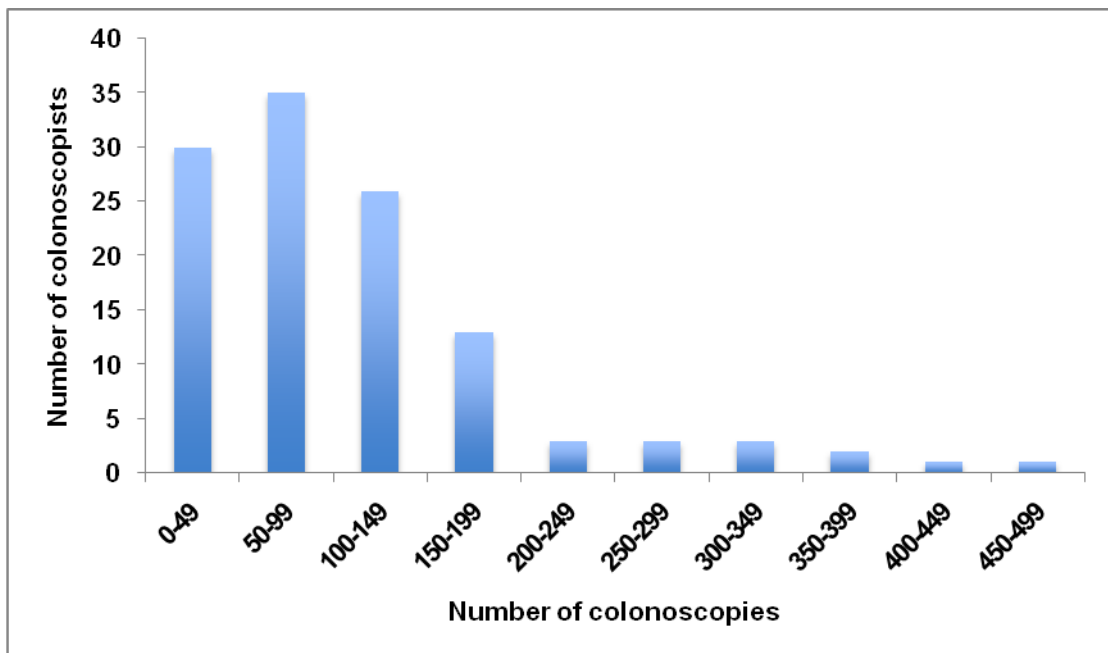


Figure 13: Summary of the number of procedures performed per colonoscopist during period after implementation of the ‘bundle’



Compliance Assessments

The compliance assessments were completed to a variable standard. Forms were completed for 103 (87.3%) colonoscopists. There were a total of 2,040 usable forms (15.5% of all procedures). The number of forms completed per colonoscopist is summarised in Figure 14. The interquartile range of the number of forms completed per colonoscopist was 5 to 23. The number completed per unit is summarised in Table 14. A summary of the results is provided in Table 15. Reasons that forms were not usable included no identification as to the colonoscopist being audited, presence of polyps, completed for a flexible sigmoidoscopy as opposed to full colonoscopy and being performed in patients with extensive bowel resections making the intervention measures irrelevant.

Figure 14: Number of forms as a proportion of the total number of colonoscopies performed per colonoscopist

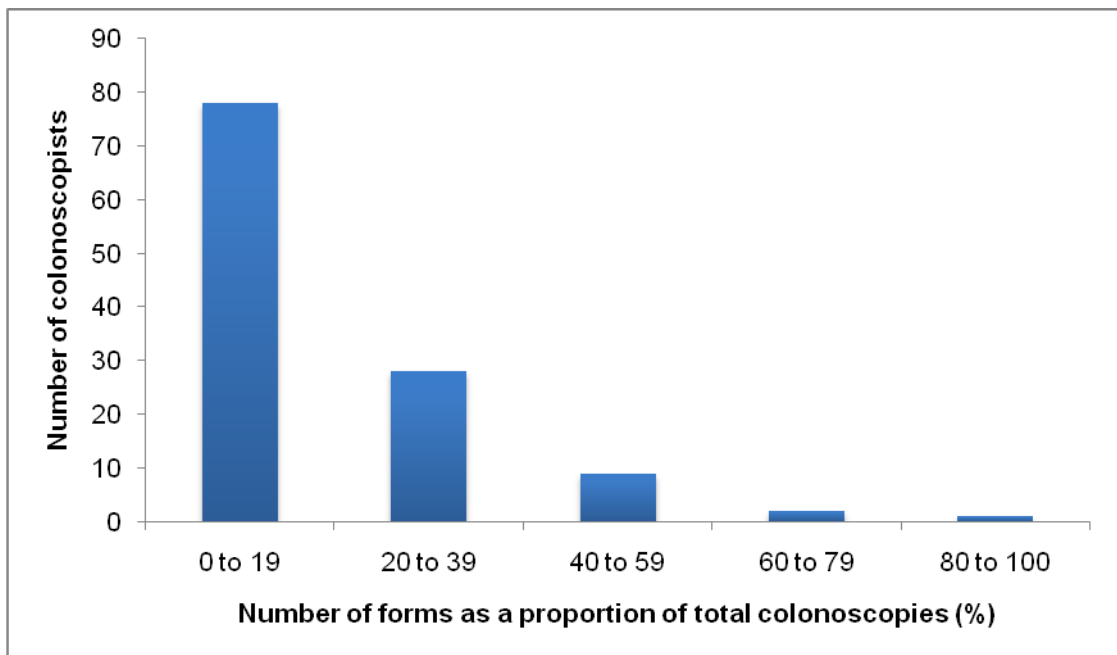


Table 14: Summary of the number of forms completed per unit

Unit	Number of forms (% of total number of forms)	Number of forms as a proportion of total number of procedures performed (%)
A	69 (3.4)	26.1
B	172 (8.4)	23.1
C	154 (7.5)	32.3
D	179 (8.8)	24.6
E	270 (13.2)	13.0
F	241 (11.8)	11.1
G	6 (0.3)	0.6
H	131 (6.4)	9.3
I	221 (10.8)	21.7
J	207 (10.1)	33.8
K	301 (14.8)	25.7
L	89 (4.4)	6.0

Table 15: Summary of results of compliance assessment results

	Yes (%)	No (%)	Field not completed (%)	Unusable (%)	CI (%)
WT	1,718 (84.2)	170 (8.3)	93 (4.6)	52 (2.5)	N/A
Buscopan	1,645 (79.2)	391 (19.2)	7 (0.3)	0 (0.0)	188 (9.2)
Position	1,822 (89.3)	235 (11.5)	12 (0.6)	0 (0.0)	N/A
Retroflexion	1,789 (87.7)	210 (10.3)	40 (2.0)	0 (0.0)	92 (4.5)

Buscopan use rate (BR)

During the baseline period, Buscopan was used in 689 procedures globally translating to a BR of 15.8% (95% CI 14.8-17.0). In the period after the intervention, Buscopan was used in 7,161 procedures globally, translating to a BR of 54.4% (95% CI 53.5-55.3). This was a statistically significant increase in BR ($p < 0.001$).

All units demonstrated a significant increase in the use of Buscopan. Table 16 summarises the change in BR for all units, the ratio of proportions and the p value for the significance level of change during the pre and post intervention periods. Table 17 summarises the number of colonoscopists per unit that demonstrated a significant increase in BR.

A total of 72 (61.0%) colonoscopists demonstrated a significant increase in their BR comprising 26 (36.6%) consultant gastroenterologists, 15 (21.1%) consultant surgeons, 1 (1.4%) general practitioner, 1 (1.4%) geriatrician, 4 (5.6%) non-consultant grade staff, 13 (18.3%) nurse endoscopists and 11 (15.5%) trainees in gastroenterology. A total of 43 (60.6%) had attended a local training session. The range of BR per colonoscopist during both the period before and after the intervention was 0 to 100%, the spread of which is shown in Figure 15 and Figure 16 respectively.

Table 16: Summary of change in BR in each unit together with the results of statistical analysis

Unit	Before			After			Ratio	p value
	N	Patients in whom Buscopan used	BR (%)	N	Patients in whom Buscopan used	BR (%)		
A	72	59	81.9	264	244	92.4	1.13	0.008
B	275	7	2.5	745	289	38.8	15.24	<0.001
C	191	9	4.7	477	321	67.3	14.28	<0.001
D	247	32	13.0	729	339	46.5	3.59	<0.001
E	556	141	25.4	2073	1382	66.7	2.63	<0.001
F	791	106	13.9	2153	1283	59.6	4.45	<0.001
G	344	70	20.4	959	408	42.5	2.08	<0.001
H	465	112	24.1	1409	714	50.7	2.10	<0.001
I	379	74	19.5	1018	731	71.8	3.68	<0.001
J	235	30	12.2	612	365	59.6	4.67	<0.001
K	341	4	1.2	1173	372	31.7	27.04	<0.001
L	455	45	9.9	1545	713	46.1	4.89	<0.001

N = number of colonoscopies

Table 17: Summary of the number of colonoscopists who demonstrated a significant increase in BR per unit

Unit	Number of colonoscopists with a significant increase in BR (proportion of colonoscopists as a %)
A	1 (50.0)
B	8 (80.0)
C	5 (83.3)
D	4 (66.7)
E	7 (46.7)
F	9 (60.0)
G	4 (44.4)
H	7 (63.6)
I	9 (64.3)
J	5 (41.7)
K	3 (42.9)
L	8 (66.7)

Figure 15: Summary of BR per colonoscopist during baseline period

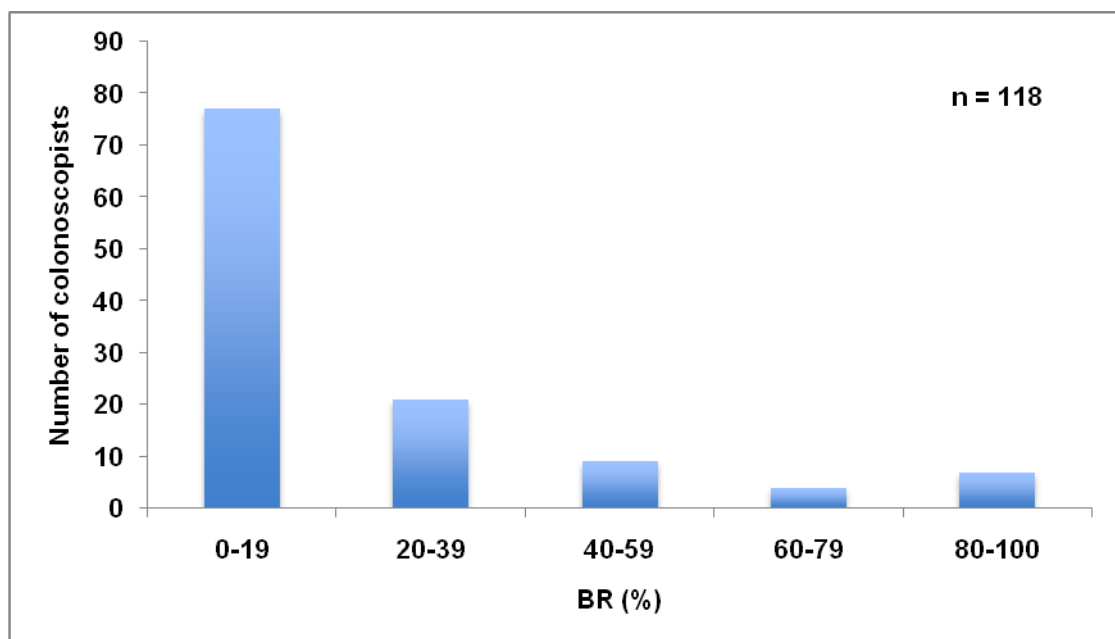
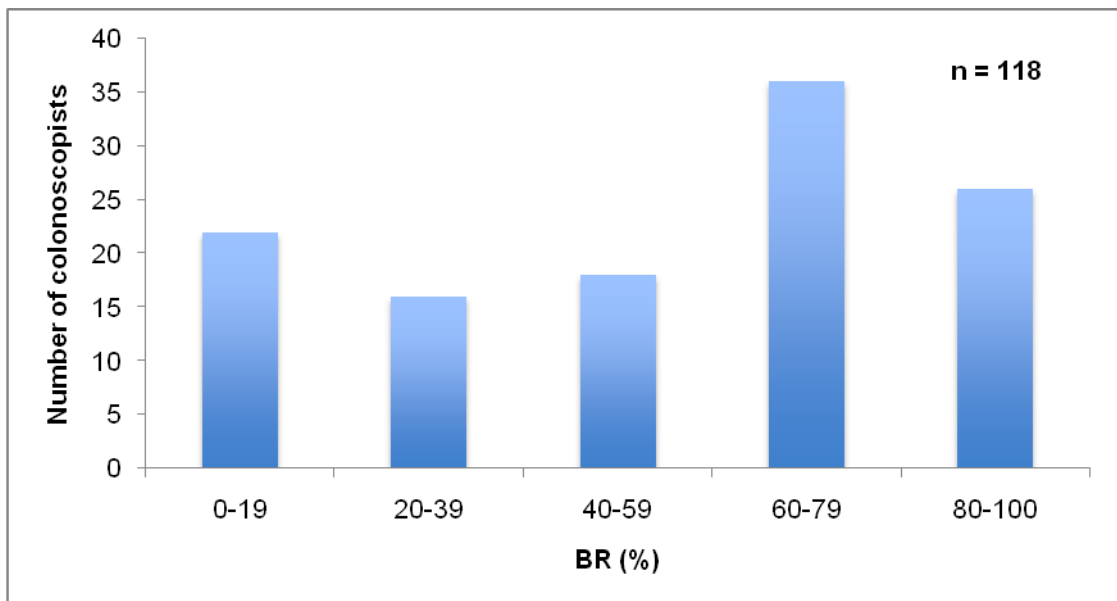


Figure 16: Summary of BR per colonoscopist during the period following implementation



A total of 68 colonoscopists were included in quartile level analyses performing a total of 3,622 and 10,571 procedures during the 'before' and 'after' periods respectively. A significant increase in BR was demonstrated in all quartiles as summarised in Table 18.

Table 18: Summary of changes in BR in each quartile together with the results of statistical analyses.

Quartile	Before			After			Ratio	p value
	N ^o . of procedures	Patients in whom Buscopan used	BR (%)	N ^o . of procedures	Patients in whom Buscopan used	BR (%)		
Upper	785	183	23.3	2508	1832	73.0	3.13	<0.001
Upper Middle	1116	214	19.2	3119	1976	63.4	3.30	<0.001
Lower Middle	785	71	9.0	2539	892	35.1	3.90	<0.001
Lower	936	74	7.9	2405	1094	45.5	5.76	<0.001

4.4. Discussion

The overall aim of this multi-faceted intervention was to introduce a ‘bundle’ into routine colonoscopy practice to improve ADR by improving mucosal visualisation. The two key questions addressed by this thesis are:

1. Can a “bundle” such as the one proposed be successfully implemented across a whole geographical region and can this be evidenced?
2. If change can be achieved, will this improve ADR in those who appear to underperform and will it also reduce variance in ADR?

In this chapter, the answer to the first of the two questions is presented and discussed.

The endoscopy nurses were asked to complete a simple compliance assessment form for a proportion of procedures performed by each colonoscopist in their unit. Forms completed for 87.3% of participating colonoscopists, however this represented only 15.5% of the total number colonoscopies performed. Among the compliance assessments completed, there was a very good uptake of all components of the 'bundle'. However, due to the limited proportion of procedures for which the forms were completed, the true level of uptake is unlikely to be as high as suggested by these data.

All medications given during colonoscopy are documented on the endoscopy report and can subsequently be reviewed. As a result of the limited number of compliance assessments completed, the most robust method of evaluating whether there had been engagement with the 'bundle' was to use change in the BR as a surrogate marker. There were no other initiatives during the study period that would have influenced BR and so it is reasonable to conclude that the change was as a result of the study intervention. This method does not allow evaluation of adherence to the remaining measures in the 'bundle' which would, in any case, be harder to evidence.

A significant increase in BR was observed globally and in all units. Regarding individual colonoscopists, 61.0% significantly increased their BR of whom 39.4% had not attended the initial training session. The proportion of colonoscopists per unit in whom a significant increase in BR was seen ranged from 41.7% to 83.3% suggesting that change was not clustered. A significant increase in BR was also seen in all quartiles.

These results suggest a good level of engagement and adoption of the 'bundle' among the participating colonoscopists with change observed in all units, rather than being focused amongst a few enthusiastic departments. Furthermore, change was also observed in those colonoscopists who did not attend a local training session. This provides evidence that the selected implementation model led to successful dissemination of the bundle out with the direct involvement of the study team.

In order to evaluate the effectiveness of our model of implementation, we must have an understanding of expected change in behaviour for this type of intervention and consider factors that may have influenced uptake. In this setting, time constraints and cost efficiency were the most important factors, as discussed previously.

Academic detailing has been used to improve patient care in a variety of clinical settings including improving colonoscopy practice, prescribing behaviour, adherence to guidelines in the management of chronic conditions and prevention of falls in care home residents. (69-71) The models used naturally differ in accordance with the aim of the project and the clinical setting.

In a recently published study by Coe et al, the effect of an endoscopic quality improvement programme on detection of colorectal adenomas was studied. (72) Colonoscopists were randomised to either receive the educational intervention or continue their routine practice. All received feedback regarding

their baseline ADR and withdrawal times and were aware they were part of a study of ADR. However, those in the control arm were not aware that the other group had undergone an educational intervention. Training consisted of two separate one hour long sessions, which included the importance of good mucosal viewing technique in combination with longer withdrawal times to improve ADR. Training also included the use of optical enhancement tools such as narrow band imaging (NBI) the primary use of which is to characterise polyps. It was demonstrated that colonoscopists in the intervention arm significantly improved their ADR. Limitations of this work were that it was performed in a single academic centre study including only 15 colonoscopists. The two colonoscopists with the lowest ADR, and therefore biggest room for improvement, were also randomised, by chance, to the training group. Another potential issue is the length of the training sessions required to achieve change, which could potentially limit effective wider rollout particularly in a busy NHS setting. This issue will be discussed further later in this thesis.

Larger scale interventions have been performed in other care settings. Grimshaw et al performed a systematic review to evaluate the effectiveness of guideline dissemination and implementation. (73) The study designs included in the analyses were cluster and individual randomised controlled trials (RCTs), controlled clinical trials, controlled before and after (CBA) studies and interrupted time series (ITS) that evaluated any guideline dissemination or implementation strategy targeting physicians and that reported an objective measure of provider behaviour and/or patient outcome. Interventions were

classified in accordance with the Cochrane-Effective Practice and Organisation of Care (EPOC) taxonomy as shown in Table 19.

Table 19: Cochrane-Effective Practice and Organisation of Care (EPOC) taxonomy classification system (reproduced with the permission of Cochrane Database of Systematic Reviews)

Table 1. Classification of Professional Interventions from EPOC Taxonomy

<ul style="list-style-type: none"> (a) <i>Distribution of educational materials</i>—distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials, and electronic publications (b) <i>Educational meetings</i>—health care providers who have participated in conferences, lectures, workshops, or traineeships (c) <i>Local consensus processes</i>—inclusion of participating providers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate (d) <i>Educational outreach visits</i>—use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice (e) <i>Local opinion leaders</i>—use of providers nominated by their colleagues as "educationally influential." The investigators must have explicitly stated that their colleagues identified the opinion leaders (f) <i>Patient mediated interventions</i>—new clinical information (not previously available) collected directly from patients and given to the provider, e.g., depression scores from an instrument (g) <i>Audit and feedback</i>—any summary of clinical performance of health care over a specified period of time (h) <i>Reminders</i>—patient or encounter-specific information, provided verbally, on paper or on a computer screen that is designed or intended to prompt a health professional to recall information (i) <i>Marketing</i>—use of personal interviewing, group discussion ("focus groups"), or a survey of targeted providers to identify barriers to change and subsequent design of an intervention that addresses identified barriers (j) <i>Mass media</i>—(i) varied use of communication that reached great numbers of people including television, radio, newspapers, posters, leaflets, and booklets, alone or in conjunction with other interventions; and (ii) targeted at the population level
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EPOC, Cochrane-Effective Practice and Organisation of Care.

Of particular relevance to the QIC study are the results from studies utilising multifaceted interventions incorporating educational outreach. Of the 11 controlled RCTs reporting dichotomous process measures, the median effect of the interventions was +6.0% (range -4% to +17.4%) absolute improvement in performance. The change reached statistical significance in five studies in which the median effect size was +10.0% (range -4.0% to +17.4%). Only the one study with a +17.4% study was statistically significant. Of the four CBA studies reporting dichotomous process measures, the median effect was +7.3% (range 5.6 to 16.4%) absolute improvements in performance. Of those

reporting continuous process measures, among the cluster RCTs analysed the median effect was +15% (range +1.7% to 24%) and for the single CBA, an 11.3% relative improvement in performance.

A sub-group analysis was also performed to evaluate the effect of educational materials and educational outreach compared to educational materials, educational meetings and educational outreach. It was concluded that the latter is likely to have the bigger effect, however, this is still likely to be only modest to moderate.

The group also evaluated the effect of multiple interventions. There was no clear relationship between the number of interventions i.e. training sessions, and the effect size overall, however, multiple interventions may have a modest additional effect on influencing prescribing behaviour.

The Cochrane group has also performed a review of the effect of educational outreach visits (EOV) on professional practice and healthcare outcomes. (61) They included RCTs of EOVs that reported an objective measure of professional performance or healthcare outcomes. For dichotomous outcomes, results were given as an adjusted risk difference (RD) defined as the difference between intervention and control group means in compliance after the intervention minus the difference between the groups before the intervention, with a positive RD meaning compliance improved more in the EOV group. For continuous outcome measures, the post-intervention raw and adjusted mean differences were calculated. When possible the relative

percentage change was also calculated (adjusted difference between the post-intervention experimental and control group means divided by the post-intervention control group mean x 100).

There were a number of comparisons performed. One looked at any intervention in which EOVs were a component of the intervention compared to no intervention. Those with dichotomous health professional outcomes reported a median improvement of 5.6% (interquartile range 3.0% to 9.0%). Those reporting continuous healthcare professional outcome reported an adjusted relative percentage change varying from 0% to 617%. The median percentage change was 21% (interquartile range 11% to 41%). When studies in which EOV alone was the intervention compared with no intervention, those with dichotomous health professional outcomes demonstrated a median adjusted RD of 5.0% (interquartile range 3.0% to 6.2%) and those with continuous health professional outcomes a median percentage change of 23% (interquartile range 12% to 39%).

The intervention in the QIC study resulted in a significant and relatively global change in health professional behaviour as evidenced by a change in BR. The primary challenge of comparing outcomes of service improvement studies is the heterogeneity that exists within the evidence base due to methodological differences and the varied clinical settings. We must also consider that, whilst our intervention 'bundle' encourages evidenced-based practice, with the exception of withdrawal time, the measures are not national guidance. Therefore, colonoscopists would not have been expected to perform the

measures as routine prior to the intervention and instead, would have done so variably as we demonstrate. This may potentially result in a larger change than in settings where guidelines already exist. Despite these considerations, the increase in BR is likely to demonstrate at least a moderate change in behaviour when compared to other educational interventions, suggesting our model of implementation was effective.

Engagement with the 'bundle' was primarily measured using BR as a surrogate marker as it was the most reliably documented. Use of a surrogate marker has inherent limitations which we accept. One such limitation is that Buscopan is potentially the simplest component of the 'bundle' to comply with and is driven primarily by endoscopy nursing staff who both prepare and provide the drug. Therefore, it is possible that BR may be higher than compliance with the other measures within the 'bundle'. However, there is evidence from our qualitative work (presented in chapter 6) that suggests nurses also encouraged the use to rectal retroflexion and that the study training sessions did help some colonoscopists consider withdrawal time more carefully than prior to the intervention suggesting the overall implementation package had the desired effect of increasing awareness of quality measures and promoting uptake.

One final consideration is that this study was conducted within an established collaborative research network and lead colonoscopists had volunteered to participate in the study. As a result, we accept that uptake may potentially be

higher than seen if rolled out to the rest of the UK where collaborative working may not be as well established.

In summary, taken together and considering the limitations, both the change in BR and compliance assessment data demonstrate that the multi-faceted study intervention resulted in successful incorporation of evidence into routine clinical practice. When compared with data from other clinical settings, it is reasonable to describe the degree of change as at least moderate. The observations also suggest that dissemination of information occurred out with the direct involvement of the study team suggesting that good local promotion took place, supporting the selected model of implementation.

Chapter Five: What was the effect on adenoma detection rate?

Chapter Five: What was the effect on adenoma detection rate?

5.1. Introduction

The hypothesis that a “bundle” of evidence based changes in colonoscopy practice could be achieved through the implementation of an educational package as presented in the previous chapter proved correct indicating that the model of implementation was appropriate and successful in achieving significant changes in practice at all levels (individual colonoscopist, unit, globally and in all quartiles). The hypothesis also included the tenet that effecting this change would improve mucosal visualisation and as a direct consequence improve ADR and reduce the variation that currently exists.

5.2. Methods

5.2.1. Data Analysis

The processes of data collection, cleaning and comparative analyses were as described previously. Changes in ADR were also analysed using funnel plots that were created as described in chapter two, relative to the reference standard of 15.9% (the baseline mean before application of the inclusion/exclusion criteria) rather than the lower BSG standard of 10%.

Calculating an appropriate sample size in the context of a service improvement project is challenging due to the heterogeneity in baseline performance and variable uptake of any intervention as discussed in the previous chapters. Regarding ADR, if we were to use the number of colonoscopies required to reliably demonstrate an absolute increase in ADR

of 5% and a relative increase of 25%, a sample size of 1504 colonoscopies would be required per analysis point for the selected level of analysis.

Whilst the measures within the 'bundle' are considered safe, adverse event data reported by each unit in their GRS reported were reviewed by the study team for any possible association with the measures in the 'bundle'.

5.3. Results

5.3.1. Global Results

Data from 118 colonoscopists who had performed procedures during the baseline period were included in the analysis, as with the analysis for change in BR. Of the 4,351 procedures performed, a total of 698 procedures were found to have at least one adenoma during this period, translating to a global ADR of 16.0% (95% CI 15.0-17.2). In the period following the intervention, a total of 2,381 of the 13,157 procedures performed were found to have at least one adenoma resulting in a global ADR of 18.1% (95% CI 17.5-18.8). This increase in ADR was statistically significant ($p=0.009$).

5.3.2. Unit level analysis

At unit level, an increase in ADR was observed in 10 of the 12 units, with one (unit L) reaching statistical significance. Table 20 summarises the results per unit.

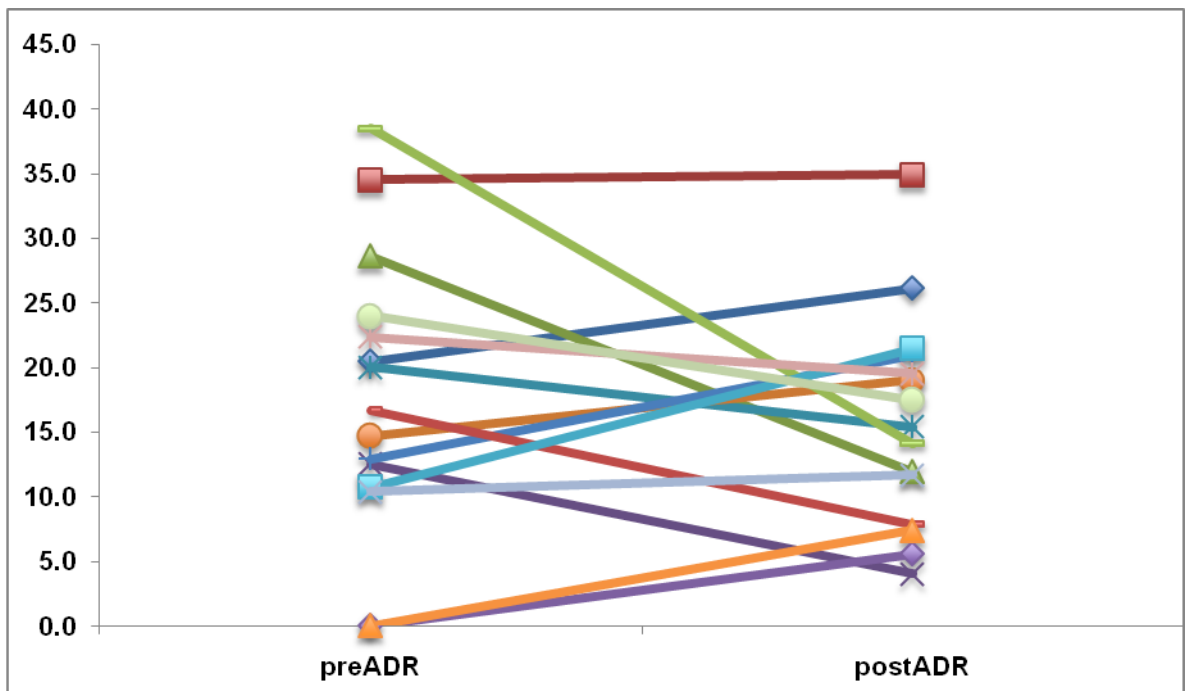
Line graphs were produced to evaluate direction of change in ADR per colonoscopist within each unit, an example of which is shown in Figure 17.

This helps to demonstrate the challenge of analysing unit level data due to the heterogeneity that exists. Graphs for the remaining units are in Appendix L. Funnel plots were created for each unit, which are not shown here but can be found in Appendix M.

Table 20: Summary of change in ADR in each unit together with the results of statistical analysis

Unit	Before			After			Ratio	p value
	N° of procedures	Patients with adenomas	ADR (%)	N° of procedures	Patients with adenomas	ADR (%)		
A	72	15	20.8	264	47	17.8	0.85	0.56
B	275	34	12.4	745	124	16.6	1.35	0.09
C	191	34	17.8	477	87	18.2	1.03	0.89
D	247	25	10.1	729	106	14.5	1.44	0.08
E	556	102	18.3	2073	371	17.9	0.98	0.81
F	791	126	15.9	2153	346	16.1	1.01	0.92
G	344	55	16.0	959	186	19.4	1.14	0.36
H	465	86	18.5	1409	288	20.4	1.11	0.36
I	379	58	15.3	1018	176	17.3	1.13	0.38
J	235	43	18.3	612	113	18.5	1.01	0.96
K	341	42	12.3	1173	182	15.5	1.26	0.14
L	455	78	17.1	1545	355	23.0	1.35	0.008

Figure 17: Line graph of ADR before and after the intervention for each colonoscopist in unit E.



5.3.3. Colonoscopist level analysis

Because of the relatively low number of colonoscopies performed by some individuals endoscopists, a significant change in ADR was detected in only 5 (4.2%), all of whom increased. The spread of ADRs per colonoscopist during the ‘before’ and ‘after’ period are shown in Figure 18 and Figure 19.

In order to evaluate how these changes had affected the spread of data, funnel plots were created with respect to the global mean during the baseline of 15.9% (prior to application of inclusion/exclusion criteria). Graphs were created for all participating colonoscopists for the periods before and after the intervention as shown in Figure 20. There were more colonoscopists below the lower 95% limit after the intervention (12 vs.10) and more above the upper

95% limit (12 vs. 4) but these changes are not significant due to wide confidence intervals. The data also demonstrates with more confidence that there continue to be colonoscopists performing a large number of procedures (>100) whose ADR is below the lower confidence limit.

Figure 18: Summary of the ADRs per colonoscopist during baseline period

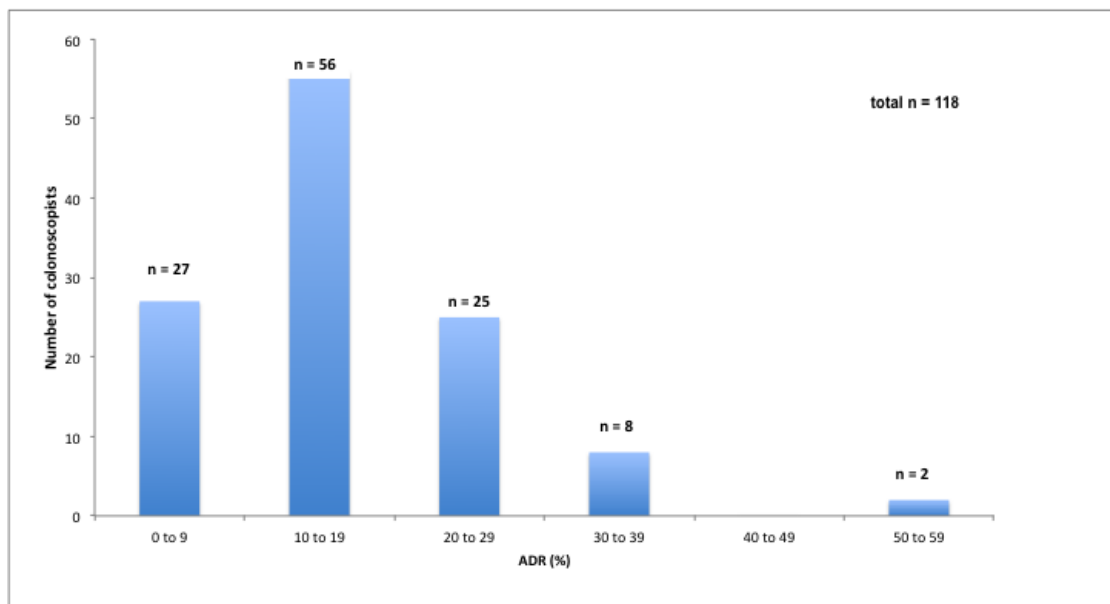


Figure 19: Summary of the ADRs per colonoscopist during the period following the intervention

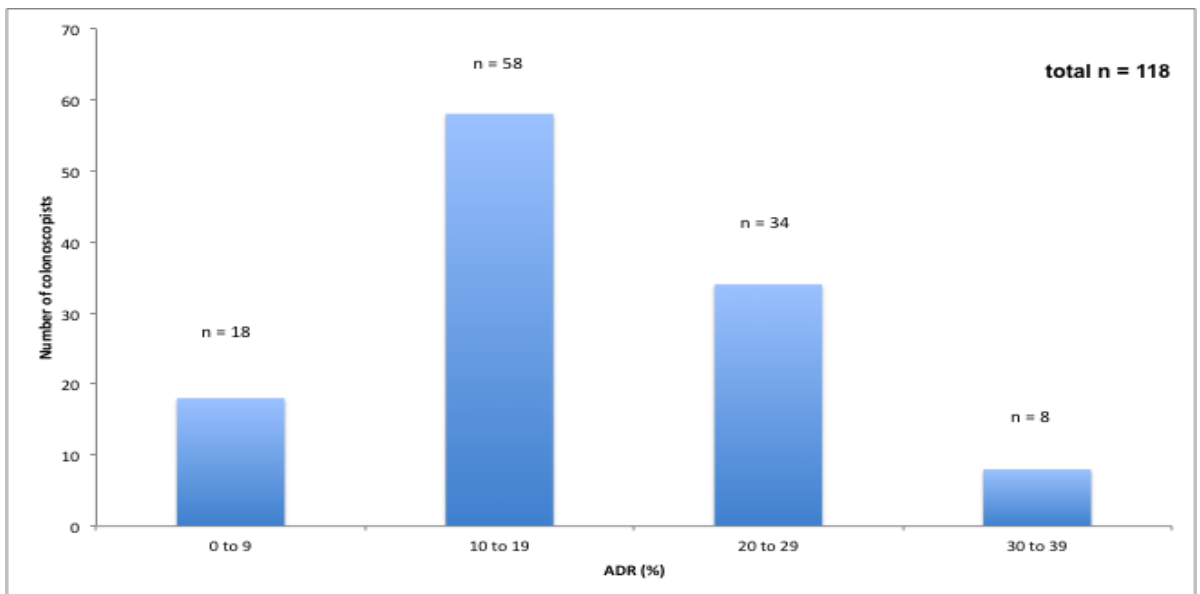
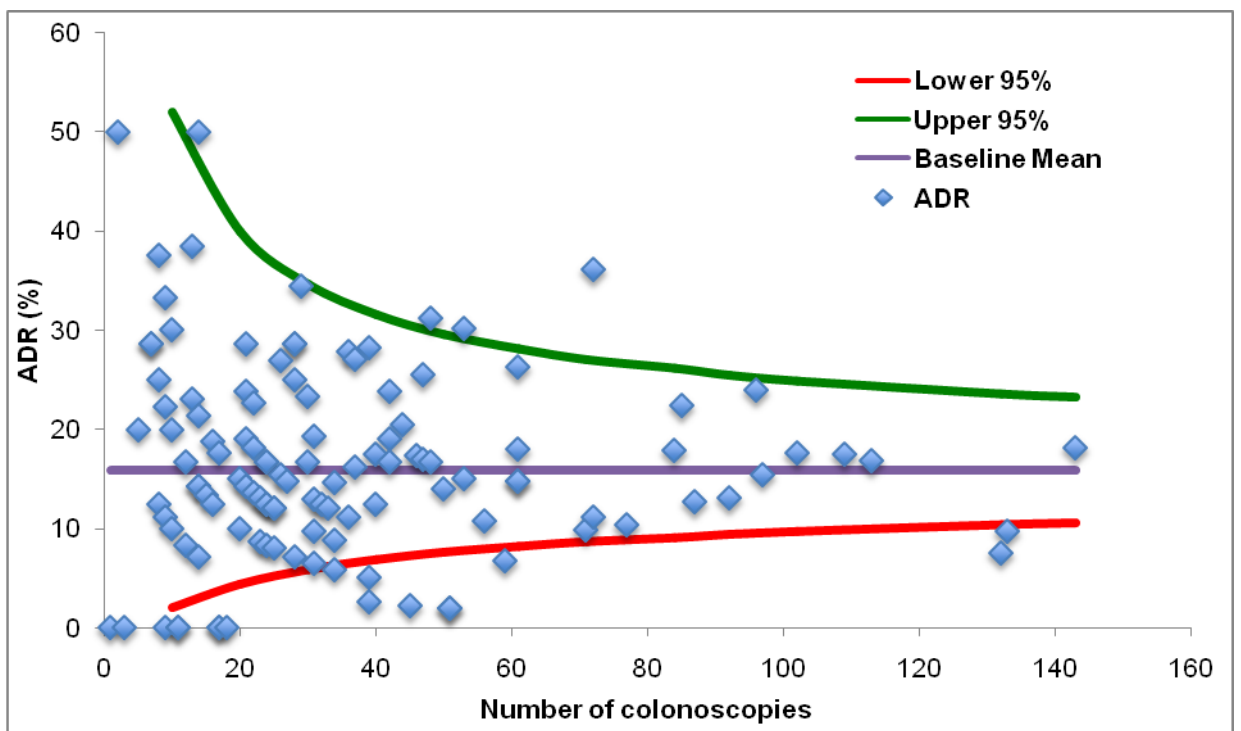
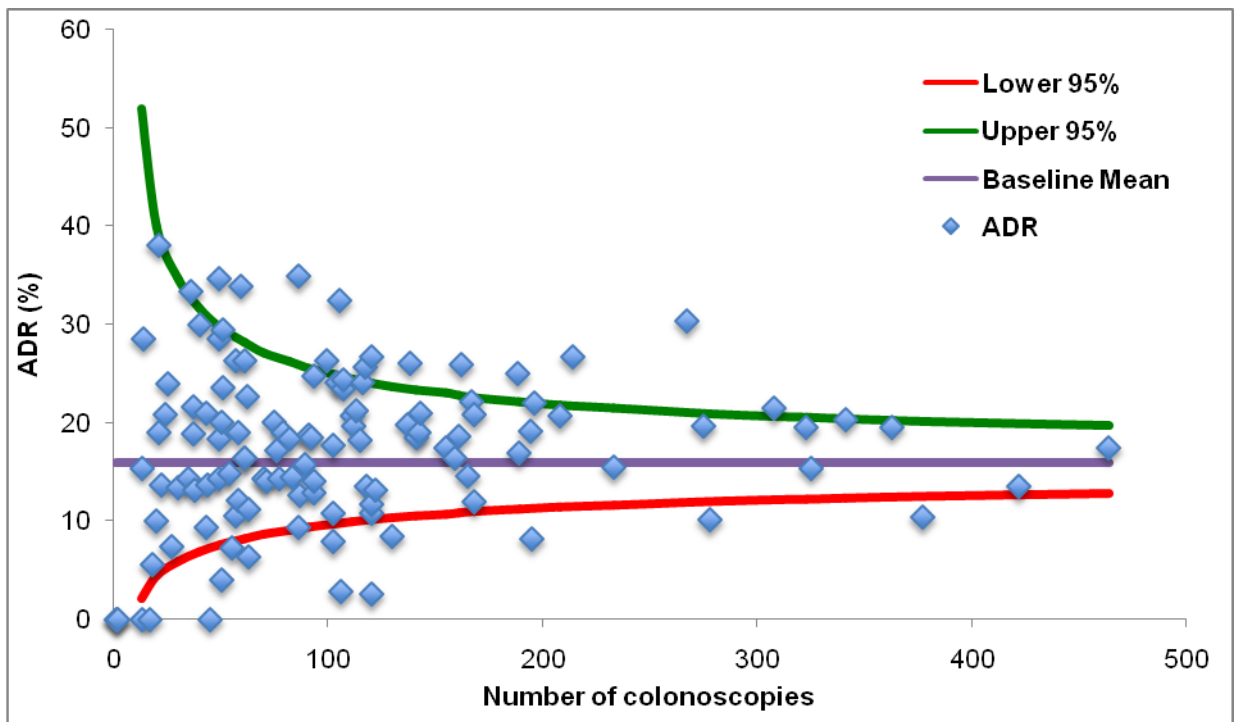


Figure 20: Funnel plot of ADRs of all colonoscopists during the period a) before and b) after the intervention with respect to the baseline mean.

a)



b)



5.3.4. Quartile Analyses

Analyses by quartiles were performed to better understand whether the 'bundle' influenced the ADR of individuals differently depending on their baseline performance. Following exclusion of colonoscopists performing fewer than 25 procedures during the period before the intervention, a total of 68 remained that were included in these analyses. This included 25 (36.8%) consultant gastroenterologists, 20 (29.4%) consultant surgeons, 12 (17.6%) nurse endoscopists, 7 (10.3%) trainees in gastroenterology 1 (1.5%) geriatrician, 1 (1.5%) GP and 2 (3.0%) non-consultant grade staff members. The number in each quartile is shown in Table 21.

Table 21: Breakdown of each quartile by colonoscopist speciality

Speciality	Upper	Upper Middle	Lower Middle	Lower
Gastroenterologist	8	8	4	5
Surgeon	2	4	8	6
Nurse	4	3	3	2
Trainee	2	2	1	2
Geriatrician	0	0	1	0
GP	0	0	0	1
Non-consultant grade	0	0	0	2

Following implementation of the ‘bundle’, there was a significant improvement in ADR in the lower and lower middle quartiles. There was also an improvement in ADR in the upper middle quartile although this did not reach statistical significance. The ADR of the upper quartile fell significantly, but was still 21.5% during the period after the intervention and still above the other quartiles. The results for ADR per quartile are summarised in Table 22.

Table 22: Summary of change in ADR per quartile with the results of statistical analysis

Quartile	Before			After			Ratio	p value
	N	Patients with adenomas	ADR (%)	N	Patients with adenomas	ADR (%)		
Upper	785	215	27.4	2508	538	21.5	0.78	<0.001
Upper Middle	1116	195	17.5	3119	599	19.2	1.10	0.24
Lower Middle	785	104	13.2	2539	490	19.3	1.45	<0.001
Lower	936	68	7.3	2405	334	13.9	1.91	<0.001

N = number of colonoscopies

Additionally, the ADR of the respective quartiles before the intervention were all significantly different from one another. Following the intervention, only the lower quartile was significantly different from the remainder.

Line graphs representing the direction of change in ADR for each quartile are shown in Figure 21 to Figure 24. Funnel plots for each quartile relative to the baseline mean are shown in Figure 25 to Figure 28.

Figure 21: Line graph showing direction of change in ADR for the lower quartile.

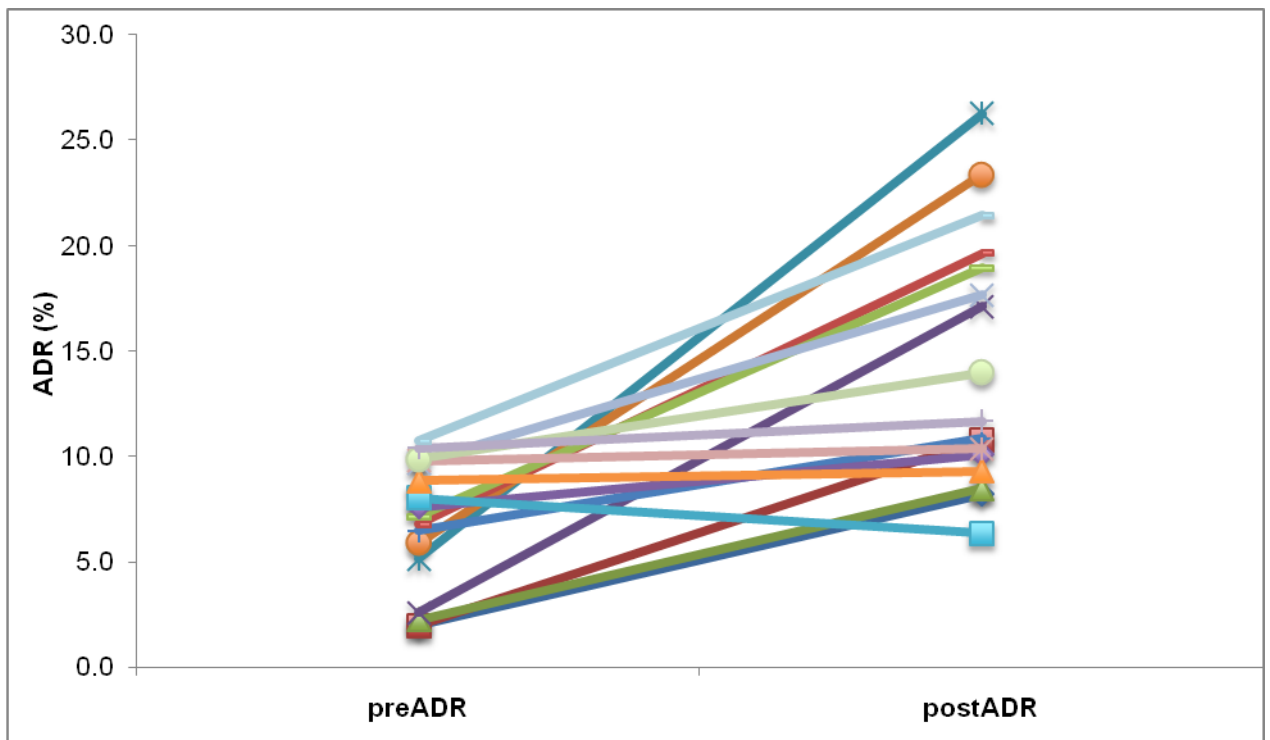


Figure 22: Line graph showing direction of change in ADR for the lower middle quartile.

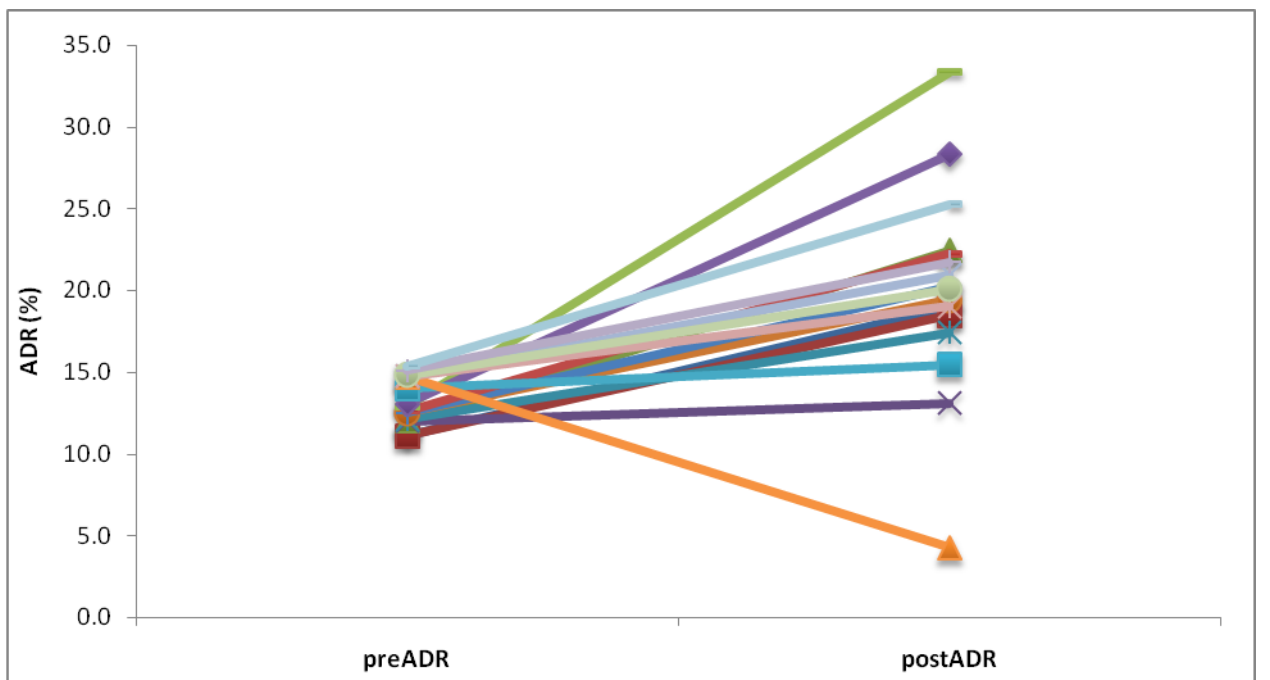


Figure 23: Line graph showing direction of change in ADR for the upper middle quartile.

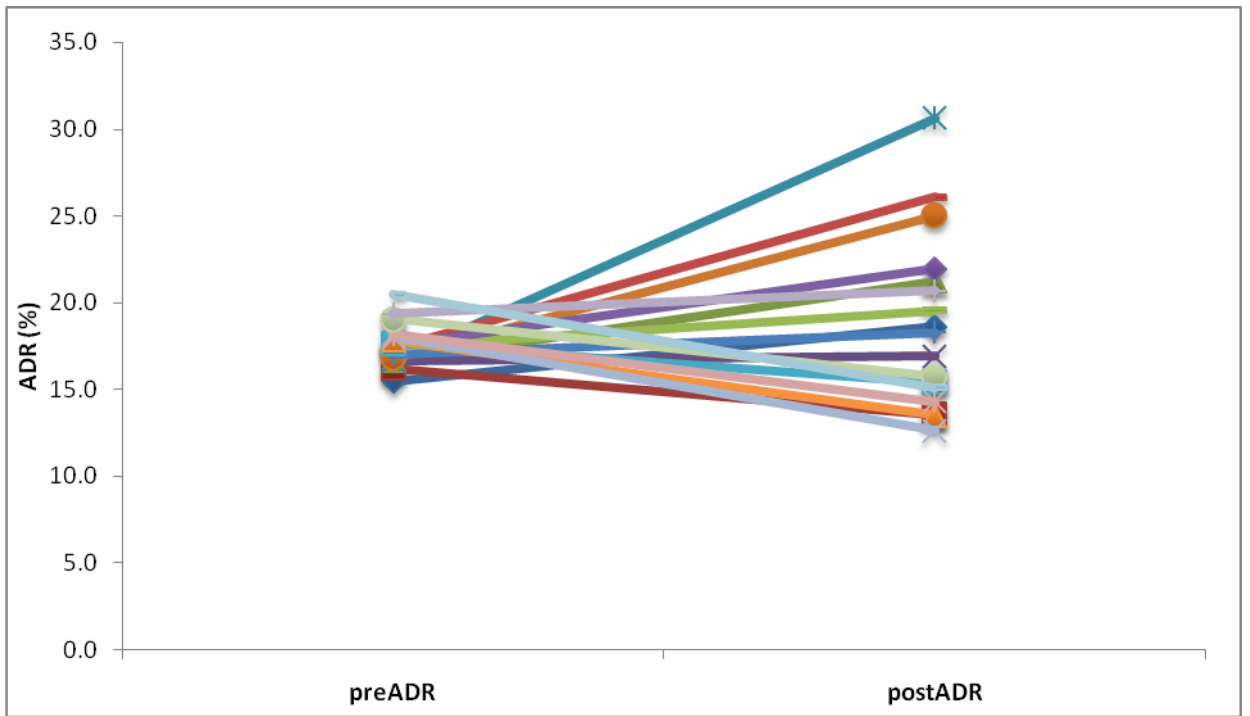


Figure 24: Line graph showing direction of change in ADR for the upper quartile.

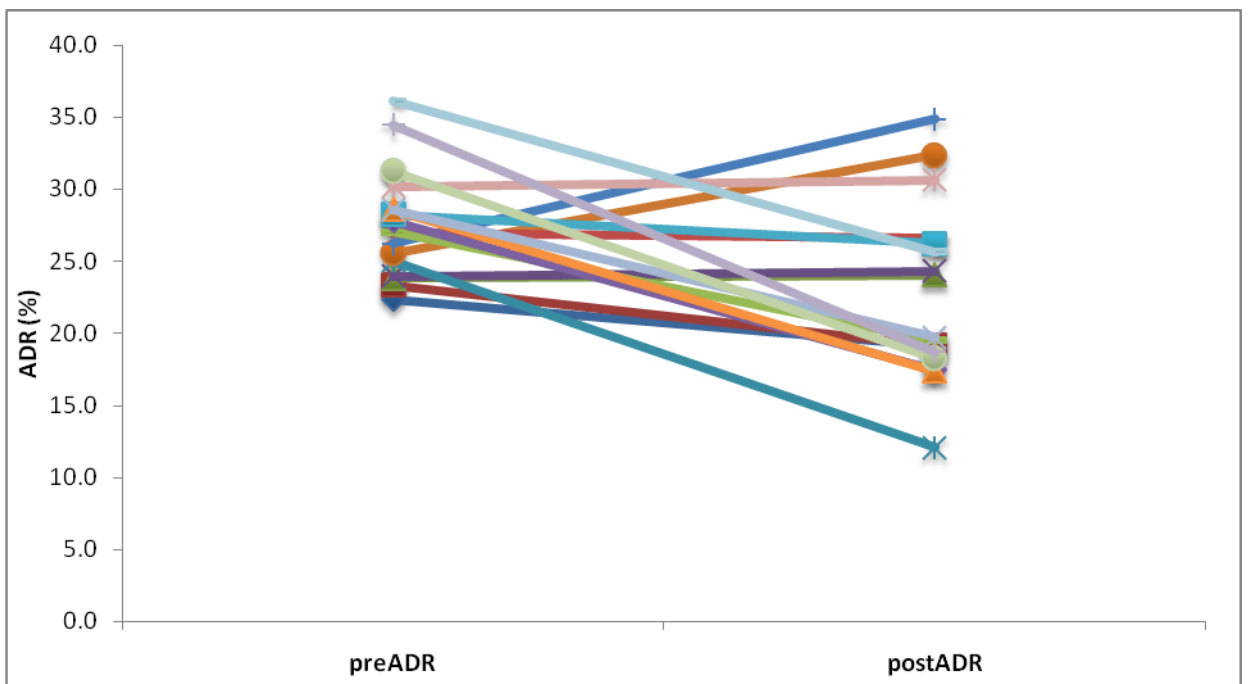


Figure 25: Funnel plot for the lower quartile.

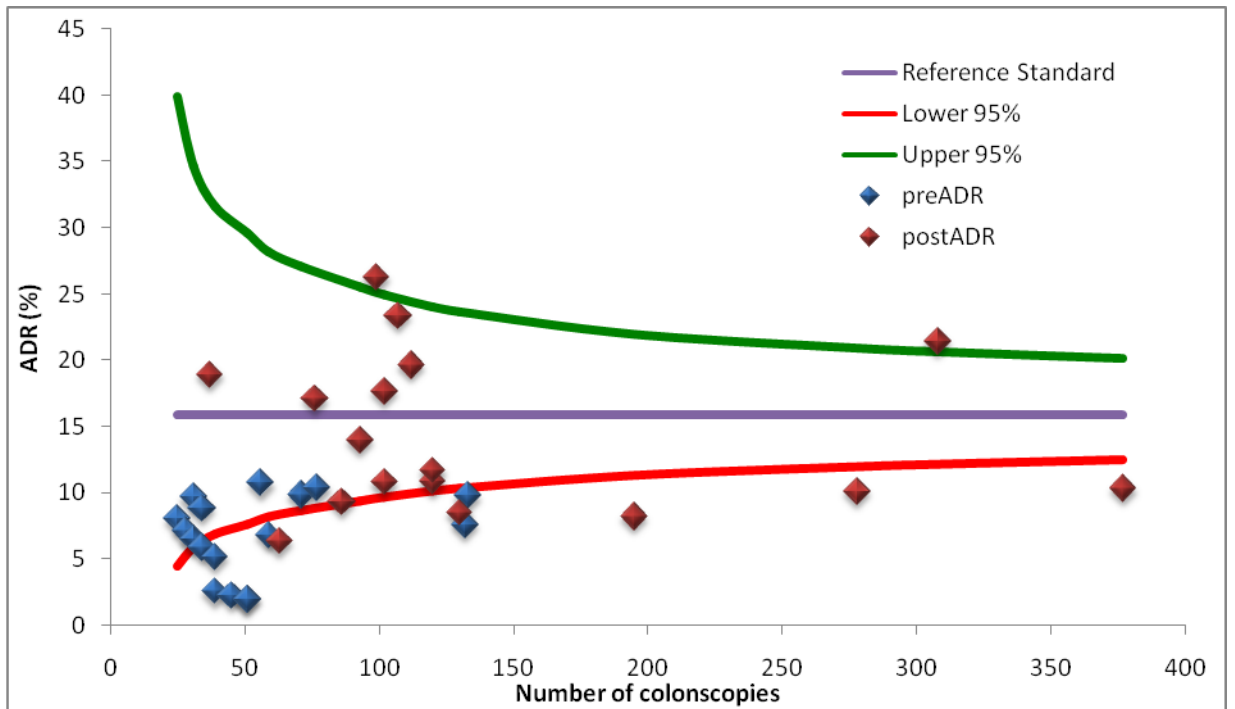


Figure 26: Funnel plot for the lower middle quartile.

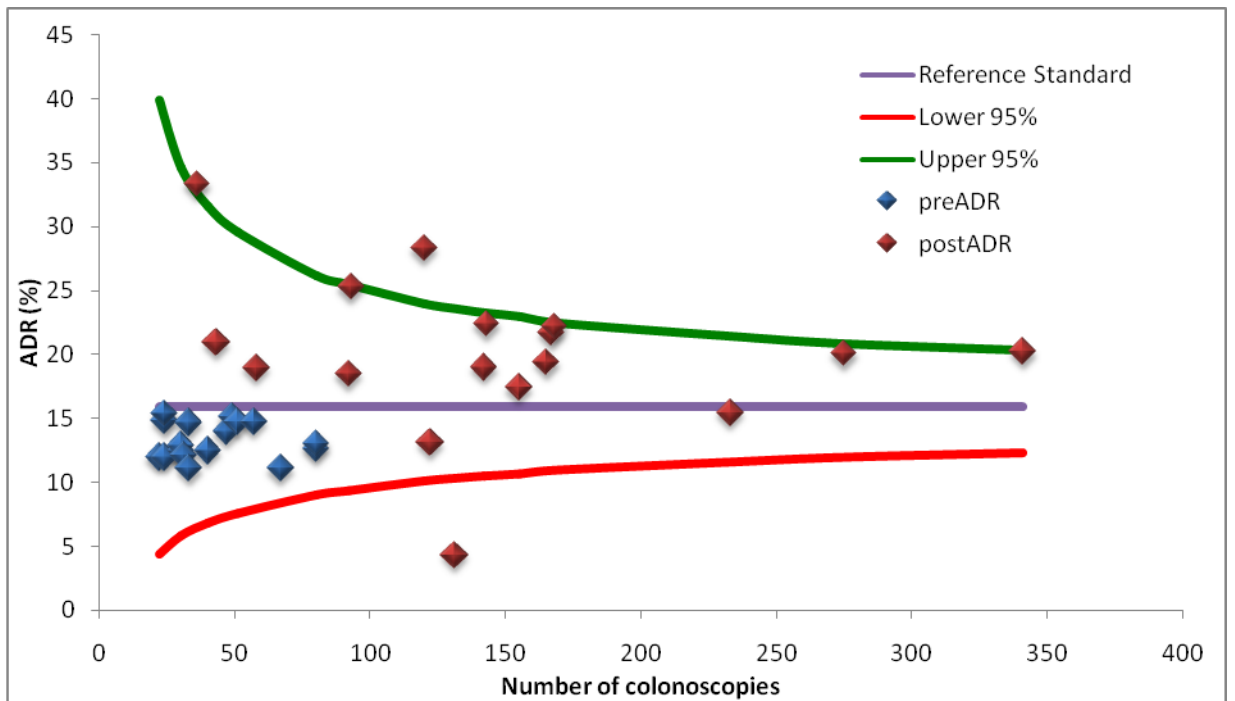


Figure 27: Funnel plot for the upper middle quartile.

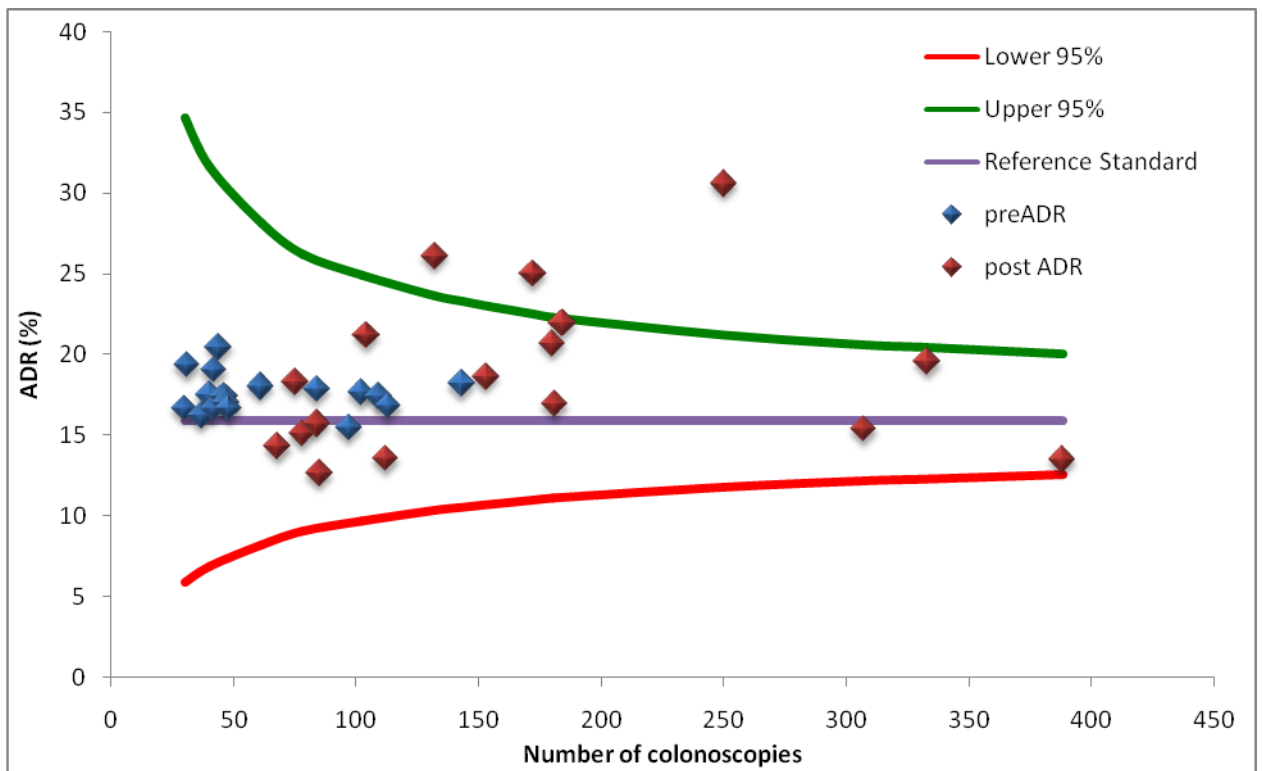
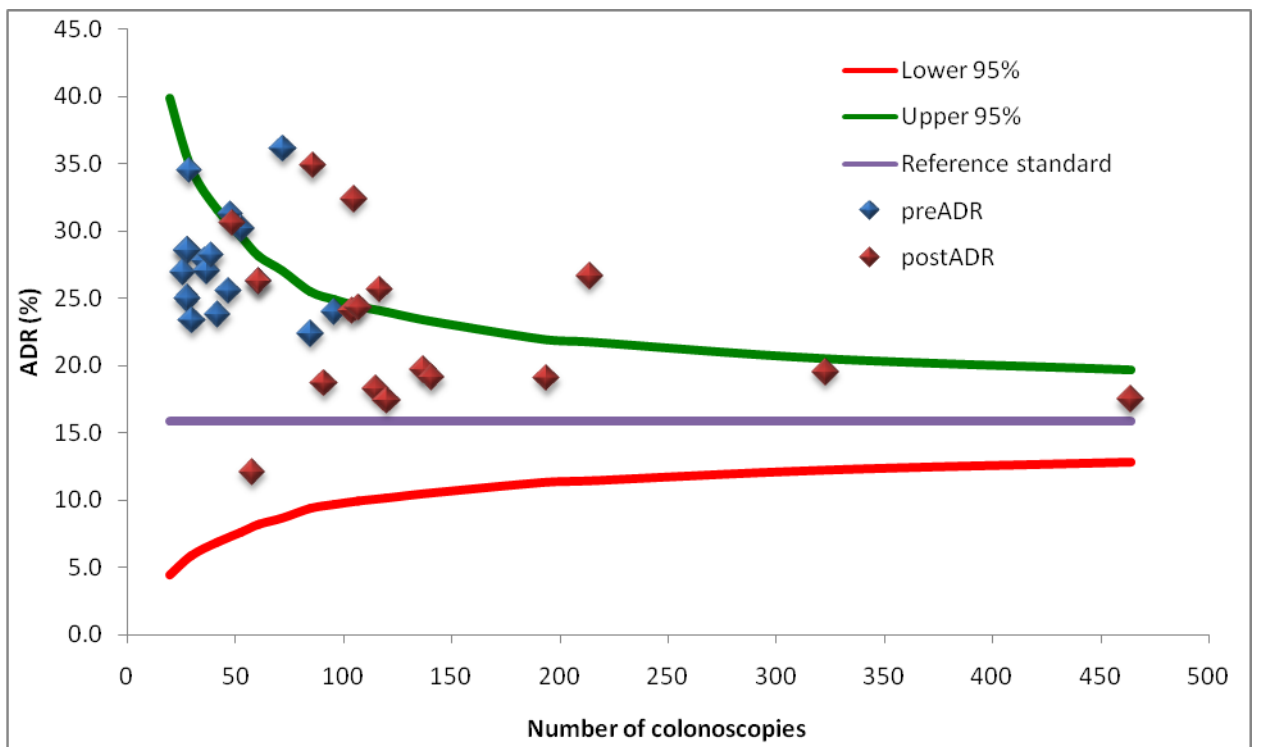


Figure 28: Funnel plot for the upper quartile.



5.3.5. Adverse events

The study team reviewed all adverse events documented by each participating unit as part of their GRS reports for the period after the study intervention. There were no adverse events that were attributable to use of the 'bundle' measures.

5.4. Discussion

We have shown in the previous chapter that the study intervention resulted in a significant increase in BR globally. This also resulted in a significant global increase in ADR (16.0 % vs. 18.1%).

All units demonstrated a significant increase in their BR with the proportion of colonoscopists per unit showing an increase ranging from 41.7% to 83.3%. Despite this level of adoption, only one unit demonstrated a significant increase in ADR. It is likely that the number of procedures performed within each unit is a major reason for the increase in ADR not achieving statistical significance. Another important consideration is that each unit is made up of colonoscopists whose performance varies greatly as indicated by the individual values of ADR. This is most evident on the unit level funnel plots and line graphs (Appendices L and M). The reason this is so important is that not all colonoscopists had the same potential or room to improve. Colonoscopists achieving the highest ADRs had much less chance of improving further as the ADR is limited by the prevalence of adenomas in the population being colonoscoped. Those who had been performing poorly had the greatest capacity for improvement. Any positive movement observed

among those performing poorly at baseline may be counter balanced by a lack of significant movement or a slight fall in those performing well at baseline. This concept is clearly illustrated in the line graphs summarising movement in ADR between the before and after periods and also in the quartile data as discussed below.

Among the 118 colonoscopists whose data were included in our analyses, at least 61.0% were judged to have changed practice in line with the aims of the improvement bundle as evidenced by a significant increase in their BR. In terms of how this affected their ADR, analysis of results has to take into account common cause variation. The numbers required to do this for individual colonoscopists is large as presented earlier in this chapter. The number of procedures performed by some colonoscopist was very low, especially during the baseline period. Despite this, five colonoscopists (4.2%) did exhibit a significant increase in ADR. Although the majority of colonoscopists performed too few examinations to allow a statistically significant result to be demonstrated at the level of the individual, the use of funnel plots did allow visual comparison relative to the selected reference standard of 15.9% (the baseline mean prior to application of the inclusion/exclusion criteria for comparative analyses). There were more colonoscopists above the upper 95% limit but also more below the lower 95% limit than prior to implementation of the improvement bundle. We must appreciate, as highlighted in chapter two, that each colonoscopist's ADR has its own 95% CI that may cross the limits of the funnel plot. However, the movement observed may indicate that, whilst a statistically significant

improvement was not demonstrated, there was a genuine improvement in ADR at colonoscopist level following the intervention. The graphs do also highlight that there continued to be some poorly performing colonoscopists that must be addressed. Finally, we must also remember that quality assurance is a continuous process and that ongoing monitoring is required to ensure positive changes continue and high performers maintain their standards.

Quality improvement programmes are tasked with improving overall quality, although those who are under performing clearly have the most room for improvement. When quartiles were constructed by ranking colonoscopists according to their baseline ADR and cumulating their results, the outcomes were very interesting. A significant increase in BR was seen within all four quartiles suggesting a good uptake amongst all. A significant improvement in ADR was seen in the lower two quartiles as might be anticipated if the uptake of the bundle was successful. However, there was also an increase in ADR in the upper middle quartile, which failed to reach statistical significance for the numbers studied. In the upper quartile, the ADR fell significantly to 21.5%. This value remained above the ADR for the remaining quartiles and the global mean following the intervention (18.1%). Furthermore, the ADR of the upper quartile both before and after implementation was above 20%, the value below which Kaminski's data suggested a higher rate of interval cancer and also the criteria for entry to be eligible to participate in most screening programmes. (7, 25) This suggests that quality within the upper quartile was still very high. Importantly, there was also a reduction in variation in ADR

observed before the intervention with only the lower quartile remaining significantly different from the others.

The data for the quartiles were the cumulative results of the colonoscopists within each group. This method provides useful information regarding the general movement of each group but does not take into account the variation of each of the colonoscopists within it. Analysing the funnel plots for each quartile, in conjunction with the cumulative data, provides additional information. For the upper quartile, the funnel plot for the group shows that the movement was within the funnel with no colonoscopists falling below the lower limit. Examination of the remaining quartiles shows that there are more colonoscopists above the upper 95% limit following the intervention for each quartile. In the lower quartile, there were also fewer colonoscopists below the lower 95% limit. In the lower middle quartile, one colonoscopist fell below the lower 95% limit.

When taken together, analysis of the cumulative data and the funnel plots demonstrate an improvement in ADR for the lower two quartiles resulting in a reduction in the variation observed before the intervention. The fall in the ADR within the upper quartile was not clinically significant as the rate remained well above the baseline and post-intervention means, the 20% criteria for screening colonoscopists and that suggested by Kaminski et al and all remained above the lower 95% confidence limit. The small number of colonoscopists who remain below the lower 95% limit should now be identified

confidentially and helped to improve their performance in order to improve patient care.

The global increase in ADR was 2.1% the clinical significance of which can be debated. In a recent study, the association between a colonoscopists ADR and subsequent CRC risk and cancer-related death was evaluated by Corley et al. (74) This study demonstrated that a 1% increase in ADR may lead to a 3% decreased risk of interval CRC. This suggests that even a small increase in ADR may be clinically significant. It must again be emphasised that the 2.1% improvement observed is a cumulative global improvement that, if considered in isolation, underestimates more significant changes amongst colonoscopist sub-groups. This is clearly observed when examining the quartile level data as described above. For those colonoscopists with below average ADRs, the improvements were in the region of 6% and so it is this group where patients are likely to benefit most.

Another consideration when evaluating the effect of our bundle on ADR at all levels is that, whilst the measures in our 'bundle' provide the optimal conditions for adenomas present to be detected, the colonoscopists own withdrawal technique and diligence towards adenoma detection must still ultimately be relied upon as has been previously demonstrated. (31, 32) Training on optimal examination technique was outside the remit of this study primarily due to the time required. This is one area that could be addressed among colonoscopists that continue to fall below national requirements.

Regarding the values for ADR observed in this study we must remember that this was a general symptomatic population with all NHS BCSP patients, in whom the prevalence of adenomas is much higher, excluded. The recent British Society of Gastroenterology (BSG) UK colonoscopy audit revealed the global PDR to be 32.1% which is likely to translate to an ADR of approximately 20%. (75) Another large UK study, as discussed in chapter 2, reported a global ADR of 19.2%. (46) Both studies included data from BCSP patients. It is, therefore, probable that a mean ADR of approximately 18% is reasonable to expect for a UK symptomatic population at present. We should, none the less, aspire to improve upon this in the near future especially given the mean age of patients colonoscoped by the majority of colonoscopists in this study.

The results of this and other studies further highlight the differences in ADR between the symptomatic and screening populations. Lee et al reported the results from the first 3 years of the NHS BCSP revealing a mean ADR per colonoscopist of 46.5% (range 21.9% to 59.8%). (8, 38) There are several possible reasons for this including the prevalence of adenomas within this population selected by positive FOB testing and the structure of the screening programme and lists. (8) It is also possible that BCSP colonoscopists, through increased exposure, may become more skilled at detecting small adenomas. Whilst it would have been difficult to evaluate accurately within this study due to the number of other variables, it would be useful to compare differences in performance of BSCP and non-BCSP colonoscopists within a similar symptomatic population in future work to better understand potential

differences in colonoscopy technique that could, if present, be incorporated into future quality improvement initiatives.

Colonoscopy performance in the UK has improved significantly over the last 10 years largely through improvements in completion rates and sedation practice. Despite this the incidence of CRC has not changed significantly. (76) Whilst improvements in ADR and PDR have occurred, there continues to be considerable variation in this performance metric and thereby mucosal evaluation. This is demonstrated clearly in our baseline data in Chapter 2, and whilst our intervention reduced variation in ADR, there continues to be a proportion of colonoscopists whose ADR is well below average. This is one factor explaining why there has not been a change in CRC incidence despite improvements in CIR. Other factors include the continued variability in detection of sessile lesions, particularly sessile serrated adenomas, and a relatively recent paradigm shift in their management. (77-79) Another problem relates to the high proportion of patients with poor bowel preparation. (75) The results of this study suggest that our intervention may help to reduce variation in ADRs, however, further work is required to ensure all colonoscopists achieve and maintain acceptable ADRs and to address the other factors discussed.

In summary, a significant increase in ADR was observed globally. The ADR among the lower two quartiles significantly improved and this resulted in a significant reduction in the variation observed prior to the intervention suggesting an improvement in colonoscopy quality. It is also important to re-

iterate that the intervention in this study was multi-faceted including an educational visit, use of the 'bundle' measures and feedback. The potential contributions and influence of these factors have been discussed in chapter 4 and will be debated further in the remaining chapters.

Chapter Six: Factors Influencing Uptake of Evidence – A

Qualitative Evaluation

Chapter Six: Factors Influencing Uptake of Evidence – A Qualitative Evaluation

6.1. Introduction

Although evidence based practice is widely recommended, the introduction of evidence into clinical practice can be challenging. (80) Implementation models are often ill conceived and non-evidence based. (55) Traditional methods optimistically relied upon passive diffusion of published research and guidelines, assuming that clinicians would read and integrate new evidence into their practice with relatively little prompting. Whilst more active models have been adopted more recently, their impact is still variable. (57) Reasons include a failure to recognise and address common barriers to implementation. (55) For this study, the identification of barriers and facilitators to implementation was performed during the development phase of our model. Despite uptake being good, it was not universal.

Identifying factors that facilitate or constrain uptake of evidence into clinical practice is vital to allow a greater understanding of which components of a given implementation model are most useful. In order to identify such factors present during the QIC study, a qualitative interview evaluation was performed with members of the endoscopy units who participated to explore experiences of introducing innovative practice in a routine clinical setting.

6.2. Methods

The qualitative evaluation was conducted following completion of the clinical study. Semi-structured, face to face interviews were carried out with study

leads, colonoscopists and endoscopy nurses, in a purposive sample of the units taking part in the study. This enabled issues to be examined from differing perspectives and to explore how innovation and change filters through organisations, altering during that process from the original intention.

Units were purposively sampled to ensure that those with the biggest and smallest changes in ADR (using preliminary data from the feedback provided at four to six months) were included. A big change was defined as a difference in ADR of $\geq 2.5\%$. Units doing a large number of colonoscopies and those doing fewer were also sampled, to explore whether issues such as workload and familiarity with new procedures influence the success or otherwise of uptake of the bundle.

Interviews took place in the workplace but in an office away from other members of staff to enable confidentiality to be maintained. The interviews were recorded, with the consent of the interviewees, and later fully transcribed. All interviews were conducted within six months of completion of the clinical arm of the study to reduce recall bias and were continued until saturation had been reached. Interviews were conducted by a member of the qualitative evaluation team (Dr Cath Nixon) who had not been part of the QIC implementation team. This was in order to reduce bias that may have been introduced had a member of the original team conducted the interviews. The structure of the interview was based on the “theoretical domains interview” developed by Michie et al and further developed by Francis et al. (81, 82) Interviews explored how the training was organised and delivered, who

attended and how those who could not attend the training sessions were instructed in the bundle. Variations in the use of the bundle included whether feedback was given, as well as why and how feedback about performance influenced the individual colonoscopist.

Thematic analysis was used to code and categorise the interviews, and to develop a framework for analysis. Two members of the study team (Dr Sally Brown and I) analysed a proportion of transcripts independently and agreed upon the framework. I subsequently used the agreed framework to re-analyse the initial and remaining transcripts. The themes identified were: time; study promotion; training; engagement; positive outcomes; modifications.

Study Registration

The qualitative evaluation was registered at all participating units through the audit or research and development departments as required.

Ethical Approval

Ethical approval for the qualitative evaluation was granted following review by the Durham University School of Medicine, Pharmacy and Health Research Ethics Committee (Appendix N).

6.3. Results

A total of eleven participants in the QIC study agreed to be interviewed. There were seven lead colonoscopists, one lead nurse and three colonoscopists that were not leads. There were six participants from larger units and five from

smaller units. Five colonoscopists were from units in which a large change in ADR was observed and six from units in which smaller changes were seen. All interviews were concluded by approximately six months after completion of the quantitative arm of the study. Quotations from interviewees are labelled with their QIC code and their role within the study. Therefore, QIC 01/lead colonoscopist is for QIC 01 who was a lead colonoscopist within the study.

Time

Time had been identified as a potential barrier to uptake during development of the implementation model. This was confirmed during this evaluation. It was reported that time pressures led to difficulty finding a suitable time and forum for local training sessions leading to limited attendance in some units. This necessitated multiple visits when feasible. The fact that there were multiple opportunities to attend the training was reported positively, however, this approach is less likely to be feasible outside the setting of this study.

“it is difficult in the NHS to get everyone into one room” (QIC128/lead colonoscopist)

“I think having multi-choice access to training is always a good idea because, you know, you can’t guarantee everyone is going to be in one place at one time” (QIC118/colonoscopist, non-lead)

Time was also a factor when implementing the ‘bundle’ into colonoscopy practice. It was reported that this was given as a reason for non-engagement

by some colonoscopists. However, this appeared not to be reflected in practice as it was reported that endoscopy lists continued to run to time during the study. The simple nature of the 'bundle' was also reported as a reason for engagement.

"I don't think we've seen any sort of unintended consequences of the study. I don't think we saw the lists fall apart or that the patients were being disadvantaged in any way" **(QIC111/lead colonoscopist)**

"if it had taken, if it involved a lot of input from me I would have been less inclined to take part" **(QIC125/colonoscopist, non-lead)**

Study Promotion

Leads for the study appeared to embrace their role in promoting and engaging colonoscopists within the study. Several methods were used, including regular e-mails, face to face meetings and using forums such as directorate meetings. A novel approach was used by one lead who took the opportunity to promote the study during the local approvals process required to erect posters in clinical areas. Leads also found the monthly e-mail contact from the study team helpful. It was also apparent that non-lead colonoscopists also became involved in study promotion indicating wider spread enthusiasm for the project.

“following his sort of one hour training presentation to us we discussed it locally within our unit and our, we have a two monthly endoscopy user group meetings” (QIC01/lead colonoscopist)

“it was just making people aware of it and then reinforcing”

(QIC118/colonoscopist, non-lead)

It was reported by two lead colonoscopists that there was some confusion over the level of promotion that they were required to undertake, their concern being that this could interfere with the results of the study. This is certainly one area in which delivery of the central training could have been improved.

“Yes yes, I guess the level of ongoing input cajoling and so on wasn't, I wasn't that clear, I didn't want to interfere too much, you know”

(QIC43/lead colonoscopist)

Endoscopy nurses were identified early on as potential facilitators for uptake of the 'bundle' and efforts were made to engage and empower them to promote the study before its commencement. This appeared to bear fruit as it was consistently reported that the endoscopy nurses did actively promote the study. This included referring to the study poster, ensuring Buscopan was readily available and reminding colonoscopists when it was due to be given. Nurses also took it upon themselves to warn patients that rectal retroflexion was about to be performed thereby reminding the colonoscopists as well. This

was an important finding of this evaluation and provides powerful evidence regarding how change within an endoscopy unit can be achieved.

“quite often now when I get to the caecum the nurse will say ‘Do you want to give Buscopan?’ so you know the nurses are prompting us”

(QIC43/lead colonoscopist)

The study posters were also reported to be very useful in reminding colonoscopists to use the ‘bundle’. The design was described as simple and high impact and also provided a method that endoscopy nurses could use to promote the study.

“I think the biggest thing to help that was the big posters on the wall saying for the QIC study please remember” **(QIC122/lead**

colonoscopist)

Training

It was also recognised that training should be short and study documents simple in order to maximise engagement. The local training sessions were felt to have been delivered well and the PowerPoint presentation appropriate. The study documents were also reported have been the suitable.

“I mean the slides were well made so it was quite easy to understand and for the main training that (PTR) delivered I think it was quite good

because there was time to ask questions so we did manage to sort of ask questions” (QIC128/lead colonoscopist)

Some colonoscopists were not keen to perform rectal retroflexion for reasons including the potential for discomfort for the patient and that it can be a difficult to perform the manoeuvre if unfamiliar with the technique. The training included a video demonstration of how to perform retroflexion. However, there was no provision for ‘hands on’ training either during or following local training sessions. This draws attention to the need to consider training when implementing evidence into clinical practice.

Whilst the training sessions were felt to have been well conducted, it was suggested that a research fellow may not have been a ‘big draw’ for those who may have been less engaged to begin with. In contrast, it was reported that units in which the research fellow had previously worked and developed good relationships may have been more engaged for this reason. It was also suggested that the training for the endoscopy nurses could have been performed by a clinical nurse or sister. These data suggest that consideration should be given to who delivers the teaching to different subgroups.

“I think that nursing staff probably like a clinical nurse or a clinical sister or an endoscopy nurse consultant to come and do the training... the feeling they get when a consultant comes along is it’s a job to be done and it is going to be put on to us we have got no choice, we have to do

it and that's somewhat the wrong kind of way to do it.” (QIC128/lead colonoscopist)

Engagement

Engagement was good but not universal. Generally, uptake among gastroenterologists and nurse endoscopists was reported as good, however, was less so among surgical colonoscopists. It was also reported that more junior colonoscopists and trainees were more engaged with the study.

The study promotion, as discussed above, was an important factor in encouraging engagement, as was the simple nature of the 'bundle'. Other reasons included the fact that the study had been conceived by leaders in the field of colonoscopy.

“I guess the fact that the trial was developed in conjunction with, you know, some of the national experts in colonoscopy, helped”

(QIC111/lead colonoscopist)

It was also reported that the longer the 'bundle' was used, the more it became embedded into practice.

“and I think because the study's gone on for so long- like for a year, it's kind of embedded those things into practice... and the more you do it, the more it becomes a routine and you know it just sticks”

(QIC122/lead colonoscopist)

The feedback provided was thought to very useful. In one unit, it was reported that some of the surgical colonoscopists who were sceptical, engaged more with the study following the feedback demonstrating that their unit had improved.

“surgeons found it very interesting that these kind of things make a difference” (QIC23/lead colonoscopist)

The colonoscopists interviewed reported a change in their own practice. In particular, an increased awareness of withdrawal time was highlighted. The use of Buscopan also increased. One lead commented that they were now more attentive to the detection of small polyps as the training had highlighted the importance of this as a quality marker.

“For me I think it’s probably just made me think about it more... and the six minute withdrawal, well I never timed myself to be honest so I am a bit more conscious about that” (QIC55/colonoscopist, non-lead)

I have been more cognizant of the fact that it matters to detect small polyps” (QIC102/lead colonoscopist)

There were several reasons suggested for poor engagement. These included scepticism over whether the ‘bundle’ in its entirety would increase ADR and also the value of certain components of the ‘bundle’. As discussed above, the

potential for retroflexion to cause patient discomfort and inexperience with the manoeuvre were also reasons.

“the Buscopan was the one where a lot of people weren’t convinced it was going to add to polyp detection but most of them were probably surgeons” (QIC128/lead colonoscopist)

Specifically regarding surgeons, reasons stated for possible poor engagement included general reluctance to consider changing their practice, being less reflective in their practice and their perception that the ‘bundle’ would only lead to increased detection of small, less clinically significant lesions. The significance of ADR as a marker of a thorough colonoscopic assessment and the clinical significance of an individual adenoma was discussed during local training, however, this comment suggests it was incompletely understood. It was also suggested that surgeons may consider colonoscopy less of a priority than physicians due to their other commitments.

“I think we’ve got certain people who are not reflective in their practice and so would not see the benefit in it to them of changing”

(QIC111/lead colonoscopist)

“I sort of look at it as they’ve (surgeons) got bigger fish to fry in their minds” (QIC01/lead colonoscopist)

Positive outcomes

There were several positive outcomes described. The general increased awareness of quality in colonoscopy within the whole endoscopy unit was a major positive. This included the involvement and empowerment of the endoscopy nurses in promoting the use of quality measures and more closely observing procedures. This also highlights how change filters through an endoscopy unit. The success of the implementation model itself was seen as the most interesting outcome by one lead.

“I mean when the whole unit is aware that these things make a difference” (QIC23/lead colonoscopist)

“I think for me is the proof of concept almost, the, for me the most positive thing was that across the region we had individuals who were willing to embrace this and to try and disseminate this information, and we followed it through and we were all agreed” (QIC43/lead colonoscopist)

The challenge of engaging certain specialties in the study was regarded as a positive outcome by one lead colonoscopist who stated that this prompted the whole unit to consider how they should approach similar issues in the future. Whilst this wasn't an aim of the study, it was an interesting additional outcome.

“it shone a light really on to working out how we deal with situations where people aren’t willing to take on new agendas or quality markers and what our response to that should be” (QIC111/lead colonoscopist)

Modifications

The interviewees were also asked their thoughts on how the implementation process used in QIC study could have been improved. One challenge was the limited attendance at set up meetings. Suggestions to improve attendance was to attach sessions to other well attended meetings, especially surgical directorate meetings, and consideration of making such initiatives mandatory although a note of caution was also added to this suggestion on the grounds that it had the potential to antagonise.

“we could make those mandatory, I mean it’s just difficult because at the moment with all of the service pressure stuff...you’ve got to be quite careful about doing is making too many things mandatory that turn people off” (QIC01/lead colonoscopist)

It was also suggested that a well known speaker may encourage attendance at local training sessions particularly in groups that may have been less likely to engage with the study.

The interviewees were from units of varied size and that had demonstrated varying levels of change in ADR during the initial feedback sessions. There

appeared to be no discernable differences in positive or negative aspects of implementation by size of unit or level of engagement, with the themes identified being consistent among all participants in this evaluation.

6.4. Discussion

Successful implementation of evidence of into clinical practice requires identifying and overcoming barriers to implementation. (55) An endoscopy unit is a complex system with many interacting components that can influence the running of a list and can, as a result, effect adenoma detection. Factors can be patient related or organisational. Therefore, interventions may have unexpected influences outside of the intent of the project and, as a result, unintended effects that cannot be anticipated or measured.

The implementation model utilised in this study was multi-faceted, selected as similar models have been shown to be successful in other clinical settings. (64) It is also natural to ask which components of the intervention produced the changes in ADR observed? This is of particular relevance if there are plans to replicate this model of implementation. For example, if we simply asked all UK colonoscopists to use the measures in the 'bundle', would this produce the same results observed in this study?

The time pressures within endoscopy units were identified as a potential barrier to implementation and this appeared to be the case in practice as evidenced by limited attendance at local training sessions with time pressure given as a likely reason. The comments regarding how the 'bundle' may

prolong procedure time (whilst this was not the case in practice) also support this concept. Suggested solutions included associating sessions with other well attended meetings, making them mandatory or inviting well known speakers to present.

In the context of the QIC study it would not have been possible to make use of the 'bundle' mandatory. However, ensuring that the medical directors were aware that a large scale quality improvement programme was underway in the trust was also one method used to encourage uptake. Associating training sessions with other meeting is certainly one method that should be considered for future initiatives. The use of a more senior member of the study team to lead local training sessions was discussed during design of the implementation model although this would not be logistically possible given the number of sessions that would be required. This strategy could be considered in other settings, however, it is likely that the same logistical challenges would apply. The fact that multiple sessions were conducted at some units was described as a positive feature but again this approach is unlikely to be feasible outside of the setting of a study.

It had also been predicted that surgical colonoscopists might engage poorly with the study, which was perceived to be the case in all units. It appeared that this was not adequately addressed during implementation of the 'bundle'. One reason for this was that the QIC study was designed to be pragmatic. A more complex implementation model, such as surgeons presenting to

surgeons, may have increased general uptake, but would have been less reproducible in routine endoscopy practice.

It was also reported that junior colonoscopists appeared to be more engaged with the study than more experienced staff. This concept has also been reported previously. (63) It is possible that a better known speaker may have more gravitas with more senior staff - another reason for considering this approach where feasible.

It has been reported that complex interventions are less likely to be integrated into clinical practice. (57, 60) This is supported by the findings of this study where the simple nature of the 'bundle' was easily integrated into colonoscopy practice encouraging uptake. Interestingly, it was reported that continued use of the 'bundle' led to it becoming embedded in routine practice and almost second nature. This, in part, is also likely to be as a result of the simple nature of the 'bundle' and continued study promotion.

It was reported that the potential discomfort caused by rectal retroflexion was a concern. The ideal technique that should be used to perform retroflexion was covered during the local training sessions and in the study DVD. There was, however, no provision for additional 'hands on' training for colonoscopists that were remained uncomfortable performing the manoeuvre. This is a negative aspect of shorter training sessions. Whilst additional training would not have been possible in the context of this study, this does draw

attention to the fact that adequate steps to ensure training for those that may require it, should be given some consideration in future initiatives.

Study promotion was well conducted with several methods utilised such as e-mails, face to face meetings and discussion at directorate meetings, successfully engaging the majority of colonoscopists. It is known that guidelines that are visible are more likely to be used. (63) The findings of this study support this with the highly visible posters described as a major factor promoting uptake.

It was recognised during study development that the endoscopy nurses were potential facilitators for uptake and this also proved to be the case with the role of the endoscopy nurses in study promotion consistently reported as a positive outcome. It was also suggested that, had a clinical sister delivered the training, it may have further enhanced engagement among endoscopy nurses. This highlights the importance of identifying facilitators for implementation and also those who should deliver training sessions.

The study was conceived and developed by colonoscopists who are considered leaders in the field. This was reported as a factor that would have positively influenced engagement. The use of opinion leaders is a strategy that has been shown to positively influence professional behaviour and is supported by our findings. (83)

Feedback and knowledge of peer performance is known to improve performance in a variety of settings. (84) This was confirmed by the findings of this study with feedback reported to be an important aspect of the implementation model. Furthermore, colonoscopists that were sceptical about the study were felt to have been engaged by the feedback provided.

A major positive outcome of the initiative was to successfully raise awareness of the importance of quality in colonoscopy in endoscopy units as a whole through the inclusive nature of the implementation model. This included empowering endoscopy nurses to encourage the use of quality measures. Inclusivity has been shown to improve uptake of protocols and guidelines and is very likely to have contributed to success of this study. (63) A positive outcome that was not envisaged was highlighting methods to engage sceptical individuals. This demonstrates the importance of analysing the results of implementation models, as unpredicted outcomes can result and these may be useful in other settings.

One factor that may have contributed to poor engagement was the scepticism as to whether the 'bundle' would significantly increase ADR. The concept behind this study included the thought that, whilst each measure in isolation may have produced a small effect, their use in combination may produce a more pronounced effect. Whilst doubts regarding this are valid, we must consider that this was a study to test a hypothesis rather than a categorical statement that the 'bundle' would definitely improve ADR.

The themes that emerged were consistent throughout all participants. There appeared to be no differences in themes when considering units by size or change in ADR. This suggests that the findings of this evaluation will be generalisable to the majority of endoscopy units.

A limitation of this work is that the majority of interviewees were lead colonoscopists or nurses who were more likely to have been engaged with the study. Furthermore, all but one were medical colonoscopists with only one surgical colonoscopist interviewed. This potential for bias must be borne in mind in particular when considering opinions regarding the challenges of engaging surgeons. It must be added that repeated attempts were made to contact and arrange interviews with clinicians who had been less enthusiastic about implementing the initiative to better understand reasons for non-engagement, however it was not possible to secure an interview. This is a common challenge faced in qualitative research and is a difficult problem to solve.

In summary, several factors are likely to have influenced the changes in ADR observed in the study outside of the measures within the 'bundle'. This is important to appreciate in any attempt to replicate the intervention. The experience of the QIC study suggests that interventions should be simple, supported by good, inclusive, local promotion and should include feedback. Identifying facilitators to implementation is crucial and can significantly influence engagement. Strategies to engage groups less likely to participate

should be developed at the outset of the implementation process. Provision for additional training, where feasible, should also be given consideration.

Chapter Seven: Summary, limitations, key findings and future work

Chapter Seven: Summary, limitations, key findings and future work

7.1. Thesis Summary

Chapter one discusses the current prevalence of colorectal cancer (CRC) and the resulting morbidity and mortality. It summarises current knowledge that the majority of sporadic CRCs develop from adenomas and that their detection and removal at colonoscopy can significantly reduce the incidence of CRC. The variability in colonoscopy quality is demonstrated in terms of adenoma detection and also how missing such lesions may expose patients to increased risk of interval cancer. The conclusion is that the quality of colonoscopy needs to improve forming the premise upon which this service improvement study is based.

Chapter two discusses the setting in which the QIC study took place, the Northern Region Endoscopy Group (NREG), and the reasons it was selected. The performance during the baseline period (three month period before the study intervention) was analysed in detail. The results showed that the caecal intubation rates (CIR) were of an acceptable standard but that there was an unacceptable variation in adenoma detection rate (ADR). Furthermore, the current 10% standard for ADR suggested by the British Society of Gastroenterology (BSG) is too low and if used as a reference standard for this study would result in inappropriate analyses and conclusions. The mean ADR of 15.9% observed during the baseline period was felt to be a much more appropriate reference standard. These data confirm that there is room to improve ADR within NREG and also that the national standard for ADR should be increased to at least 15%.

In chapter three, methods of improving adenoma detection are discussed. The challenges of implementing evidence into clinical practice are also reviewed, including methods of how barriers can be overcome. An example of an implementation model that succeeded in improving central line management in an intensive care setting is presented (Pronovost et al). Having demonstrated unacceptable variation in ADR, the hypothesis presented in this chapter is that implementation of the measures discussed could be feasible and result in an increase in ADR using a similar model to Pronovost's group

Chapter four outlines how the model of implementation was designed taking into account the factors discussed in the preceding chapter. All facets of the implementation model are discussed in detail including additions that were made after potential barriers were identified. The changes in practice following the intervention are presented, demonstrating a good uptake at the level of the individual colonoscopist, endoscopy unit and across the whole of Northern Region. The results are compared to other studies in which educational interventions were utilised. Limitations including use of a surrogate marker for uptake are discussed. The results indicate that the intervention utilised in the QIC study resulted in a significant change in clinical practice for the majority (but not all) of the colonoscopists in the study. Compared with the results of studies utilising similar models of implementation, we can describe the uptake of the measures as "good".

In chapter five, the effect of the change in practice on ADR are presented and discussed. There was limited change observed at the level of the colonoscopist and unit, the probable reasons for which are discussed. Importantly, a significant improvement was observed in the lower two quartiles resulting in a significant reduction in variation after the intervention. The fall observed in the upper quartile is discussed and how and why this is unlikely to represent a clinically significant fall. Limitations are discussed, including low procedure numbers in the individual and unit level analyses. We conclude that the intervention (educational visit, 'bundle' measures, promotion and feedback) may be particularly useful among colonoscopists whose ADR is below the baseline mean of 15.9% and could reduce variation. Further controlled studies required to confirm these findings.

Chapter six explores factors that facilitated and constrained implementation of the 'bundle' into clinical practice. Colonoscopists and endoscopy nurses that took part in the QIC study were invited to participate in semi-structured interviews that were utilised to collect the data that was evaluated using thematic analysis. Positive themes included the general increased awareness of quality in colonoscopy throughout units, the positive influence of endoscopy nurses in promoting quality measures, the usefulness of the simple study poster and the importance of feedback. Challenges included restricted time within the NHS for meetings and during endoscopy lists and engaging surgical colonoscopists. The results highlighted the importance of developing strategies to engage such groups at the outset of any quality improvement interventions. This also highlight that factors outside use of the 'bundle' are

likely to have influenced the changes observed and must be considered if wider roll out is to be considered.

7.2. Limitations of the study

All studies have limitations that are important to consider when interpreting results. The possible implications for the observations in this study will be discussed and also why certain limitations had to be accepted for this particular project.

7.2.1. Study design and other factors

The QIC study was intended to be a large scale, pragmatic service improvement study aiming to encourage evidenced-based best colonoscopy practice as routine thereby improving overall quality. The hypothesis was that if measures to increase mucosal visualisation could be incorporated into routine colonoscopy practice, then following on from this, more adenomas would be detected compared to if no intervention had occurred. Introduction of the 'bundle' was supported by an educational visit, promotion and feedback. Service improvement work involves introducing change into complex, 'real world' settings or systems, often with minimal resources. As a result, interventions must be simple, cause minimal disruption to existing systems and, importantly, be both time and cost effective. (63) An overly complicated or complex intervention runs the risk of not being adopted during the study phase and if wider implementation is required. Service improvement work must, therefore, often take a pragmatic approach. Furthermore, such projects must be continuous, often iterative processes. A benefit of this type of work is

that it is potentially more widely reproducible in contrast to more tightly controlled research studies. A limitation is that the often numerous variables, particularly in multi-centre studies, can make interpretation of results challenging.

In our study we did not randomise which units underwent the intervention nor did we have a control group. When deciding upon our methodology, the use of a randomised control design was considered. Prior to this, the study had been classified as a service improvement project in which all units would receive the intervention as the measures are considered by many to be best practice. As such, our local research ethics committee chairman had stated we did not need ethical approval to perform the study. For this pragmatic reason, we were unable to stipulate that some units would not receive the intervention without invalidating this statement. An alternative that was considered was to use a randomised stepped approach to implementation. This has the advantage of providing some units who would not have undergone the training to act as controls. This approach would also have provided a few challenges. Firstly, units entering later in the study would have less exposure to it resulting in fewer procedure numbers during this stage. This would have further reduced the power to detect a significant change, particularly in ADR, as has been discussed. Secondly, some units that work independently are actually part of the same NHS trust. This would have proved a logistical difficulty to the implementation process, as there would have been a risk of units becoming aware of the components of the intervention 'bundle' prior to training should units within the same trust be

randomised to receive training during different phases. This would have made data analysis difficult. Another major difficulty would have been selecting the level at which randomisation should take place. Ideally, this should be at the level of the colonoscopist in order to provide groups with similar baseline characteristics such as experience and baseline ADR. This is likely to have resulted in some colonoscopists within a unit receiving the intervention whilst others were not. Maintaining blinding of the control group and the quality of study promotion in this setting would have been very challenging as it would have required endoscopy nurses to differentiate colonoscopists that were in the intervention group from the controls and also for the study posters to be removed and replaced between lists. The increased complexity of this methodological type is likely to have limited enthusiasm for the study. Controlling at the level of the unit would have been logistically simpler, however, would present other problems such as the heterogeneity of colonoscopist's performance, variable uptake and differing number of procedures that each would contribute to the total, a difficulty we faced even with our more simple study design. This could result in the difference between the intervention and control groups being inconsistent. This would also have been difficult to estimate as our most robust marker of compliance (change in BR) is a surrogate, and does not provide us with information regarding use of the other components of the bundle.

When analysing any dataset, it is important to consider whether any changes observed could be as result of regression (or reversion) to the mean. Sir Francis Galton described this phenomenon in 1885 when studying, among

other areas, the relationships between parents and their children's heights. (85) He found that parents that were either very tall or very short tended to have children that were shorter or taller than them respectively. He proposed that the reason for these findings were that, as the parents' heights were at the extremes of a normal distribution, their children were statistically more likely to attain a height closer to the population mean. If we were to apply this concept to our dataset, we would expect the ADRs of those in the upper and lower quartiles to fall and improve respectively. We do see this effect within our dataset for quartiles, albeit the effect is not as dramatic as it may seem in the cumulative data when analysed using funnel plots. If we examine the results of the upper middle quartile, the baseline ADR of 17.5% is above the mean and might be expected to fall if reversion to the mean was the explanation for all results observed. It does, however, climb to 19.2%. Whilst this result is non-significant, it does add some weight to the argument that the study intervention did influence the changes in ADR observed albeit we cannot completely exclude regression to the mean as a contributing factor.

Changes in behaviour and improvement in performance can be seen when individuals are aware they are being more closely observed than usual. The term "the Hawthorne effect" is often used when describing this phenomenon. (86) It was first observed in the 1920-30's in a study of productivity performed at the Hawthorne Works, which produced electrical equipment, in the US state of Illinois. In this study, it was assumed that providing more light to the workers would improve productivity, however, it was found that productivity improved both in groups provided with more light and those that worked under

more limited lighting. Mayo, a member of the research team, felt that the input from the additional attention on workers afforded by the study team was the factor that had influenced behaviour. Since this description, others have attempted to refute the theory offering other explanations for the changes observed such as the feedback received by the workers on productivity that were not previously provided.

Despite the debate surrounding the Hawthorne effect, the term has been extended to other areas including medical research. McCarney et al demonstrated the effect in their RCT of Ginkgo biloba in the treatment of mild to moderate dementia. (87) Participants were also randomised to receive either intensive or minimal follow up. It was demonstrated that those in the intensive follow up arm had a significantly better cognitive function scores. Other studies have found less of an effect including that performed by Fernald et al in their quality improvement study on the management of skin and soft tissue infections (SSTIs) by family practitioners. (88) They found that the intensity of the intervention, in terms of amount of contact with the research team, had no significant effect on management of SSTIs.

Another potential influence on behaviour, as reported in our qualitative work in the previous chapter, is knowledge of peer performance. (84) This method of engagement was deliberately utilised during the feedback sessions in which preliminary data were presented including performance from other units. This appeared to have the desired effect as reported in the qualitative work. It is possible that presenting performance data from other units participating in the

study during the initial local training sessions may have increased uptake from the outset of the study. Unfortunately these data were not available during this study, however, this should be given serious consideration to aid uptake in future work.

The feedback provided in this study was anonymised and kept at unit level. It had been discussed whether we should provide colonoscopist and even named performance data. The study team felt anonymised, unit level was the most appropriate in the context of a study in which uptake was key as providing named data had the potential to antagonise and potentially lead to disengagement.

The use of performance tables in quality assurance and improvement is an interesting concept and one that does require further work through carefully designed studies that will allow the effect of such tables to be distinguished from other contributing factors. The use of performance tables, of course, is not without challenges. Firstly, it is important to present and interpret performance data appropriately. The potential problem of interpreting performance data from units performing variable procedure numbers is discussed in Chapter 2. Whilst the use of funnel plots helps adjust for this it does not take into account other variables. (89) Adjusting for all variables can be challenging as can separating factors intrinsic to an individuals or unit from extrinsic factors regarding which an organization may have little control. Other potential issues include the risk of gaming results to achieve targets both at the level of the colonoscopist and organization and over emphasis on

quantitative targets in order to avoid penalties including inappropriately stopping individuals performing colonoscopy rather than re-assessing or providing additional training. (90) Despite the above, the use of comparative results can be useful but must be used with care and sensitivity.

The study design options available within the time and resource constraints of this project were considered in detail and it was felt that our method of performing a pragmatic study using a simple before and after design for a designated period of time was the most likely to succeed. The implementation method was feasible and any clinical benefit could be measured relatively easily. We cannot completely exclude reversion to the mean or the Hawthorne effect having some influence on the results nor the contribution from feedback, an intentional component of the intervention to improve engagement. Therefore, the change in behaviour observed in this study is likely to have been as a result of the study intervention with a possible contribution from outside factors including the Hawthorne effect and regression to the mean.

7.2.2. Study Power

The limitation of the study imposed by low procedure numbers has been previously mentioned. This becomes a particular issue when analysing data at the level of the individual colonoscopist. When considering change in BR, this is less of a problem as the changes in question were mostly large and so a statistically significant increase in BR could still be demonstrated. Despite this it is still possible to have missed individuals who did significantly increase their

BR but to a smaller degree. Had we stated that a minimum number of colonoscopies needed to be performed by each colonoscopist for inclusion in the study, we would have had to either exclude a large number of colonoscopists, or alternatively run the study for an extended period of time.

Of the options above, the first would have been unhelpful in this type of work as service improvement projects must be maximally inclusive. Furthermore, there is some evidence to suggest that colonoscopists performing the fewest procedures have poorer quality markers and show the greatest variation in practice. (40, 91, 92) Therefore, it is this group that could potentially benefit most from an intervention such as the one in this study. Running the study over a prolonged period of time may have been possible but would have risked decreased compliance over time. Whilst this would have provided interesting data with regard to durability of the intervention, it would also have limited evaluation of its efficacy. It may have also have been logistically difficult to carry out with the resources available.

The study was also underpowered to detect a change at the level of the hospital unit. Using a traditional sample size calculation at the level of the unit is overly simplistic. It considers the endoscopy unit as the smallest unit of measurement whereas the unit is made up of individual colonoscopists. Each colonoscopist will also contribute a different number of colonoscopies to the unit total. Furthermore, the heterogeneity in baseline performance within units dictates each colonoscopist has a different potential to improve. Lastly, it assumes a high level of compliance with all components of the 'bundle' and

that this will be uniform amongst the participating units. The colonoscopists themselves may also demonstrate varying compliance to different components of the bundle and may have been using them routinely prior to the intervention, accurate data on which was unavailable with the exception of Buscopan use. The same issues arise when considering power calculations at a global level if not more so.

In summary, when considering the many variables that exist, power calculations to detect small changes in clinical outcomes can be problematic in service improvement work. Selecting an appropriate end point in service improvement work is discussed further below.

7.2.3. Data collection

The data collection for the study was performed by interrogating the endoscopy reporting software at each unit and so can be considered to be retrospective. This is not ideal as it relies heavily on accurate documentation from the endoscopist entering the report. The quality of report writing was also variable, as has been previously reported in the published literature. (34) As a result, other data that would potentially have been of interest, such as total number of polyps and adenomas and polyp morphology, could not be collected. The latter may have been of particular value given the greater variability in detecting flat lesions although the study was not powered to detect changes at polyp level. (79) The ideal approach would have been to data collection would have to gather it contemporaneously, however, resources dictated that this was not feasible. Furthermore, such an approach

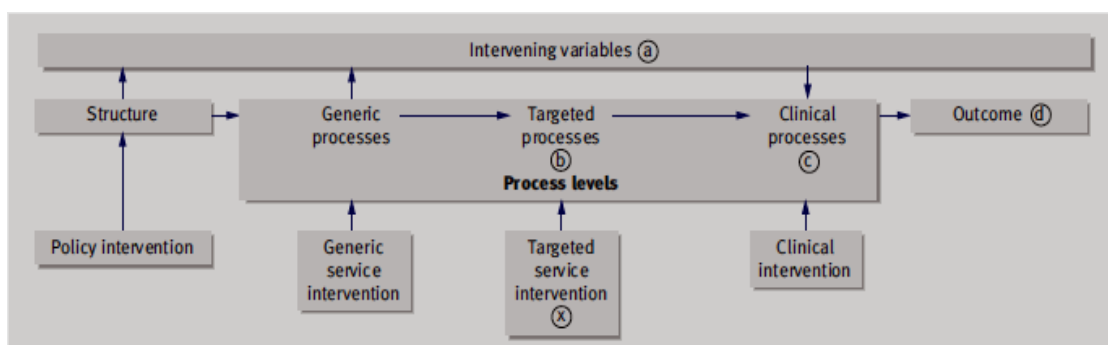
would have had the potential to further influence colonoscopist behaviour (Hawthorne effect), requiring a member of the research team to be present in the endoscopy room to enable accurate data collection. I certainly acknowledge that evaluation of factors effecting detection of polyps of differing morphologies would be useful and should be studied in future work.

7.3. End-points in service improvement studies: predicting future improvements

The end-point of clinical studies has traditionally been given at the level of patient outcome. This may not be appropriate, however, for service improvement studies. The primary reason for this is that, whilst the selected intervention may be important, outcomes at the patient or individual level may be small or infrequent requiring large numbers to demonstrate significance, as discussed above. In order to help select appropriate end-points, Lilford et al proposed a model based on the Donabedian causal chain of structure, process and outcome and is shown in

Figure 29. (93)

Figure 29: Modified Donabedian causal chain (used with permission of the British Medical Journal).



This model is based on the concept that interventions to the left of the chain will have effects further downstream. Therefore, if the intervention X is implemented, it will affect clinical processes and subsequently patient outcomes. Certain interventions may also have upstream effects, such as the implementation of a new set of guidelines in one area encouraging reference to guidelines in other areas, thereby improving these services. Using this model, if there is a clear relationship between a process and outcome but the outcome measure is small, it may be reasonable to assume that a measurable change at the process level will result in a significant change in outcome over time.

The converse may also be true depending on the respective process and outcome to be investigated. A good example would be the study performed by Pronovost et al and discussed in chapter three. (64) In this study, whilst compliance with the intervention was recorded locally, the data was not analysed or published as this would have taken considerable resource. Instead, the outcome, which was expected to be large based on the results of prior studies, was indeed so and measurement of this was much simpler and yielded results that were within the realms of expectation. A potential flaw in not analysing the data on uptake of the intervention at the process level is that cause and effect is more difficult to prove and may have been the result of other processes underway in the same organisation. In this particular study, however, this was not the case to the best knowledge of the study team.

When considering the QIC study, it is certainly feasible that encouraging best practice will, in the longer term, yield positive results by way of increased ADR at the level of the colonoscopist. Therefore, as we have demonstrated change, evidenced by change in BR, it is reasonable to assume that we will see an increase in ADR among colonoscopists that took up the intervention when sufficient procedure numbers can be included. This is supported by the results we observed at the quartile level and globally. This, again, highlights the importance of the continuous process required in service improvement work.

7.4. Evidence to support use of the ‘bundle’ measures

The use of a minimum withdrawal time of 6 minutes is supported by high quality evidence and is recommended by national guidelines. However, the remaining measures within the ‘bundle’ utilised in this study are supported by varying degrees of evidence and, therefore, their individual contribution to increased adenoma detection is less predictable. Following the completion of this study, further data have been published that we must consider.

Yoong et al perform a randomised double-blind controlled trial evaluating the effect of Buscopan on CIR and speed of completion published in 2004. (94) They found no significant difference in either CIR or completion time. A survey of Buscopan use and whether concurrent glaucoma effected use was performed by Bedford et al. (95) This survey of BSG and Association of Coloproctology of Great Britain and Ireland member revealed that 85.6% (123/183) of respondents sometimes or always use Buscopan, 77.4%

(137/177) always enquire about glaucoma history and 70.8% (126/187) withhold the drug if glaucoma of any kind is reported. The self reported use of Buscopan was much higher than observed in our study possibly due to a degree of selection bias among respondents.

There have also been three randomised, double blind, placebo controlled trials evaluating the use of Buscopan on polyp and adenoma detection that have yielded conflicting results. Corte et al reported a significant increase in the total number of polyps detected per patient in the Buscopan group. The PDR and ADR was also higher in the Buscopan group but did not reach statistical significance. (96) The other two studies revealed no significant difference between the Buscopan and placebo groups. (97, 98) A potential limitation was the fact that the ADRs in the placebo group of all the studies were high ranging from 21.8% to 30.0%. The findings of our study suggest that this group are less likely to improve and so one may have been predicted that the addition of Buscopan was less likely to have made a significant difference when compared to colonoscopist sub-groups with a lower ADR. Further work evaluating the benefit of Buscopan among colonoscopists whose ADR is below average would be of interest.

The data surrounding the additional lesion yield provided by rectal retroflexion are also variable and likely to be relatively small. In addition to the study by Hanson et al discussed in Chapter 3, further studies by Tellez-Avila et al and Saad et al revealed a non-significant increase in lesion detection using retroflexion compared with examination in the forward view. (99, 100) Tellez-

Avila, however, still recommended its use in light of the low associated risks whereas Saad suggested it should remain at the discretion of the colonoscopist. Based on the evidence available I would suggest that continued training in retroflexion is essential but would accept that its use should be left to the colonoscopist. Its safety when used appropriately means that it should be strongly considered in the majority of procedures, particularly in the older age group.

The data regarding the use of dynamic position change is limited. In addition to the study by East et al discussed in chapter 3, two further studies have been published by Koksai et al and more recently Ou et al. In their study of 102 patients, Koksai et al found that the use of position change, as described in chapter 3, resulted in a significant increase in ADR, a significant increase in the number of adenomas detected in the transverse and sigmoid colon and also an resulted in the a shortening of the colonoscopy surveillance intervals in 8.8%. (101) The study performed by Ou et al included 776 patients and revealed no difference in PDR or ADR with position change. (102) Despite the conflicting results as to the benefit of this measure, given its simplicity and safety, I would recommend its routine use.

The rationale for using a 'bundle' of measures rather than a single change was that, whilst the effect of each in isolation may be small, their use in combination may yield a significant increase in ADR, that, in light of the work of Corley et al is worth striving for. Furthermore, each is simple, safe and both cost and time efficient and can be performed by all colonoscopists in all

endoscopy units. Also, the results of this study, accepting its limitations, suggest that they may be useful especially for colonoscopists whose ADR is below average and we would continue to recommend their use particularly in this subgroup. Further work is required to confirm the findings of this study as discussed below.

In summary, the results of this study confirm that change in clinical practice can be successfully achieved using a multi-faceted educational intervention. The changes in ADR indicate that colonoscopists with below average ADR may see the greatest benefit. The Donabedian model also suggests that by encouraging best practice, it is reasonable to expect an improvement in the future at the level of the individual colonoscopist and a more significant increase in ADR may be seen in time. The reasons for the changes in ADR observed are likely to be multi-factorial including those intrinsic to the study intervention ('bundle' measures, feedback, awareness of peer performance, increased awareness of quality measures and indicators) and possible contributions from unintended factors (the Hawthorne effect and regression to the mean) all of which are important to appreciate if similar initiatives are to be conducted in the future.

7.5. Key findings from the QIC study

- This study demonstrates clearly that unacceptable variation in ADR does exist despite acceptable CIRs.

- The pre-intervention ADR funnel plots demonstrate that the current recommended national standard is too low and should now be reviewed in the light of this work and that of others. Serious consideration should be given to resetting the standard to be achieved at 15% initially, with aim of raising it further in the not too distant future.
- The model of implementation used in the study resulted in successful integration of evidence into routine clinical practice.
- The study intervention led to an improvement in the ADR, particularly for colonoscopists who were below average for this key performance indicator. Variation was reduced although not completely eliminated.
- Good local study promotion and feedback were important components of the implementation model.
- Factors influencing the observed results are multiple including those intrinsic to the study intervention and unintended factors (the Hawthorne effect and regression to the mean).
- Consideration should be given for similar future projects to encourage participation among groups predicted to engage poorly at the outset.

7.6. Further work

Service improvement work, as discussed above, must be a continuous process. Questions raised in the analyses of the current study highlight several areas for further work.

Durability

A follow up study to evaluate whether performance and uptake of the bundle were maintained would be of great value.

The Implementation Model

The qualitative evaluation confirmed that there were several components of the implementation model that influenced uptake of 'bundle' such as endoscopy nurse involvement and feedback. Given that quality improvement projects often have limited resources, it would be useful to understand which components had the greatest influence. For example, if it were to be demonstrated that feedback or knowledge of peer performance (benchmarking) played the greatest role, this would be of significant use when designing future models. Such a project would be a complex undertaking could result in a significant cost saving in future implementation programmes.

Reproducibility

It is now enormously important to understand if the changes in practice seen in the QIC study could be replicated using the same implementation model in endoscopy units outside of NREG.

There is a need to evaluate whether a similar degree of change been demonstrated using a similar implementation model in other clinical care settings.

Clinical Outcome

It would be important to confirm whether the changes in ADR observed were as a result of use of the intervention. This would require a randomised controlled trial, which would also be a challenge to undertake, but would provide an answer to the question. The effect on total number of adenomas detected and polyp of differing morphologies could also be evaluated.

7.7. Overall Summary

The QIC study was a large scale service improvement study using evidence based methodology with the aim of improving ADR of participating colonoscopists by implementing evidence based measures into routine colonoscopy practice. The results demonstrated that a multi-faceted implementation model brought about a significant change in practice. This resulted in a global increase in ADR and more importantly an improvement in the poorest performance, reducing in the variation observed at the outset of the study. The reasons for the changes observed are multi-factorial including the components of the intervention and outside factors. The value of an inclusive approach to study promotion and feedback were highlighted together with the importance of developing methods to engage groups predicted to resist change. The questions raised by the results have provided impetus for further work the early development of which is underway.

7.8. Summary of publications and presentations

Below is a summary of the work published and presented as a result of this project.

Full Publications

- **A multicenter pragmatic study of an evidence-based intervention to improve adenoma detection:** the Quality Improvement in Colonoscopy (QIC) study. *Endoscopy*, 2015. (In Press) (103)
- **Achieving high quality in colonoscopy:** using graphical representation to measure standards and reset standards. *Colorectal Diseases*, 2012. (104)

Published Abstracts

- **A multi-centre pragmatic study of an educational intervention to improve adenoma detection at colonoscopy.** Oral presentations at United European Gastroenterology Week (Awarded an oral free paper prize), 2013 and the British Society of Gastroenterology Annual Meeting, 2014 and poster presentation at Digestive Diseases Week, 2014. (105-107)
- **The Challenges of Implementing Evidence into Practice: A Qualitative Study.** Poster presentations at the British Society of Gastroenterology, 2013, United European Gastroenterology Week, 2013 and Digestive Diseases Weeks, 2014. (108, 109)
- **Using a 'conversion factor' to estimate adenoma detection rate.** Poster presentation at the Digestive Disorders Federation, 2012 and United European Gastroenterology Week, 2012.(110)

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Appendices

Appendix B



National Research Ethics Service

Sunderland Research Ethics Committee

Room 002
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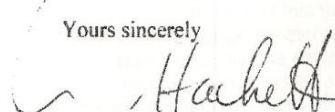
28 January 2010.

Dr C Rees
Consultant Physician/Gastroenterologist
South Tyneside NHS Foundation Trust
South Tyneside District Hospital
Harton Lane
South Shields
NE34 0PL

Dear Dr Rees,

Thank you for your letter dated 26 January 2010. I agree with your views that this project is service improvement and as such, does not require review by a NHS Research Ethics Committee.

Yours sincerely



(Pw) Paddy Stevenson
Chairman

This Research Ethics Committee is an advisory committee to North East Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Appendix C

QIC Training Day Minutes

Introduction by MR

- Aims of QIC (intervention bundle to improve ADR – surrogate marker of quality)
- Designed as a service improvement study
- Potential problems highlighted – how to influence people/get people to “buy in”

Overview of QIC including evidence base (by JE)(Appendix C)

- Overview presented.
- ADR as a marker of quality in colonoscopy (Kaminski et al).
- Why use ADR – most closely associated with interval cancer rate
- Varying standards worldwide – GRS 10%/BCSP 35%/US 15-25%
- Standards vary greatly (Barclay et al)
- Factors effecting ADR discussed (Rex et al)
- Reasons why increasing ADR important i.e. future cancer risk
- Factors that influence future improvement – simple feedback of poor performance appears not to.
- Example of an “intervention bundle” implemented in ITU to reduce line sepsis presented
- Components of intervention bundle in QIC discussed.
 - Time – increased time = increased ADR (Barclay et al)
 - Buscopan

- old data and whilst used in CT colonography demonstrating increased PDR when used in those with visible spasm.
 - Variation in use
 - Must be used in caecum at latest but can be used sooner
 - Glucagon is an alternative when contraindicated
 - Probably can use in glaucoma if used drops (? Liaise with ophthalmology)
 - Position change –left lateral for right colon, supine for transverse and right lateral for left colon – supine and right lateral have largest influence.
 - Rectal retroflexion – small effect.
- Time line discussed including when implementation of bundle planned and subsequent data gathering points.
- Summary

NREG and QIC (by CJR) (Appendix C)

- About NREG including past and current projects
- Importance of academic detailing
 - Outline today
 - How “leaders” train their units
 - How were those who didn’t agree persuaded (or not)
 - Nursing influence
- Incentives
 - Training for those who need it

- CPD points
- External speakers (added influence?)
- What should we do about right sided lesions?
 - Build into DVD? i.e. use of cold snare techniques
- Training in rectal retroflexion (also on DVD)
- How will be audit?
 - PR to get feedback on how the trainers trained (we will provide protocols/suggestions on how this was might be done).
 - Need random and single blinded audit (frequency to be decided)
 - Need to document size of lists before/after implementation of bundle
- How quality will be assessed.
 - ADR
 - Interval cancer rate in the future??

Academic detailing and educating doctors (by MGB) (Appendix C)

- Discussed all those involved in a colonoscopy that can influence outcome/participation – endoscopist/patient/nurse/assistant
- Trainees can influence unit culture change i.e. those who have trained in other units.
- How do we get people to change?
 - Instruct i.e. from high up in the organisation
 - Negotiate (two or more way discussions)
 - Pilot study

- Persuade – audit/research/benchmark
- Educate
- What factors influence change in behaviour?
 - Willingness i.e. possible resistance from the very experienced endoscopist
 - Influence of the leader/enthusiast
 - Hearing objections +/- persuade
 - Sanctions for non-compliance
 - Peer pressure
- What are the incentives?
 - Improved quality for patients.
 - Improved quality/performance of the unit
- How do we ensure limit on list length (i.e. stick to 12 points)?
 - Role of leaders/nurses in this
- When is data fed back?
 - What about monthly scores?
- Regarding QIC things we need to do are:
 - Decide strategy
 - Decide methods
 - Quick ???
 - Get nurses on board
 - Listen to colleagues
 - Audit
 - Support units and feedback

Questions and comments

- How will the indication for colonoscopy effect ADR? (SP). Answer: We need to try and record indication as this will need to be analysed.
- Will the BCSP limit the potential to improve ADR i.e. less polyps out there? (AD). Answer: Difficult to say.
- Bringing about change will be difficult. Nursing staff pressure will be important. (MB)
- Does time include time for polypectomy? (JP). Answer: No. Normal scopes only.
- How do we ensure uniform withdrawal? (JP) Should we consider 2 minutes from caecum to hepatic, hepatic to splenic, splenic to sigmoid, sigmoid to rectal retroflexion with photographic evidence at each point? Should we use a bell as a reminder of time? Answer: Probably too time consuming and not all centres have reliable access to photo capture.
- How robust is the evidence? How will we convince endoscopists that increasing from 6 to 8 minutes worth while? Vote taken and decision use **6 minutes**.
- Enthusiasts more likely to engage than non-enthusiasts. How do we convince surgeons?
 - Suggestion: 1) Surgeons to talk to surgeons (surgical buddy). 2) Medical director support. 3) Competition (i.e. monthly/bimonthly ADR tables) 4) Outside speaker.
- How will increased time affect length of lists? Will lists end up being cut? Answer: Need to monitor this as may affect enthusiasm and pressure from management.

- Poster in each room will help with compliance.

Overall (after ideas debated and votes taken)

- **The “Bundle”**
 1. Colonoscopy withdrawal time = 6 minutes (no bell)
 2. Routine use of Buscopan (or glucagon if contra-indicated)
 3. Supine position for examination of transverse colon
 4. Routine retroflexion in the rectum
- Training to be delivered by research fellow for consistency.
- Training sessions should be a maximum of 45 minutes.
- Engage endoscopy nurses to promote study.
- Compliance assessments to be performed by nursing staff.
- Posters for all rooms.

The Quality Improvement in Colonoscopy (QIC) Study

on behalf of the Northern Region Endoscopy Group (NREG)

Remember to ROUTINELY

1. Give buscopan on reaching the caecum if not before
2. Take at least 6 minutes to withdraw
3. Use supine to examine transverse colon
4. Retroflex in rectum



Thank You !



Quality Improvement in Colonoscopy (QIC) Study

Colorectal Cancer

- Common problem in the UK.
- 3rd most common cancer and 2nd most common cause of cancer death (approx. 16,000 per year)
- Most detected when symptomatic.
- NHS BCSP commenced roll-out in 2006
 - In addition to earlier stage cancers a high number of adenomas were detected
- The majority of colonoscopies are done outside of the BCSP – offers an opportunity to detect and remove adenomas potentially reducing the incidence of colorectal cancer.

Background

- Colonoscopy is the criterion standard for dysplasia detection and therapy
- High quality colonoscopy is fundamental to National Bowel Cancer Screening Programmes (BCSP)
- We should also strive for high quality in diagnostic services.
- Recent emphasis on colonoscopic quality via GRS
 - Polyp / adenoma detection rates

Current Benchmarks/Standards

- Joint Advisory Group (JAG)/ GRS
 - 10% adenoma detection rate
 - Advanced adenomas
 - >2 adenomas
- United Kingdom BCSP
 - FOBT +ve: 35% adenoma detection rate
- US Multi-society guidelines
 - 1st screening colonoscopy aged ≥ 50 Y
 - ADR: >15% female, >25% male patients

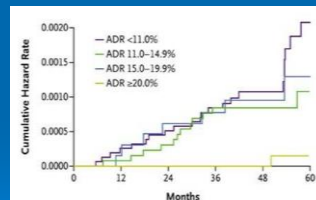
Does adenoma detection matter?

- Adenomas matter (even small ones!).
 - Patients undergoing surveillance colonoscopy following baseline colonoscopy were evaluated and relative risks for advanced neoplasia calculated.
 - Those with ≥ 3 small adenomas (10mm) at baseline had a RR 5.0 (95%CI 2.1-12.0) for advanced neoplasia at 3-5 years¹.
- Current British Society of Gastroenterology (BSG) recommends that those with 3-4 adenomas < 1cm undergo surveillance colonoscopy at 3 years.

¹Lieberman DA *et al.* Gastroenterology 2007;133:1077-1085

Does Adenoma Detection Rate matter?

- ADR is associated with interval cancer¹
 - ADR <20% had hazard ratio for interval cancer of 10 times that of ADR > 20%.
- ADR is a marker of quality in colonoscopy and a lower ADR is associated with an increased risk of interval cancer.



¹Kaminski MF *et al.* N Engl J Med 2010;362:1795-1803

Summary

- Colorectal cancer is an important problem.
- Potentially preventable by high quality colonoscopy which detects and removes pre-malignant colorectal adenomas.
- The presence of colorectal adenomas is associated with future cancer risk.
- Colonoscopist's ADR is linked to interval cancer and therefore is a marker of quality in colonoscopy.

The problem is.....

- Variability in adenoma detection (therefore quality).
 1. 10-fold variation for adenomas all sizes¹
 - 0.1-1.05 adenomas per patient
 2. 3-4 fold for adenomas $\geq 10\text{mm}^2$
 3. Cancer miss rates³
 - 3.0% vs 5.6% missed/new within 3 years of colonoscopy
 4. Failure to prevent right sided cancers⁴

¹ Barclay R *et al.* N Engl J Med 2006; 355:2533-2541

² Chen SC *et al.* Am J Gastroenterol 2007;102:856-61

³ Bressler B *et al.* Gastroenterology 2007;132:96-102

⁴ Baxter N *et al.* Ann Intern Med 2009;150:1-8

Adenoma miss rates

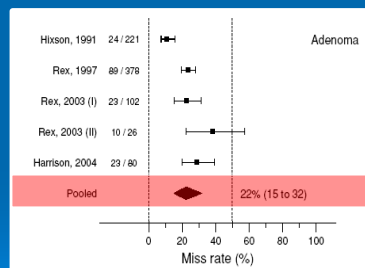
- Meta-analysis of six studies involving same day colonoscopies x2.

➤ Pooled (for all polyps) = 22%

➤ Adenomas > 10 mm = 2.1%

➤ Adenomas 5-10 mm = 13%

➤ Adenomas 1-5 mm = 26%

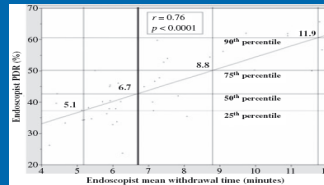


- van Rijn JC *et al.* Am J Gastroenterol 2006;101:343-50

Operator performance as a factor in miss rate

➤ Withdrawal times¹

- $r=0.76$
- $p<0.0001$



➤ 48% miss rate vs 17% miss rate²

1. adequacy of time spent viewing
2. cleaning and suctioning
3. examining the proximal sides of flexures, folds and valves
4. adequacy of distension

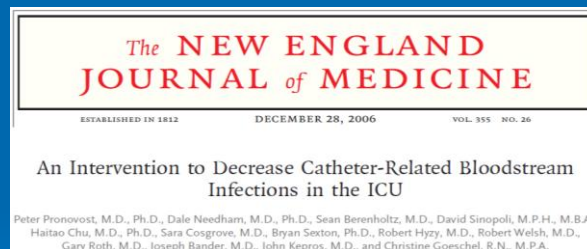
¹Simmons DT *et al.* *Aliment Pharmacol Ther* 2006;24:965-71

²Rex DK. *Gastrointest Endosc* 2000;51:33-36

Summary

- Wide variation in adenoma detection rates
- Adenoma detection rates important
- Operator performance is a (major) factor

Concept



- Collaborative cohort study
- “Before and after” design - service development

Intervention

- 108 ICUs: 5 evidence based procedures
 1. Hand washing
 2. Full barrier precautions
 3. Chlorhexidine skin cleaning
 4. Avoiding femoral site
 5. Removing unnecessary catheters
- Team leaders
 - Instructed in science of safety & interventions
 - Coaching, teleconference, state-wide meets 6/12
 - Info on efficacy, implementation suggestions
 - Leaders disseminated the information back to their units.
- 18 months follow up, 1981 ICU months

Baseline

Table 3. Rates of Catheter-Related Bloodstream Infection from Baseline (before Implementation of the Study Intervention) to 18 Months of Follow-up.^a

Study Period	No. of ICUs	No. of Bloodstream Infections per 1000 Catheter-Days				
		Overall	Teaching Hospital	Nonteaching Hospital	<200 Beds	≥200 Beds
Baseline	55	2.7 (0.6–4.8)	2.7 (1.3–4.7)	2.6 (0–4.9)	2.1 (0–3.0)	2.7 (1.3–4.8)
During implementation	96	1.6 (0–4.4)†	1.7 (0–4.5)	0 (0–3.5)	0 (0–5.8)	1.7 (0–4.3)†
After implementation						
0–3 mo	96	0 (0–3.0)‡	1.3 (0–3.1)†	0 (0–1.6)†	0 (0–2.7)	1.1 (0–3.1)‡
4–6 mo	96	0 (0–2.7)‡	1.1 (0–3.6)†	0 (0–0)‡	0 (0–0)†	0 (0–3.2)‡
7–9 mo	95	0 (0–2.1)‡	0.8 (0–2.4)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.2)‡
10–12 mo	90	0 (0–1.9)‡	0 (0–2.3)‡	0 (0–1.5)‡	0 (0–0)†	0.2 (0–2.3)‡
13–15 mo	85	0 (0–1.6)‡	0 (0–2.2)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.0)‡
16–18 mo	70	0 (0–2.4)‡	0 (0–2.7)‡	0 (0–1.2)†	0 (0–0)†	0 (0–2.6)‡

Concept summary

- Collaborative cohort design
- Implementing “bundle” of best evidence
- Local team leadership with support
- Efficacy and durable outcomes

QIC Study Design

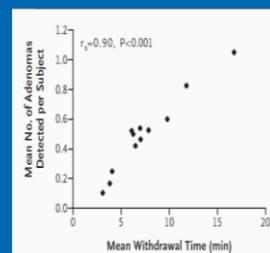
- Collaborative cohort design
 - “Before and after” observations
 - Use NREG as a network
- Introduce a ‘bundle’ of evidence based measures
 - Educational package
 - Supported team leaders and study team
- Measureable improvement in colonoscopy quality in multiple endoscopy units
 - Number of patients with ≥ 1 polyp recorded
 - Adenoma detection rates

Evidence based interventions

1. Minimum withdrawal time of 6 minutes.
2. Routine antispasmodic use - buscopan 20mg IV
3. Position change
 - Specifically supine position for examination of transverse colon
4. Routine rectal retroflexion

Minimum withdrawal time (1)

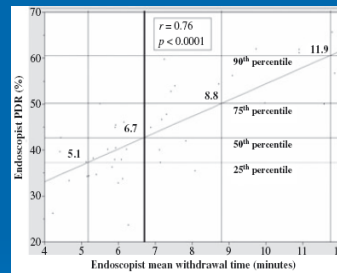
- 2053 screening colonoscopies studied.
- Association between adenoma detection and both mean total withdrawal time and mean withdrawal time (MWT) of normal colonoscopies evaluated.
- Longer withdrawal time is associated with higher adenoma detection.
- All lesions
 - MWT < 6min = 11.8%
 - MWT > 6min = 28.3%
 - Statistically significant ($p < 0.001$)
- Advanced lesions
 - MWT < 6min = 2.16%
 - MWT > 6 min = 6.4%



¹Barclay R. *et al.*
N Engl J Med 2006; 355:2533-2541

Minimum Withdrawal time (2)

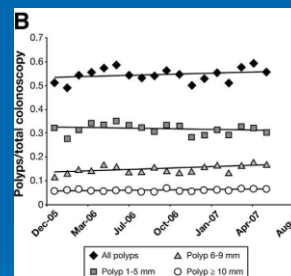
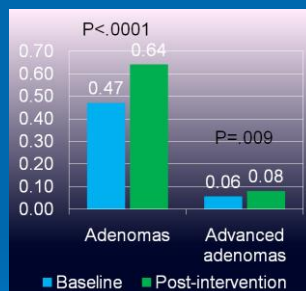
- Study designed to find optimal colonoscopy withdrawal time for maximal lesion detection.
- 10,995 colonoscopies analysed
- PDR correlated with withdrawal time
- Median PDR = 42.7% found to be at 6.7 min
- Variation on PDR decreased within increasing polyp size.



"In all models, only mean procedure time was associated with polyp detection rates"
Imperiale TF *et al.* *Gastrointest Endosc* 2009;69:1296-8

1. Simmons DT *et al.* *Aliment Pharmacol Ther* 2006;24:965-71

Minimum withdrawal time (3)



Barclay R *et al.* *Clin Gastroenterol Hepatol* 2008;6:1091-8

Sawhney M *et al.* *Gastroenterology* 2008;135:1892-8

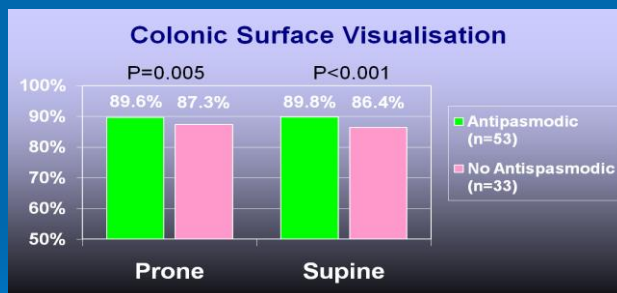
Antispasmodic

- Antispasmodics are used by 20% UK colonoscopists¹
 - Hyoscine N-butylbromide (Buscopan)
 - Glucagon
- Potentially flatten haustral folds revealing more colonic mucosa
- Reduce peristaltic waves and spasm
- No improved polyp detection with glucagon²

¹Bowles CJ *et al.* *Gut* 2004;53:277-83

²Cutler CS *et al.* *Gastrointest Endosc* 1995;42:346-50

Antispasmodic



East JE *et al.* Gut 2009;58 (Suppl 1);A122

Antispasmodic

- Randomised study (n=116)¹
 - Spasm score was reduced with Buscopan
 - Improved polyp detection in those with severe spasm
 - 1.2 versus 0.4, p=0.06
- Expert opinion favour antispasmodics for difficult to detect lesions²

¹Lee JM *et al.* Hepatogastroenterology 2010;57:90-4

²Kiesslich R *et al.* Gut 2004;53:165-76

Dynamic position changes (1)



- 14 patients had back to back colonoscopies video taped.
- One solely in left lateral position and then with position changes.
- Videos reviewed by blinded reviewer and luminal distension scored.
- 42% of patient examined in left lateral alone had diagnostically unacceptable distension scores

East JE *et al.* Gastrointest Endosc 2007;65:263-69

Dynamic position changes (2)

- 130 patients underwent back to back colonoscopy – one left lat. only and one with dynamic position change.
- Outcome measure were polyp/adenoma detection rate and luminal distension scores.

1. East JE et al. Gastrointest Endosc. 2010 (In Press)

Dynamic position changes (3)

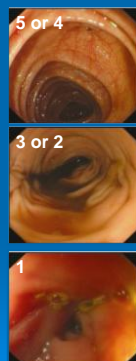
TABLE 2. Patients with ≥ 1 adenoma detected by colon segment

Colon segment	Left lateral position, n (%)	Position changes, n (%)	P value
Cecum	20 (16)	21 (16)	.94*
Ascending colon	28 (22)	28 (22)	.73*
Hepatic flexure	18 (14)	24 (19)	.09*
Transverse colon	19 (15)	31 (24)	.02*
Splenic flexure	9 (7)	15 (12)	.13*
Descending colon	8 (6)	4 (3)	.11*
Cecum + ascending colon + hepatic flexure	55 (43)	56 (43)	.95
Splenic flexure + descending colon	16 (12)	19 (15)	.64
Transverse colon + splenic flexure + descending colon	30 (23)	44 (34)	.01

*Because of multiple testing of the data, these P values should be considered as statistically significant where $P < .008$.

- East JE et al. Gastrointest Endosc 2010 (In press)

Dynamic position changes (4)



16%

- Luminal distension improved with dynamic position change¹
- Adenoma detection improved with better luminal distension ($p < 0.001$)²
- Luminal distension correlates with adenoma detection $r = 0.12$

7%

1. East JE et al. Gastrointest Endosc. 2007;65:263-69
2. East JE et al. Gastrointest Endosc. 2010 (In Press)

Rectal retroflexion

- Flexiscope trial (480 patients)¹
 - 12 (2.5%) polyps seen only on retroflexion
 - 4 (1%) adenomas (3 TAs <5mm, 1 x 15mm TVA)
- Large colonoscopy series (1502 cases)²
 - 40 (2.7%) had a distal rectal polyp
 - 8 polyps seen in retroflexed view only
 - 1 x 4mm tubular adenoma

¹Hanson J *et al.* Dis Colon Rectum 2001;44:1706-82

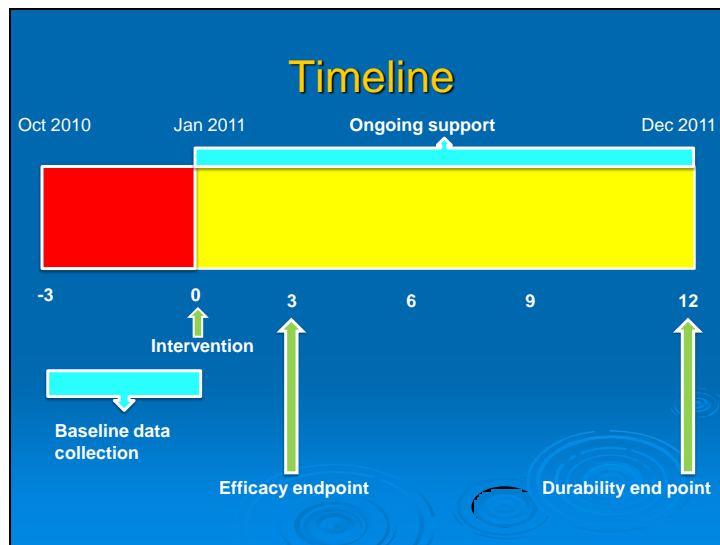
²Saad A *et al.* World J Gastroenterol 2008;14:6503-5

Evidence based 'bundle' of changes

1. Minimal withdrawal time (> 6mins)
 - In all cases (intact colon)
2. Antispasmodics (buscopan 20mg IV)
 - Should be given at caecum at latest in all cases unless contraindicated
3. Position change
 - Minimum of supine for transverse colon
4. Rectal retroflexion
 - All cases unless contraindicated

Outcome measures

1. Uptake of the intervention 'bundle'
2. Change in polyp/adenoma detection rate



Central Training Day

- All lead endoscopists and lead endoscopy nurses attended training day 16/9/10.
- Principles of study outlined.
- Potential local implementation problems discussed.
- Solutions agreed.
- Study design refined in light of above.
- Letters sent to all medical directors to acquire support for QIC.

What data will we record?

- | | |
|---|--|
| <ul style="list-style-type: none"> ➤ Unit ➤ Month ➤ Colonoscopist (anonymized) ➤ Time of list (AM/PM) ➤ Mean list length (points) ➤ Mean age of patient ➤ Sex distribution (percentage M/F) ➤ Indication for colonoscopy ➤ Mean sedation/analgesia dose ➤ Buscopan use ➤ Mean bowel prep score ➤ Mean comfort score | <ul style="list-style-type: none"> ➤ Polyp detection rate ➤ Polyp retrieval rate ➤ Polyp size??? ➤ Adenoma detection rate ➤ Complications |
|---|--|

Recording your data

- Please record all polyps detected using the drop down menus where possible - makes collecting polyp/adenoma detection rate data much easier.
- Please record if polyps are retrieved.
- Please record size of polyps (??should we record this)
- Please include bowel preparation scores in your colonoscopy report,

Compliance assessments

- Will be performed by endoscopy nursing staff using a 4 point score
- Will include 30 normal colonoscopies.
- Will occur once in initial 3 months (efficacy) and twice during subsequent 9 months (durability).
- Will be blinded ("Hawthorn effect").

What happens next?

- Please implement changes from your next colonoscopy list – all lists except bowel cancer screening lists (excluded).
- Blinded compliance audit at 3, 6 and 12 months.
- Please record data as fully as possible.

Summary

- Problem
 - Wide variation in polyp and adenoma detection rates
 - Due to operators factors
 - Adenoma detection rate is a marker of quality in colonoscopy
- Concept
 - Pronovost NEJM educational intervention to reduce infection
- Evidence
 - “Bundle” of 4 evidence based measures
- Design
 - Before and after collaborative cohort study
 - Intervention championed by local “team leaders”

QIC study

We thank you for your help and enthusiasm!!

Any questions?

Appendix F



The Quality Improvement in Colonoscopy (QIC) Study

Colorectal Cancer (CRC)

- Common problem in the UK.
- 3rd most common cancer and 2nd most common cause of cancer death.
- Most detected when symptomatic.
- NHS BCSP commenced roll-out in 2006
- Most colonoscopies are done outside of BCSP
- Great opportunity to detect and remove adenomas
- Potentially reducing the incidence of colorectal cancer.



Background

- Colonoscopy is the criterion standard for dysplasia detection and therapy
- High quality colonoscopy is fundamental to National Bowel Cancer Screening Programmes (BCSP)
- Need to strive for high quality in diagnostic services.
- Recent emphasis on colonoscopic quality via GRS
 - Polyp / adenoma detection rates



Current Benchmarks/Standards

- Joint Advisory Group (JAG)/ GRS
 - 10% adenoma detection rate
- United Kingdom BCSP
 - FOBT +ve: 35% adenoma detection rate
- US Multi-society guidelines
 - 1st screening colonoscopy aged ≥ 50 Y
 - ADR: >15% female, >25% male patients



Why does adenoma detection matter?

- Removal of adenomas reduces incidence of CRC¹.
- Small adenomas are associated increased risk of future advanced neoplasia.
 - Those with ≥ 3 small adenomas (<10mm) at baseline had a RR 5.0 (95%CI 2.1-12.0) for advanced neoplasia at 3-5 years².
- Currently BSG recommends that those with 3-4 adenomas < 10 mm undergo surveillance colonoscopy at 3 years.

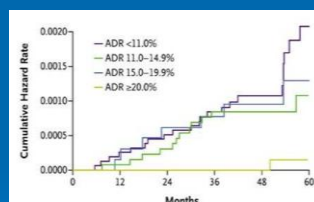
¹Winawer *et al.* N Engl J Med 1993;329:1977-1981

²Lieberman DA *et al.* Gastroenterology 2007;133:1077-1085



Why does adenoma detection rate matter?

- ADR <20% had hazard ratio for interval cancer of 10 times that of ADR > 20%¹.
- A lower ADR is associated with an increased risk of interval cancer.
- ADR is therefore a marker of quality in colonoscopy.



¹Kaminski MF *et al.* N Engl J Med 2010;362:1795-1803



Summary

- CRC is an important problem.
- Potentially preventable by high quality colonoscopy which detects and removes pre-malignant colorectal adenomas.
- The presence of colorectal adenomas is associated with future cancer risk.
- Colonoscopist's ADR is linked to interval cancer and therefore is a marker of quality in colonoscopy.



The problem is.....

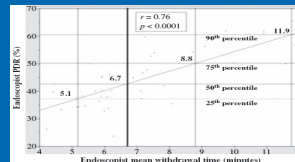
- Variability in adenoma detection (therefore quality).
- Systematic review of 6 studies involving same day colonoscopies x 2¹.
- Pooled (for all polyps) = 22% miss rate.
- Adenomas > 10 mm = 2.1%
- Adenomas 5 -10 mm = 13%
- Adenomas 1-5 mm = 26%

1. van Rijn JC *et al.* Am J Gastroenterol 2006;101:343-50



Operator performance as a factor in miss rate

- Withdrawal times¹
 - $r=0.76$
 - $p<0.0001$



- 48% miss rate vs 17% miss rate²
 1. adequacy of time spent viewing
 2. cleaning and suctioning
 3. examining the proximal sides of flexures, folds and valves
 4. adequacy of distension

¹Simmons DT *et al.* Aliment Pharmacol Ther 2006;24:965-71

²Rex DK. Gastrointest Endosc 2000;51:33-36



Summary

- Wide variation in adenoma detection rates
- Adenoma detection rates important
- Operator performance is a (major) factor



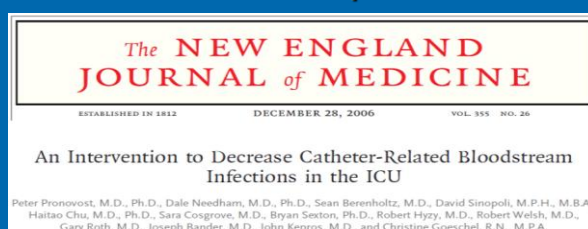
How can we improve things?

- Examination performed during colonoscopy withdrawal.
- Will a standard withdrawal technique reduce the current variation in adenoma detection?
- Which measures should we incorporate?

The Quality Improvement in Colonoscopy (QIC) Study.



Concept



- Collaborative cohort study
- “Before and after” design - service development



Concept summary

- Implemented “bundle” of best evidence
 1. Hand washing
 2. Full barrier precautions
 3. Chlorhexidine skin cleaning
 4. Avoiding femoral site
 5. Removing unnecessary catheters
- Team leaders centrally trained and disseminated information to their units.
- Implementation supported by leaders/study team.
- Significant reduction in blood-stream infections - sustained for the follow up period (durability).



The QIC Study

- Service development study
- Design
 - Collaborative cohort study with “before and after” observations using NREG as a network
- Intervention
 - Introduce a ‘bundle’ of evidence based measures to improve polyp/adenoma detection rate.
 - Support from team leaders and study team
- Outcome
 - Improvement in colonoscopy quality measured by change in PDR/ADR (number of patients with 1 or more polyps detected).



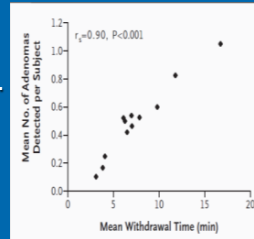
What is the ‘bundle’?

1. Minimum withdrawal time of 6 minutes.
2. Routine antispasmodic (for withdrawal)
 - Buscopan 20mg IV or (glucagon 1mg IV if buscopan contraindicated)
3. Routine use of supine position for examination of transverse colon (during withdrawal)
4. Routine retroflexion in the rectum



Minimum withdrawal time

- 2053 screening colonoscopies performed by 12 colonoscopists.
- Longer withdrawal time assoc. with higher adenoma detection.
- All lesions
 - MWT < 6min = 11.8%
 - MWT > 6min = 28.3%
 - p < 0.001
- Advanced lesions
 - MWT < 6min = 2.16%
 - MWT > 6 min = 6.4%
 - P = 0.005



¹Barclay R *et al.*
N Engl J Med 2008; 355:2533-2541

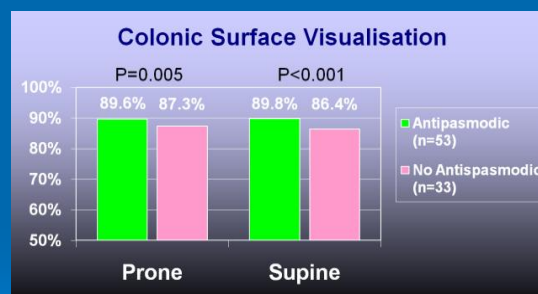


Antispasmodics (1)

- Antispasmodics are used by 20% UK colonoscopists - buscopan, glucagon.
- Flatten haustral folds revealing more colonic mucosa
- Reduce peristaltic waves and spasm



Antispasmodics (2)



East JE *et al.* Gut 2009;58 (Suppl 1);A122



Antispasmodics (3)

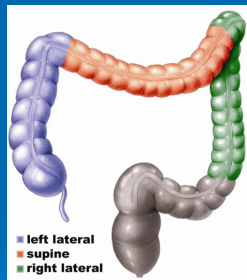
- Randomised study (n=116)¹
 - Spasm score was reduced with Buscopan
 - Improved polyp detection in those with severe spasm
 - 1.2 versus 0.4, p=0.06
- Expert opinion favour antispasmodics for difficult to detect lesions²

¹Lee JM *et al.* Hepatogastroenterology 2010;57:90-4

²Kiesslich R *et al.* Gut 2004;53:165-76



Dynamic position changes (1)



- 14 patients had back to back colonoscopies video taped - one solely in left lateral position and then with position changes.
- Videos assessed by reviewer (blinded) and luminal distension scored.
- 42% of patient examined in left lateral alone had diagnostically unacceptable distension scores

East JE *et al.* Gastrointest Endosc 2007;65:263-69



Dynamic position changes (2)

- 130 patients underwent back to back colonoscopy – one left lat. only and one with dynamic position change.
- Outcome measure were polyp/adenoma detection rate and luminal distension scores.

1. East JE *et al.* Gastrointest Endosc. 2010 (In Press)



Dynamic position changes (3)

TABLE 2. Patients with ≥ 1 adenoma detected by colon segment

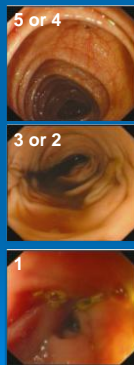
Colon segment	Left lateral position, n (%)	Position changes, n (%)	P value
Cecum	20 (16)	21 (16)	.94*
Ascending colon	28 (22)	28 (22)	.73*
Hepatic flexure	18 (14)	24 (19)	.09*
Transverse colon	19 (15)	31 (24)	.02*
Splenic flexure	9 (7)	15 (12)	.13*
Descending colon	8 (6)	4 (3)	.11*
Cecum + ascending colon + hepatic flexure	55 (43)	56 (43)	.95
Splenic flexure + descending colon	16 (12)	19 (15)	.64
Transverse colon + splenic flexure + descending colon	30 (23)	44 (34)	.01

*Because of multiple testing of the data, these P values should be considered as statistically significant where $P < .008$.

➤ East JE et al. *Gastrointest Endosc* 2010



Dynamic position changes (4)



- Luminal distension improved with dynamic position change¹
- Adenoma detection improved with better luminal distension ($p < 0.001$)²
- Luminal distension correlates with adenoma detection $r = 0.12$

1. East JE et al. *Gastrointest Endosc*. 2007;65:263-69
 2. East JE et al. *Gastrointest Endosc*. 2010 (In Press)



Rectal retroflexion

- Flexiscope trial (480 patients)¹
 - 12 (2.5%) polyps seen only on retroflexion
 - 4 (1%) adenomas (3 TAs <5mm, 1 x 15mm TVA)
- Large colonoscopy series (1502 cases)²
 - 40 (2.7%) had a distal rectal polyp
 - 8 polyps seen in retroflexed view only
 - 1 x 4mm tubular adenoma

¹Hanson J et al. *Dis Colon Rectum* 2001;44:1706-82

²Saad A et al. *World J Gastroenterol* 2008;14:6503-5



Evidence based 'bundle'

1. Minimal withdrawal time of 6mins
 - All cases with an intact colon.
2. Routine antispasmodics (buscopan 20mg IV)
 - All cases unless contraindicated when glucagon 1mg IV may be used
 - Should be given at caecum at latest
3. Routine use of supine position for transverse colon examination (during withdrawal).
4. Routine rectal retroflexion
 - All cases unless contraindicated

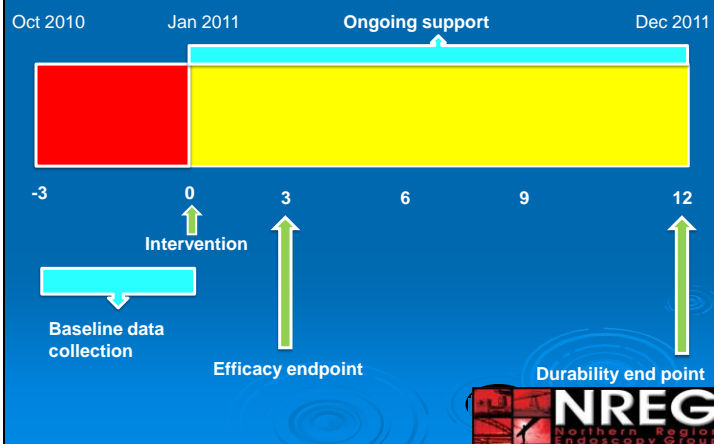


Outcome measures

1. Uptake of the intervention 'bundle'
2. Change in polyp/adenoma detection rate



Timeline



Central Training Day

- 12 units participating
- All lead endoscopists and lead endoscopy nurses attended training day.
- Principles of study outlined.
- Potential local implementation problems discussed.
- Solutions agreed and study design refined.
- Letters sent to all medical directors to acquire support for QIC.



What data will we record?

- Unit
- Month
- Colonoscopist (anonymized)
- Time of list (% AM/PM)
- Mean list length (points)
- Mean age of patient
- Sex distribution (% M/F)
- Indication for colonoscopy
- Mean sedation/analgesia dose
- Buscopan use
- Polyp detection rate
- Polyp retrieval rate
- Adenoma detection rate
- Polyp size
 - <10mm and >10mm
- Complications



Recording your data

- Please record all polyps detected using the drop down menus where possible - makes collecting polyp/adenoma detection rate data much easier.
- Please record if polyps are retrieved.
- Please record polyp size in millimeters compared to open standard biopsy forceps (6mm).



Compliance assessments

- Will be performed by endoscopy nursing staff using a 4 point score.
- Will include 30 normal colonoscopies.
- Will occur once in initial 3 months (efficacy) and twice during subsequent 9 months (durability).
- Will be blinded (“Hawthorn effect”).



What happens next?

- Please implement changes from your next colonoscopy list – bowel cancer screening lists excluded.
- Please record data as fully as possible.
- Please complete QIC feedback questionnaire – you will receive it in a few weeks.



The QIC study

- Collaborators
 - Durham University
 - St. Marks Hospital
- Funded by an SHA ‘Good ideas’ grant.
- Supported by the BSG endoscopy research group.
- Department of health have shown support for QIC.



Summary

- Problem
 - Wide variation in polyp and adenoma detection rates.
 - Operators performance is a factor.
- Design
 - “Before and after” collaborative cohort study
- Intervention
 - “Bundle” of 4 evidence based measures
- Outcome measures
 1. Change in PDR/ADR
 2. Uptake of “bundle”.



QIC study

We thank you for your help and enthusiasm!!

Any questions?



QIC STUDY FACT SHEET

Bottom Line

1. Polyps and adenoma detection rates are a marker of colonoscopic quality endorsed by national societies
2. Poor quality colonoscopy fails to comprehensively detect polyps and adenomas and risks not detecting and preventing colorectal cancer
3. The following interventions during colonoscopy withdrawal improve polyp and adenoma detection:
 - **A withdrawal time of at least 6 minutes**
 - **Patient position changes to optimise luminal distension**
 - **Rectal retroflexion**
 - **Use of anti-spasmodics**

Current Unit Performance

Our Unit's current unit polyp/adenoma detection rate (ADR): XX%

Recommended ADR for asymptomatic patients age ≥ 50 years undergoing colonoscopy: 20%

Colonoscopists with an ADR $<20\%$ in a large Polish screening colonoscopy study had a hazard ratio for interval colorectal cancer that was TEN-TIMES that of colonoscopists with an ADR $\geq 20\%$.

Kaminski MF, *et al.* Quality indicators for colonoscopy and the risk of interval cancer. *N Engl J Med.* 2010;362:1795-803.

TAKE AT LEAST 6 MINUTES FOR COLONOSCOPE WITHDRAWAL

Bottom line: Withdrawal time from caecum to anal verge in intact colons should take at least 6 minutes

Observational data from a number of studies has shown that increases in withdrawal time are correlated with improvements in adenoma detection. This has led national societies in the USA to recommend a minimum colonoscopy withdrawal time of six minutes. When low detecting colonoscopists who took less than 6 mins to withdraw slowed their withdrawal their adenoma detection rate improved.

Refs: Barclay R et al. N Engl J Med 2006;355:2533-2541, Simmons DT et al. Aliment Pharmacol Ther 2006;24:965-71, Barclay R et al. Clin Gastroenterol Hepatol 2008;6:1091-8

CHANGE PATIENT POSITION DURING COLONOSCOPE WITHDRAWAL

Bottom line: Change patient position to supine for examination of transverse colon and ideally to right oblique / lateral for splenic-descending to optimise luminal distension.

Examination in left lateral position alone can result in poor views of the transverse colon splenic flexure and descending colon, as these lie in a dependant position. Changing to supine for the transverse and right lateral for examination of the splenic-descending improves luminal distension and adenoma detection. Most of the benefit is seen by changing to supine for examination of the transverse colon.

Refs: East JE et al. Gastrointest Endosc 2007;65:263-69, East JE et al. Gastrointest Endosc 2010; In Press

RETROFLEX IN THE RECTUM

Bottom line: Rectal retroflexion enhances detection of lesions in the distal rectum and at the anal verge

Polyps low in the rectum and at the anal verge are difficult to detect with conventional forward viewing instruments. CT colonography studies have shown the low rectum is a common site for polyp misses. Rectal retroflexion allows comprehensive examination of this area and is recommended by experts. In a study of flexible sigmoidoscopy there was a 1% absolute increase in adenoma detection with use of rectal retroflexion.

Refs: Pickhardt PJ et al. Ann Intern Med. 2004;141:352-9, Hanson J et al. Dis Colon Rectum 2001;44:1706-82

GIVE ANTI-SPASMODICS BEFORE STARTING WITHDRAWAL

Bottom line: Antispasmodics reduce peristalsis and smooth muscle tone to give a still, flat mucosal surface to aid polyp detection

Intravenous antispasmodics (hyoscine butylbromide 20mg, Buscopan; Glucagon 1mg) reduce smooth muscle tone. This potentially flattens folds and has been shown to increase the amount of surface area visualised in a CT simulation of colonoscopy. Peristalsis is reduced which is recommended by some experts to aid neoplasia detection. Use of hyoscine improved polyp detection in a sub group of patients with colonic spasm in a randomised study.

Refs: East JE et al. Gut 2009;58 (Suppl 1);A122, Kiesslich R et al. Gut 2004 ;53:165-7, Lee JM et al. Hepatogastroenterology 2010;57:90-4

Appendix G

A hard copy of the training DVD is available at Durham University (via Professor Pali Hungin) or upon request from the author.

Appendix H

The Quality Improvement in Colonoscopy (QIC) Study
Pre-presentation questionnaire

Date:

Colonoscopist QIC code:

Please circle the response that you feel is most accurate

How often do you do/use the following during colonoscopy:

1. Withdraw the scope from caecum to anus in 6 minutes or more?

Always/nearly always Often Rarely Never

2. Use buscopan for withdrawal?

Always/nearly always Often Rarely Never

3. Use position change to improve luminal views during withdrawal?

Always/nearly always Often Rarely Never

4. Retroflex in the rectum?

Always/nearly always Often Rarely Never

Thank You

Appendix I

The Quality Improvement in Colonoscopy (QIC) Study
Compliance Assessment Form

Date: AM or PM list:
Colonoscopist QIC code: Number of points:

1. Withdraws scope from caecum to anus in 6 minutes or more? (NB: This is assessed in normal colonoscopies only where no polyps are removed)

Yes No

2. Uses buscopan (must be given at caecum at latest)?

Yes No

If no, was there a contra-indication?

Yes No

3. Uses supine position for examination of the transverse colon during withdrawal?

Yes No

4. Retroflexes in the rectum?

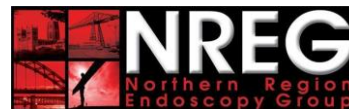
Yes No

If no, was there a contra-indication?

Yes No

Thank You

Appendix J



The QIC Study: Preliminary results

Unit	Before			After		
	No. of colons	PDR (Range)	ADR (Range)	No. of colons	PDR (Range)	ADR (Range)
A	379	23.5 (0.0-57.1)	15.3 (0.0-50.0)	455	26.4 (6.3-45.6)	16.9 (5.0-29.4)
B	341	27.0 (16.1-41.7)	12.3 (2.0-27.8)	547	33.6 (21.8-39.6)	18.5 (10.9-25.0)
C	525	26.7 (0.0-51.7)	18.7 (0.0-38.5)	687	30.3 (0.0-43.3)	18.3 (0.0-25.4)
D	247	28.2 (0.0-35.7)	17.6 (0.0-28.6)	278	32.7 (0.0-44.4)	20.9 (0.0-44.4)
E	819	25.4 (8.8-42.9)	16.5 (7.1-31.3)	972	27.1 (0.0-53.3)	15.5 (0.0-22.0)
F	267	18.7 (15.0-33.3)	10.1 (5.1-18.8)	312	21.8 (17.6-60.0)	12.2 (4.3-15.6)
G	154	39.0 (26.1-50.0)	17.5 (13.0-37.5)	119	32.8 (23.3-38.5)	16.0 (14.3-23.1)
H	120	41.7 (27.1-66.7)	17.5 (12.5-23.8)	266	40.6 (34.4-47.5)	17.7 (15.6-20.3)
I	275	26.5 (18.2-39.3)	12.4 (0.0-23.3)	399	27.3 (13.1-43.3)	14.8 (0.0-18.9)
Tot.	3,124	26.6 (0.0-66.7)	15.5 (0.0-50.0)	4,035	29.5 (0.0-60.0)	16.8 (0.0-53.3)

Dear [Unit lead(s) name here],

Here are some preliminary results from the QIC study which I hope you will find interesting. XXXXXXXXXXXXXXXXXXXXXXXXXXXX Hospital is unit X. The QIC study was presented at the NHS Innovations Expo this year as our SHA's leading project. We would like to take this opportunity to thank you on behalf of the study team for your enthusiasm both to date and for the remainder of the study.

Best Wishes on behalf of the QIC study team,

Colin J Rees (NREG Chair)

Praveen Rajasekhar (NREG Fellow)

The QIC Study team

Dr Colin J Rees South Tyneside District Hospital

Dr Matthew D Rutter University Hospital North Tees

Dr James E East John Radcliffe Hospital, Oxford




Prof. Mike Bramble Durham University

Dr Brian P Saunders St. Marks Hospital, London


Dr Praveen Rajasekhar South Tyneside District Hospital



Appendix K



The Quality Improvement in Colonoscopy (QIC) Study



Summary of QIC

- ▶ Service improvement study.
- ▶ Problem
 - Wide variation in polyp and adenoma detection rates.
 - Operators performance is a factor.
- ▶ Design
 - “Before and after” collaborative cohort study
- ▶ Intervention
 - “Bundle” of 4 evidence based measures
- ▶ Outcome measures
 1. Uptake of “bundle”.
 2. Change in PDR/ADR



The QIC study

- ▶ 14 units within NREG participating.
- ▶ Collaborators
 - Durham University
 - St. Marks Hospital
- ▶ Funded by an SHA ‘Good ideas’ grant.
- ▶ Supported by the BSG endoscopy research group.
- ▶ Department of health have shown support for QIC.



Evidence based 'bundle'

1. Minimal withdrawal time of 6mins
 - All cases with an intact colon.
2. Routine antispasmodics (buscopan 20mg IV)
 - All cases unless contraindicated when glucagon 1mg IV may be used
 - Should be given at caecum at latest
3. Routine use of supine position for transverse colon examination (during withdrawal).
4. Routine rectal retroflexion
 - All cases unless contraindicated



Outcome measures

1. Change in polyp/adenoma detection rate
2. Uptake of the intervention 'bundle'
 1. Compliance assessments.
 2. Buscopan use.

Data will be analysed on a unit, colonoscopist (anonymised) and aggregated patient level.



Preliminary results (1)

Unit	Before				After			
	Colons	PDR	ADR	BR	Colons	PDR (Range)	ADR (Range)	BR
BAGH	120	41.7 (27.1-66.7)	17.5 (12.5-23.8)	49.2	266	40.6 (34.4-47.5)	17.7 (15.6-20.3)	33.1
DMH	154	39.0 (26.1-50.0)	17.5 (13.0-37.5)	0.6	119	32.8 (23.3-38.5)	16.0 (14.3-23.1)	71.4
UHND	341	27.0 (16.1-41.7)	12.3 (2.0-27.8)	1.2	547	33.6 (21.8-39.6)	18.5 (10.9-25.0)	36.6



Preliminary results (2)

► Compliance assessments

Unit	Time (%)	Busc. (%)	CI (%)	Position (%)	Retro. (%)	CI (%)	N (%)
BAGH	86.5	91.9	2.7	81.1	94.6	0	13.9
DMH	79.5	95.5	4.5	100	95.5	0	37.0
UHND	75.7	77.1	5.7	92.9	91.4	2	12.8



Preliminary results (2)

Unit	Before			After		
	No. of colons	PDR (Range)	ADR (Range)	No. of colons	PDR (Range)	ADR (Range)
A	379	23.5 (0.0-57.1)	15.3 (0.0-50.0)	455	26.4 (6.3-45.6)	16.9 (5.0-29.4)
C	525	26.7 (0.0-51.7)	18.7 (0.0-38.5)	687	30.3 (0.0-43.3)	18.3 (0.0-25.4)
D	247	28.2 (0.0-35.7)	17.6 (0.0-28.6)	278	32.7 (0.0-44.4)	20.9 (0.0-44.4)
E	819	25.4 (8.8-42.9)	16.5 (7.1-31.3)	972	27.1 (0.0-53.3)	15.5 (0.0-22.0)
F	267	18.7 (15.0-33.3)	10.1 (5.1-18.8)	312	21.8 (17.6-60.0)	12.2 (4.3-15.6)
I	275	26.5 (18.2-39.3)	12.4 (0.0-23.3)	399	27.3 (13.1-43.3)	14.8 (0.0-18.9)
J	294	23.2 (12.0-35.5)	14.6 (12.0-19.4)	387	26.6 (5.1-44.6)	17.3 (2.6-23.3)
K	455	27.7 (13.0-50.0)	17.1 (8.7-26.2)	606	33.8 (12.8-53.6)	20.6 (6.4-35.7)



Reasons for variable results

- Variable uptake – compliance assessments currently being analysed.
- Manoeuvres already being used?
- Possible ceiling affect?



Summary of initial results.

- ▶ There continues to be a variation in PDR/ADR.
- ▶ There has been uptake of the intervention 'bundle' but not uniformly.
- ▶ Initial data from QIC demonstrates an increase in PDR in all units and ADR in 7 out of the 11 participating units with 'after' data.



QIC study

Thanks for you continued
enthusiasm.

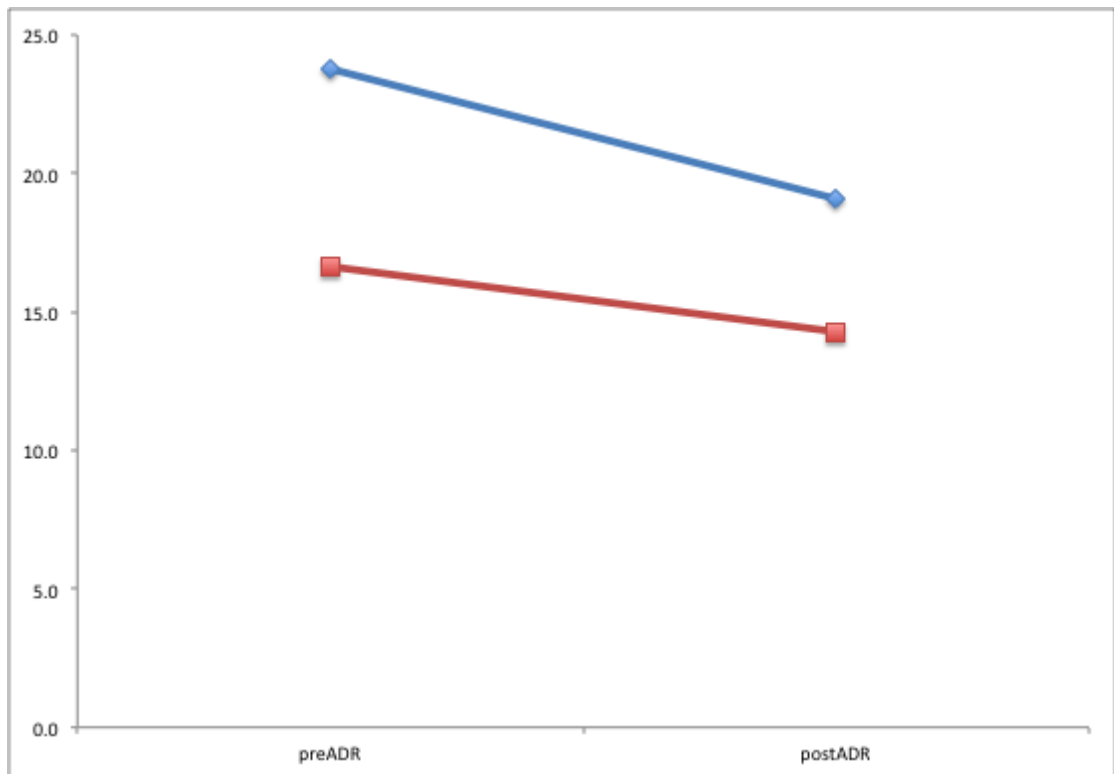
Any questions?



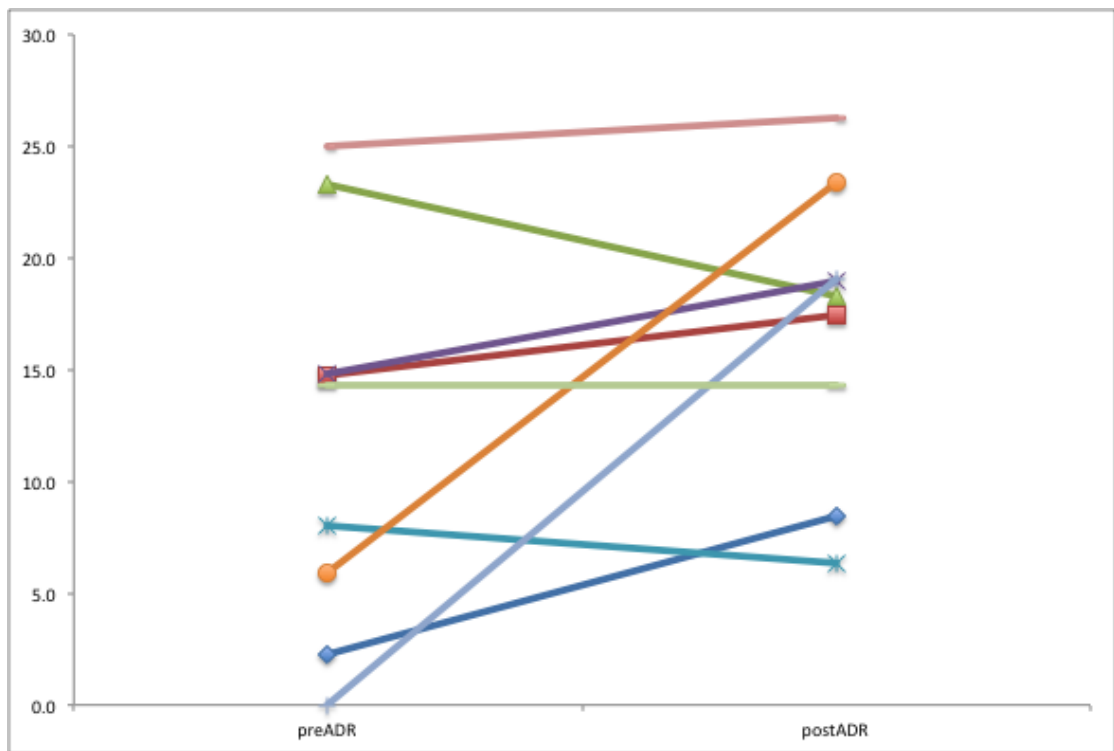
Appendix L

Line graphs depicting the direction of movement in ADR of each colonoscopist per unit.

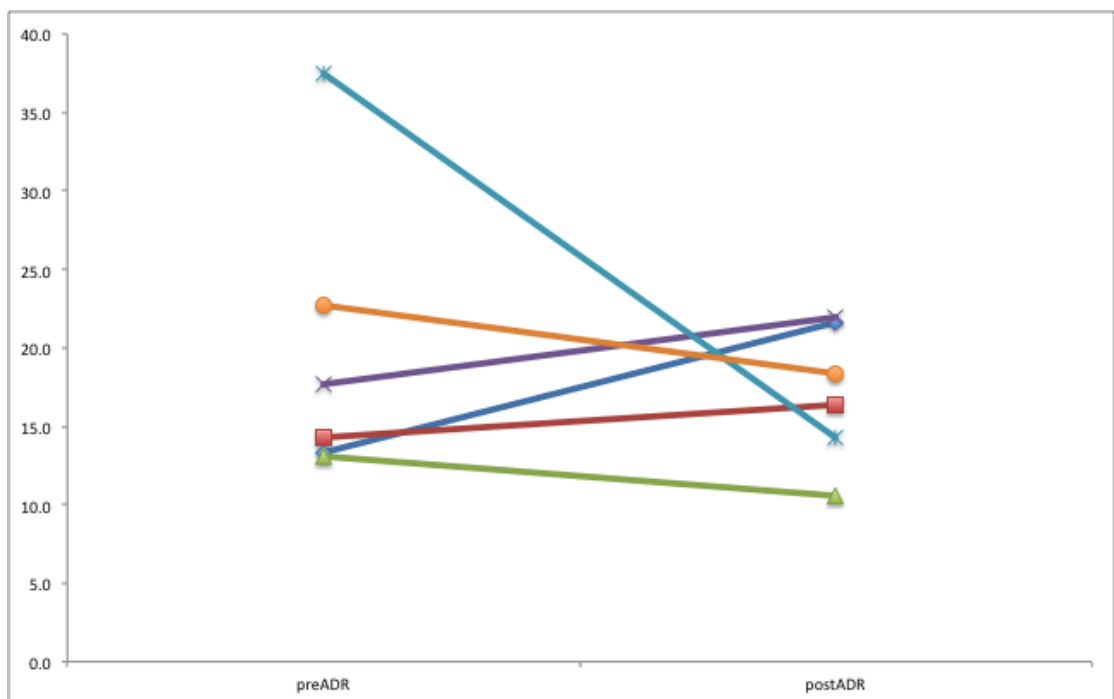
Unit A



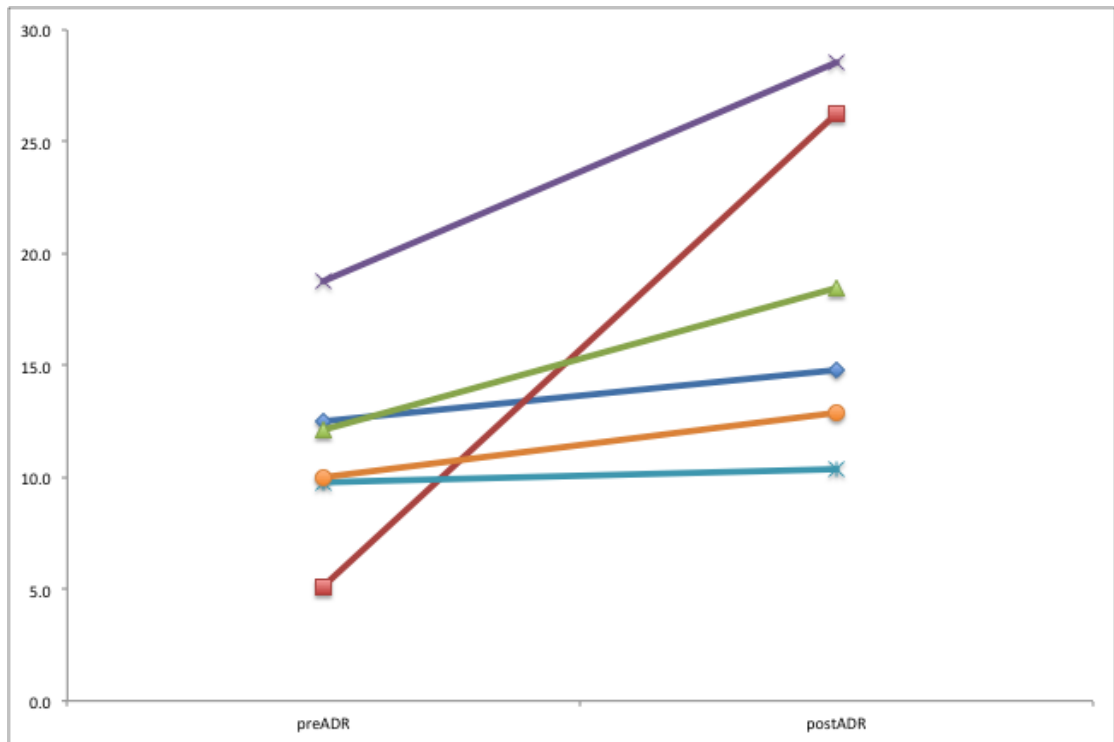
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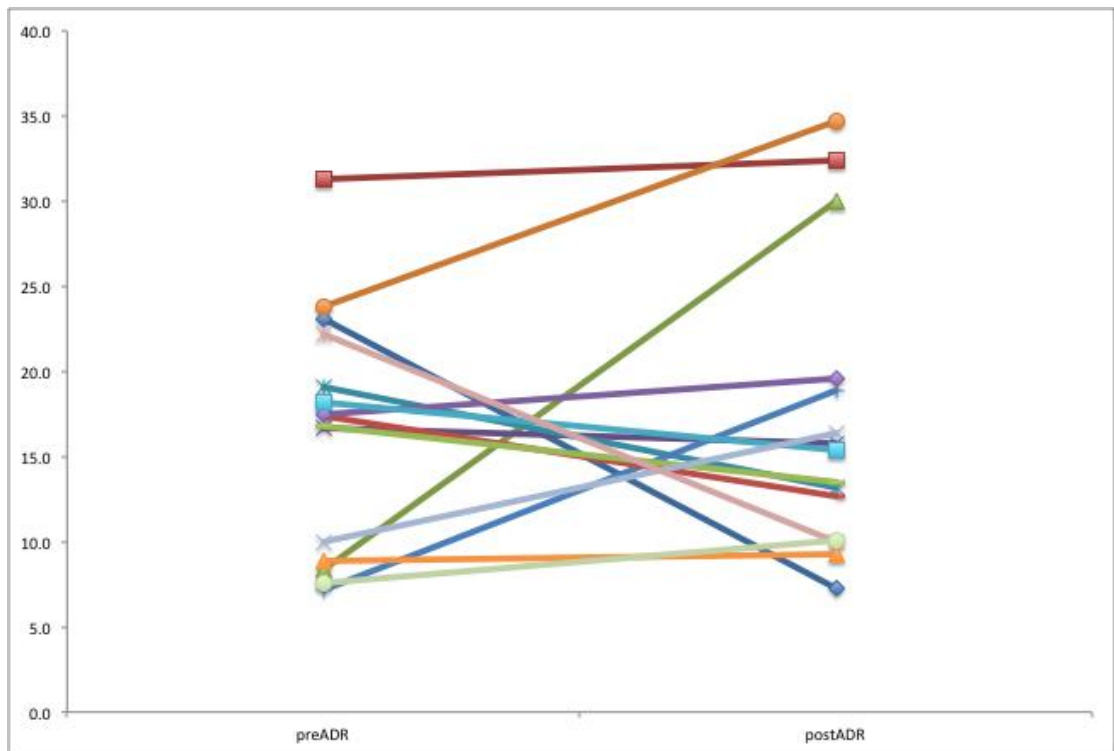
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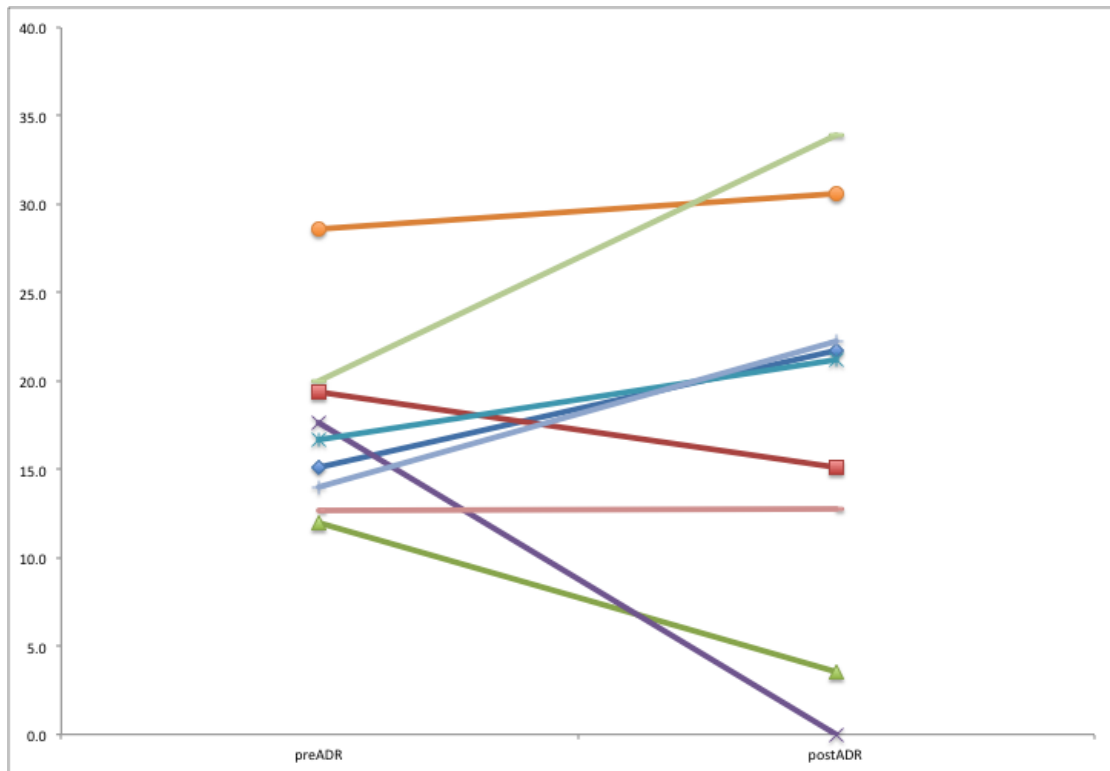
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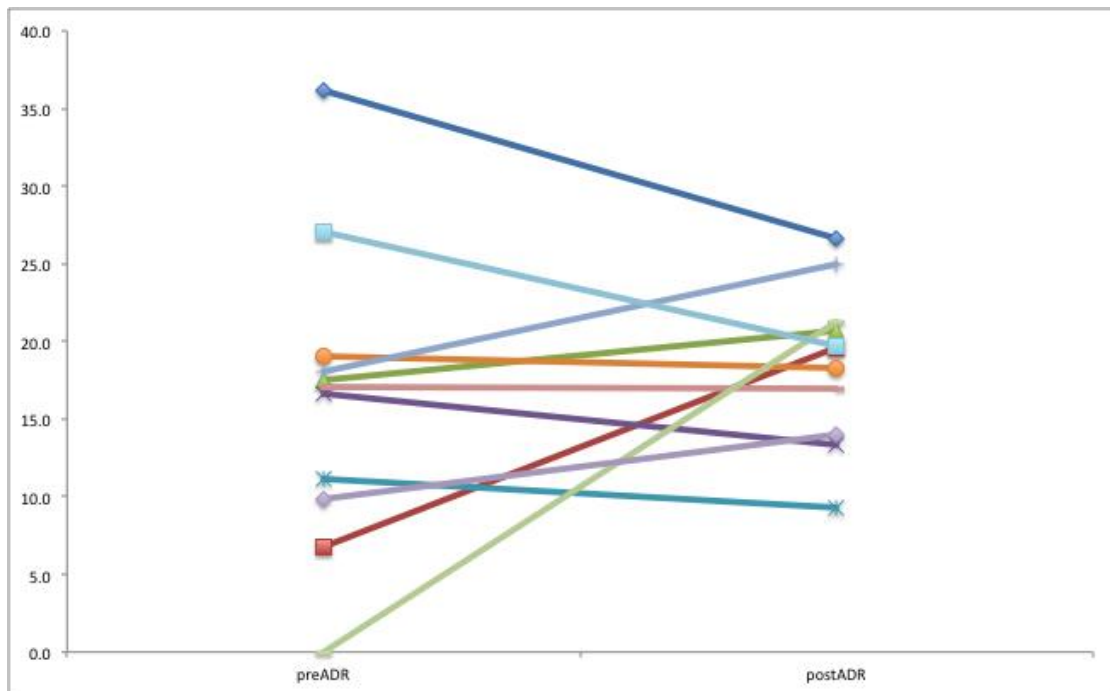
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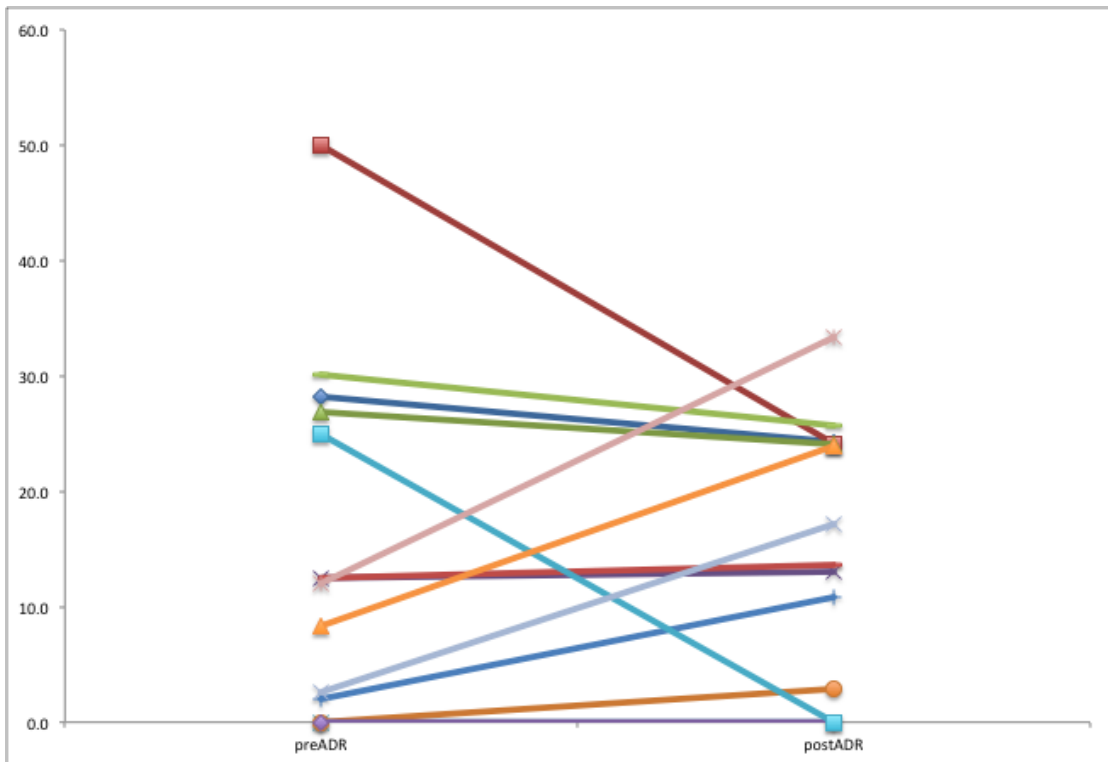
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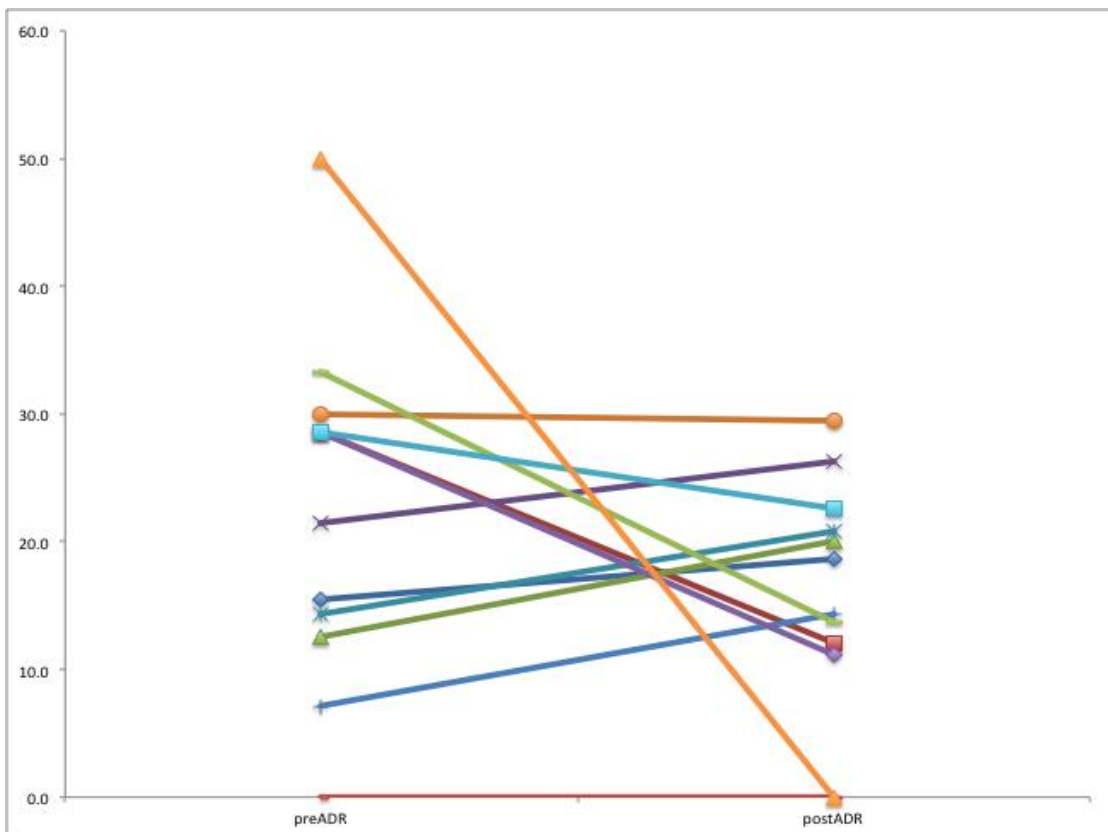
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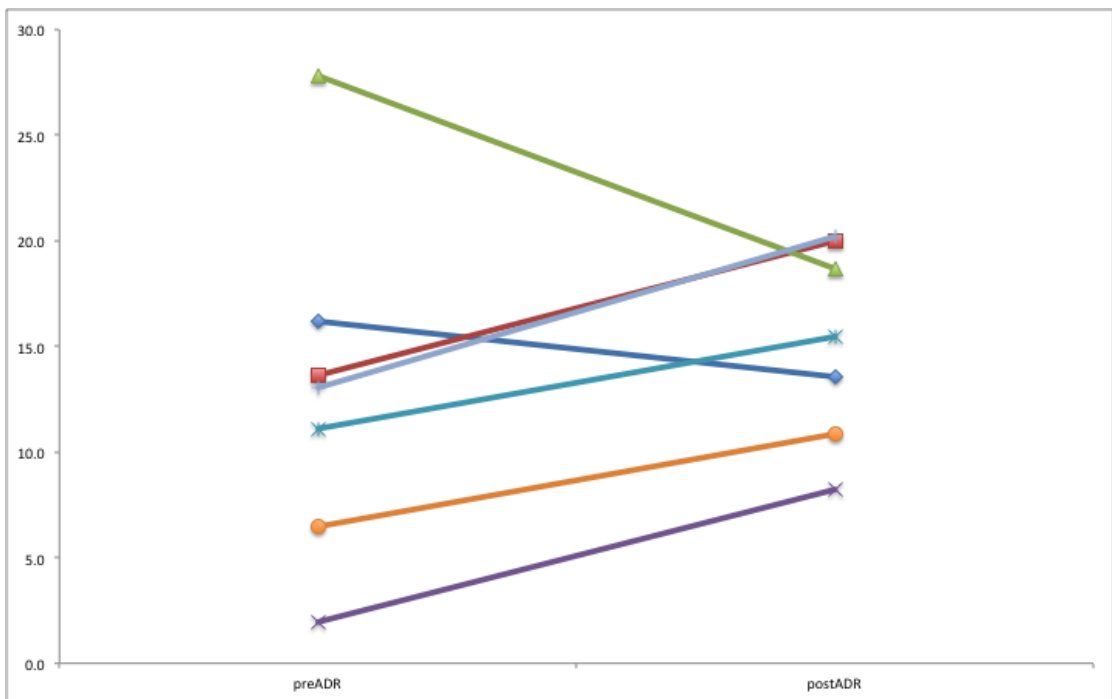
Unit I



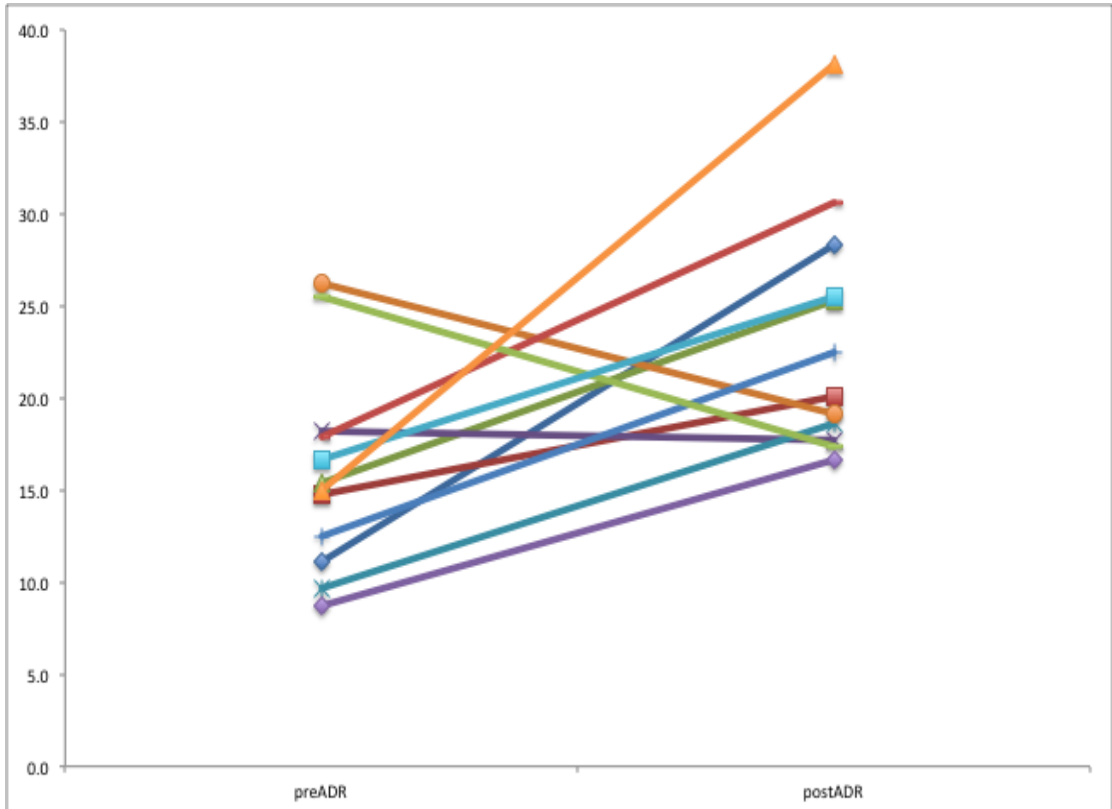
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Unit K



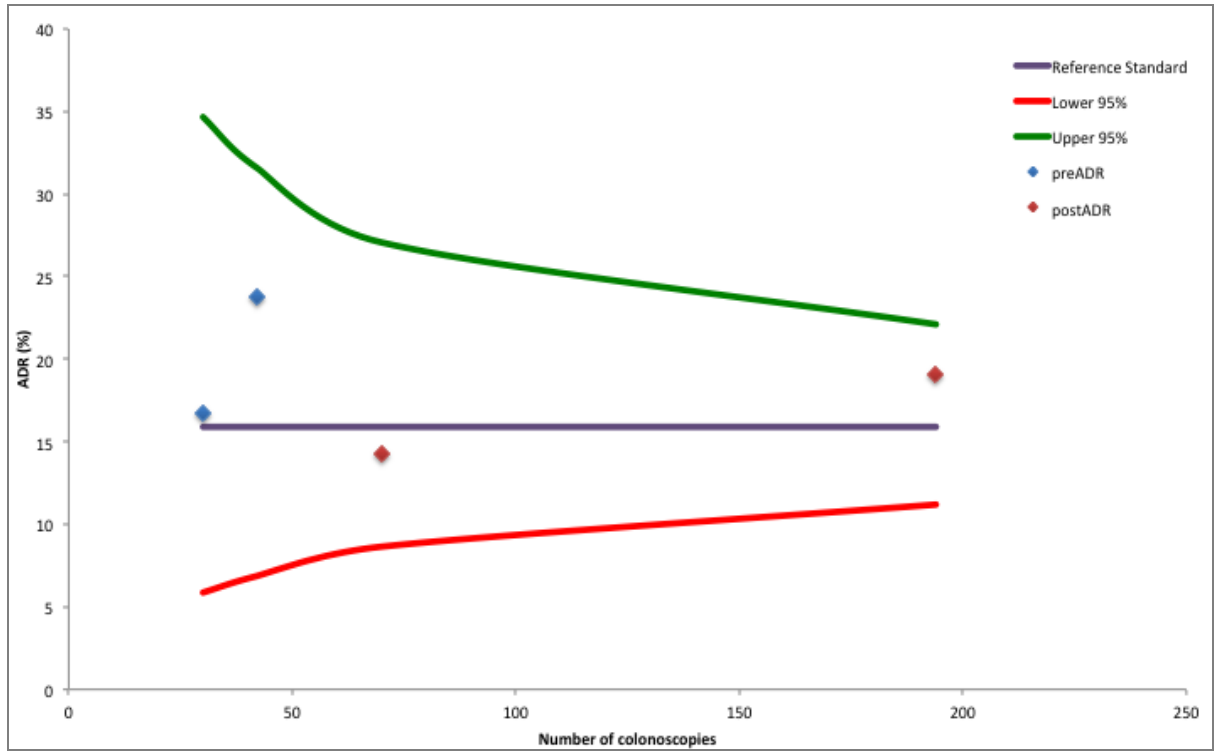
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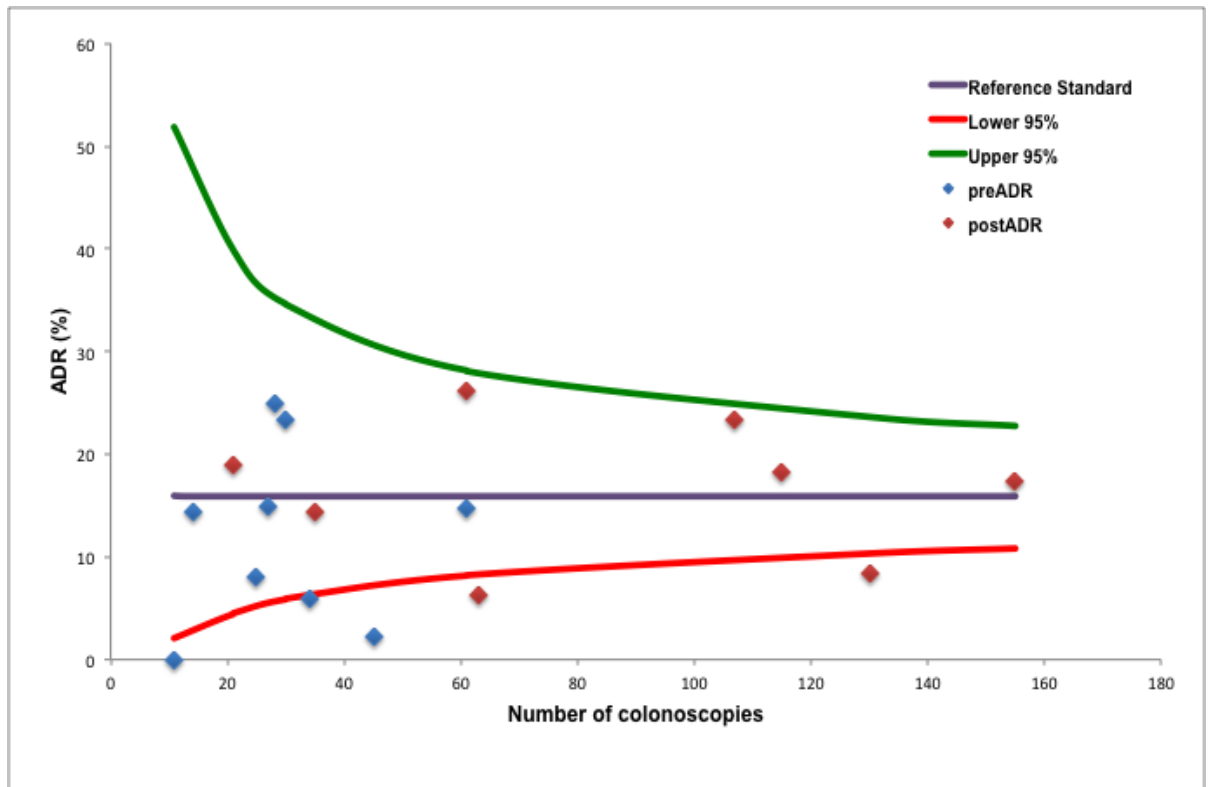
Appendix M

Funnel plots demonstrating change in ADR for each colonoscopist with their respective unit.

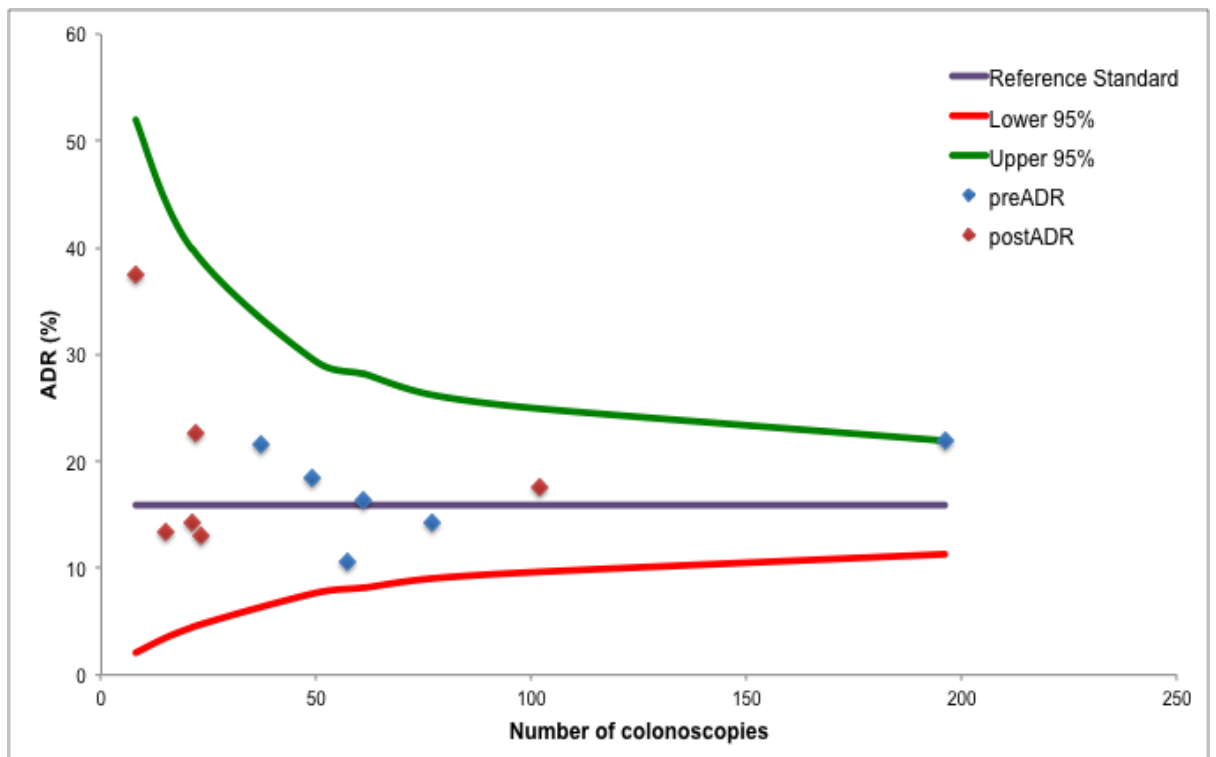
Unit A



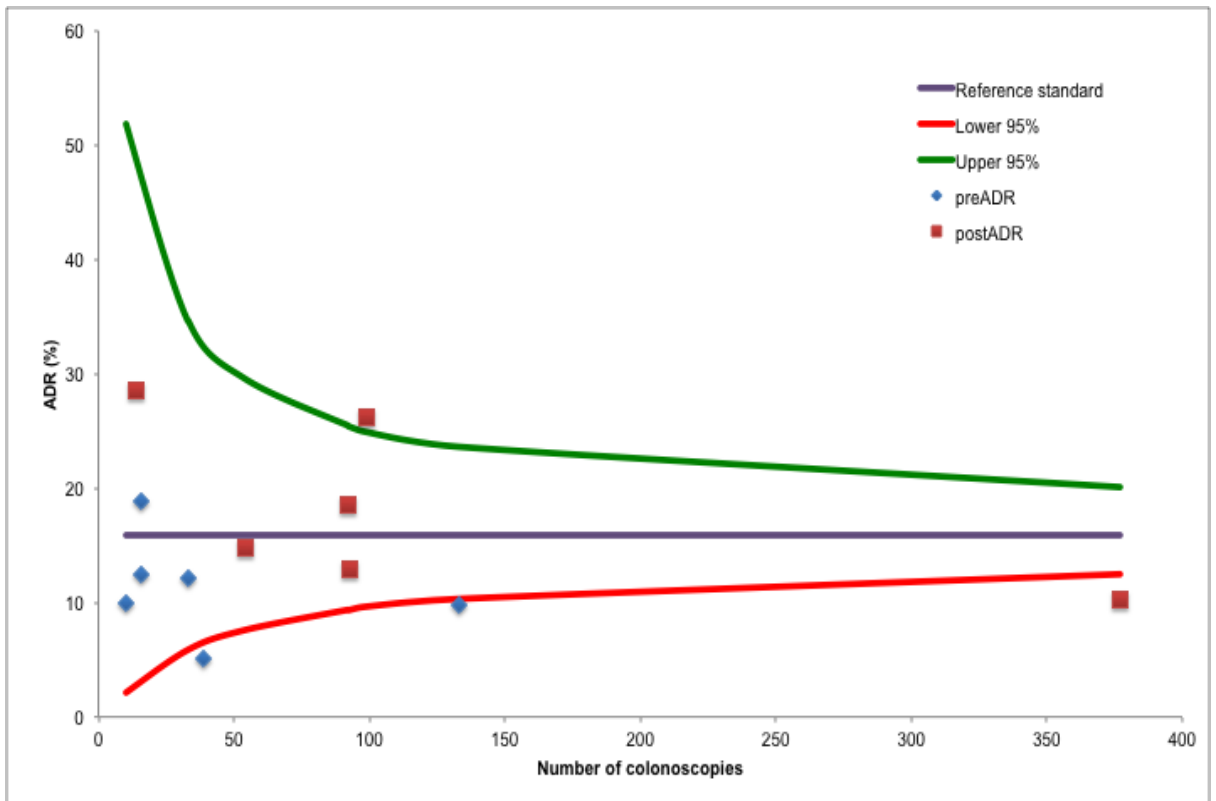
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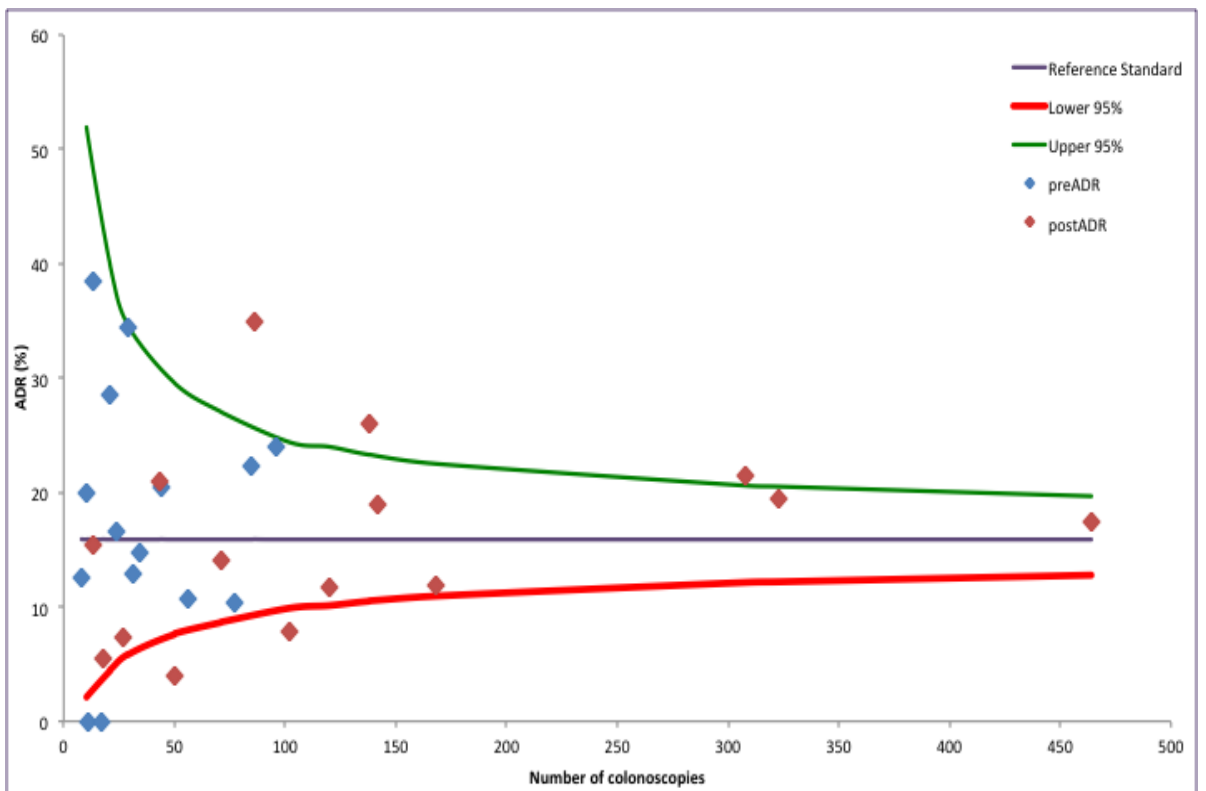
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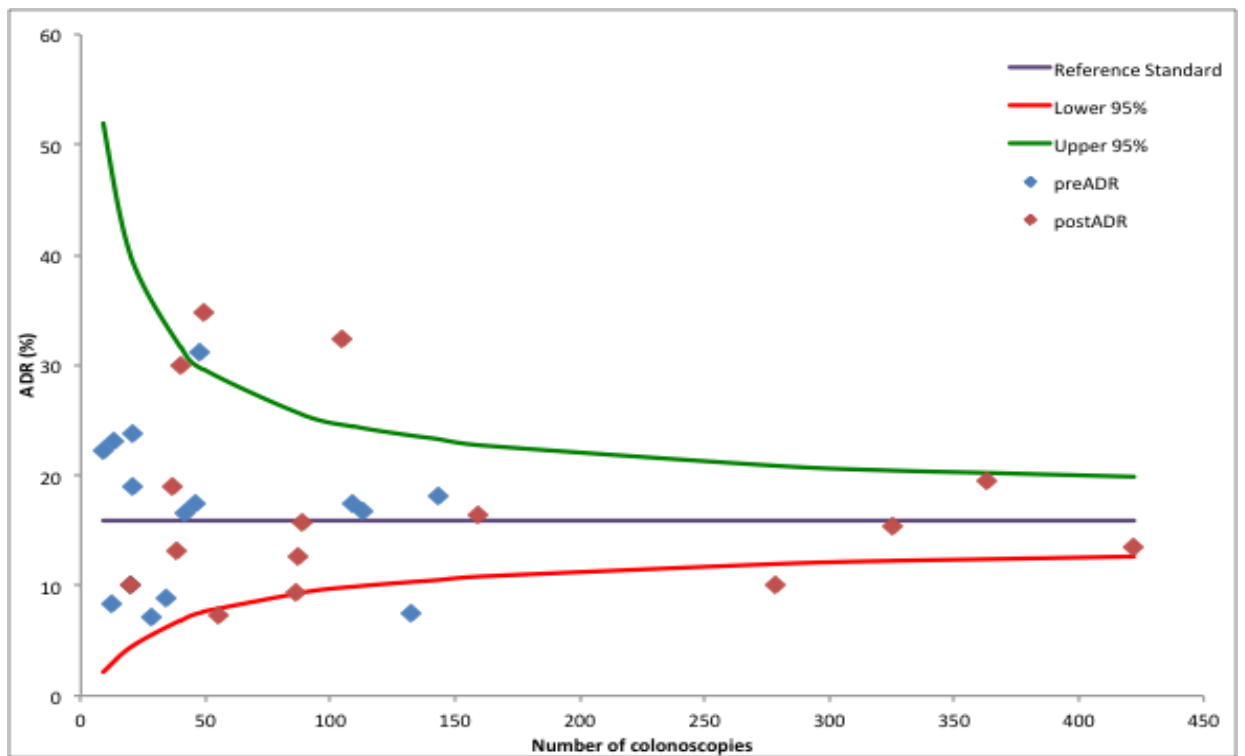
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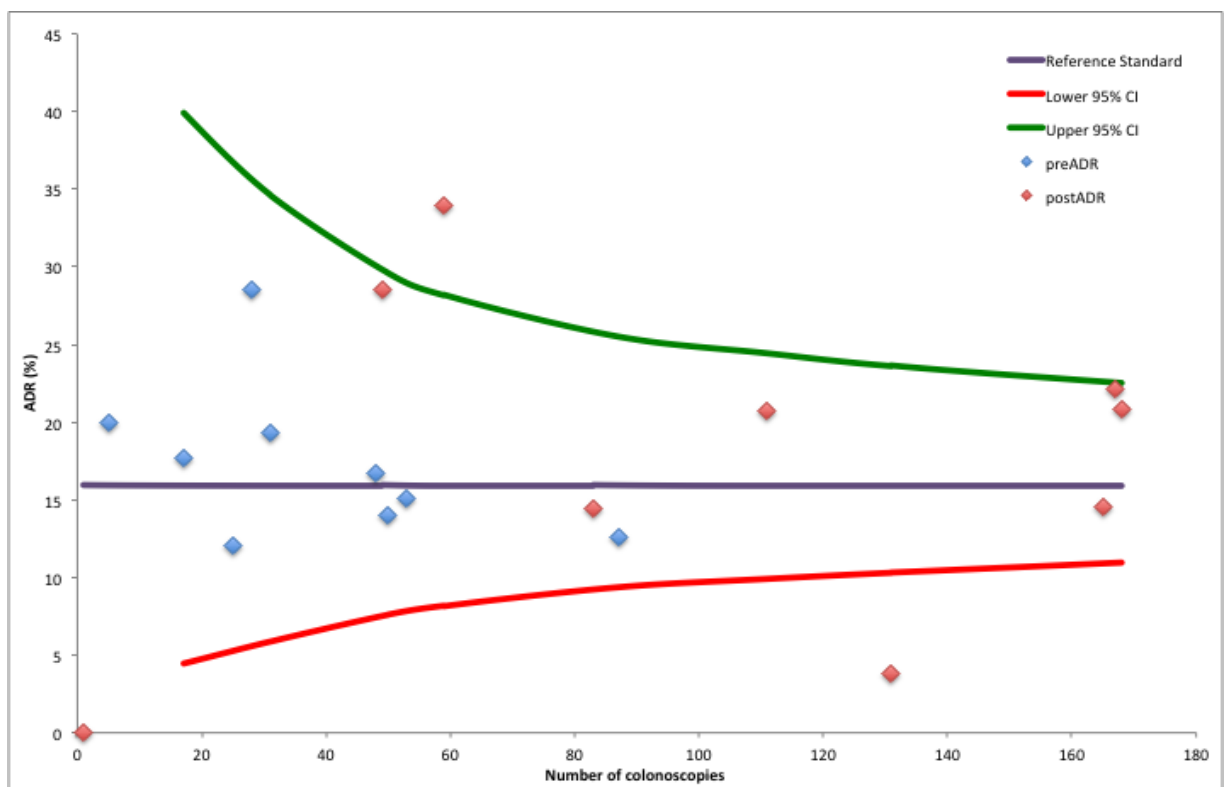
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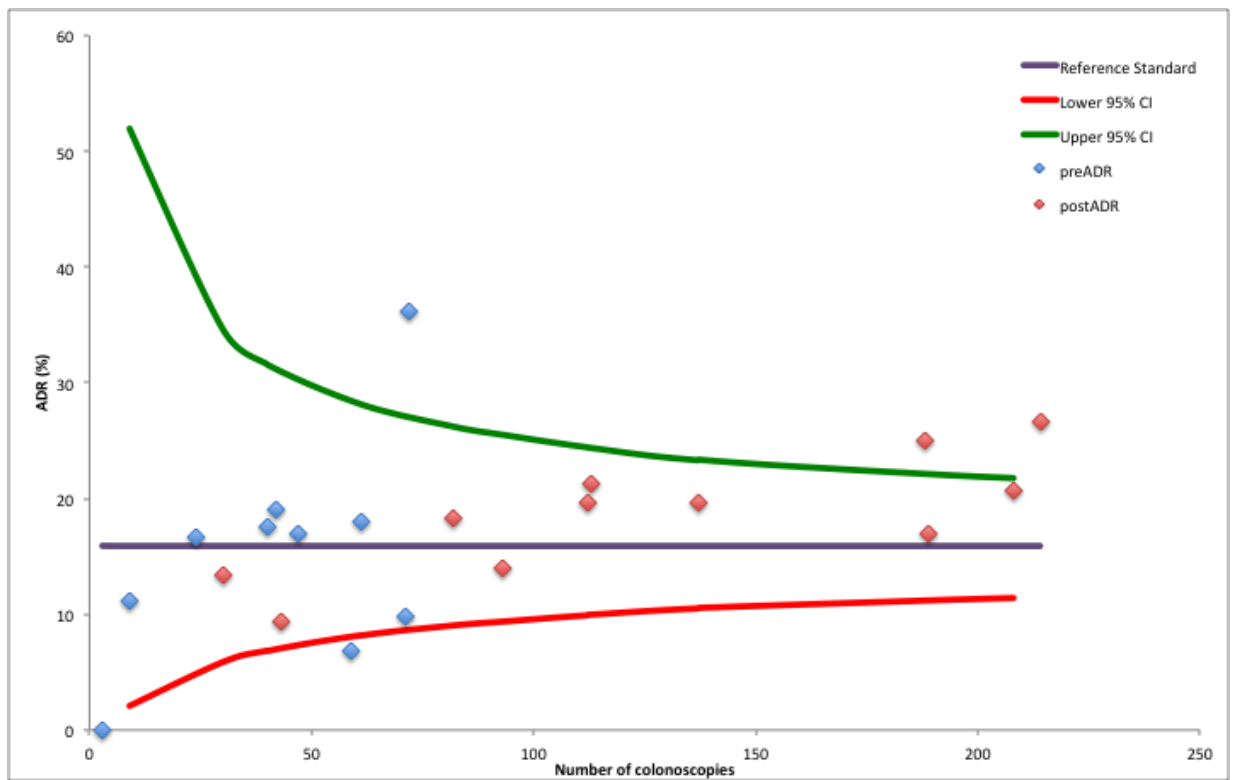
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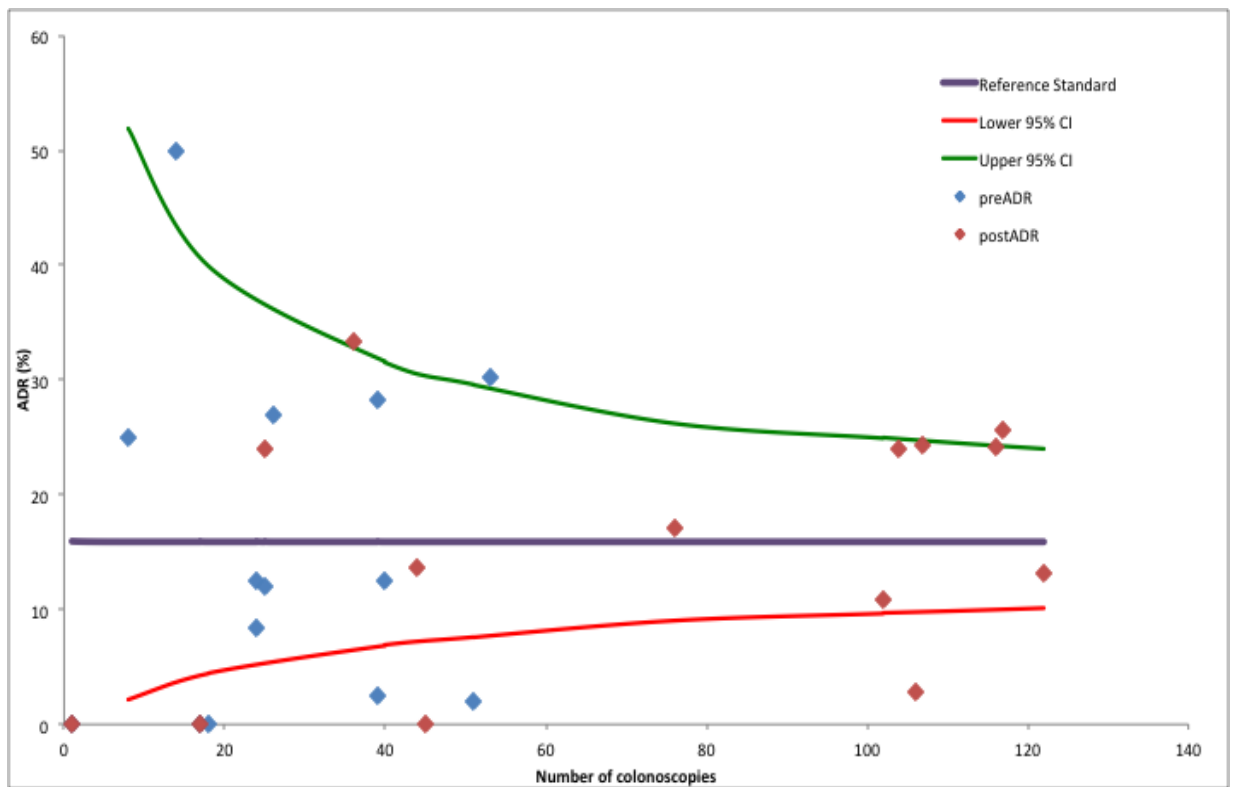
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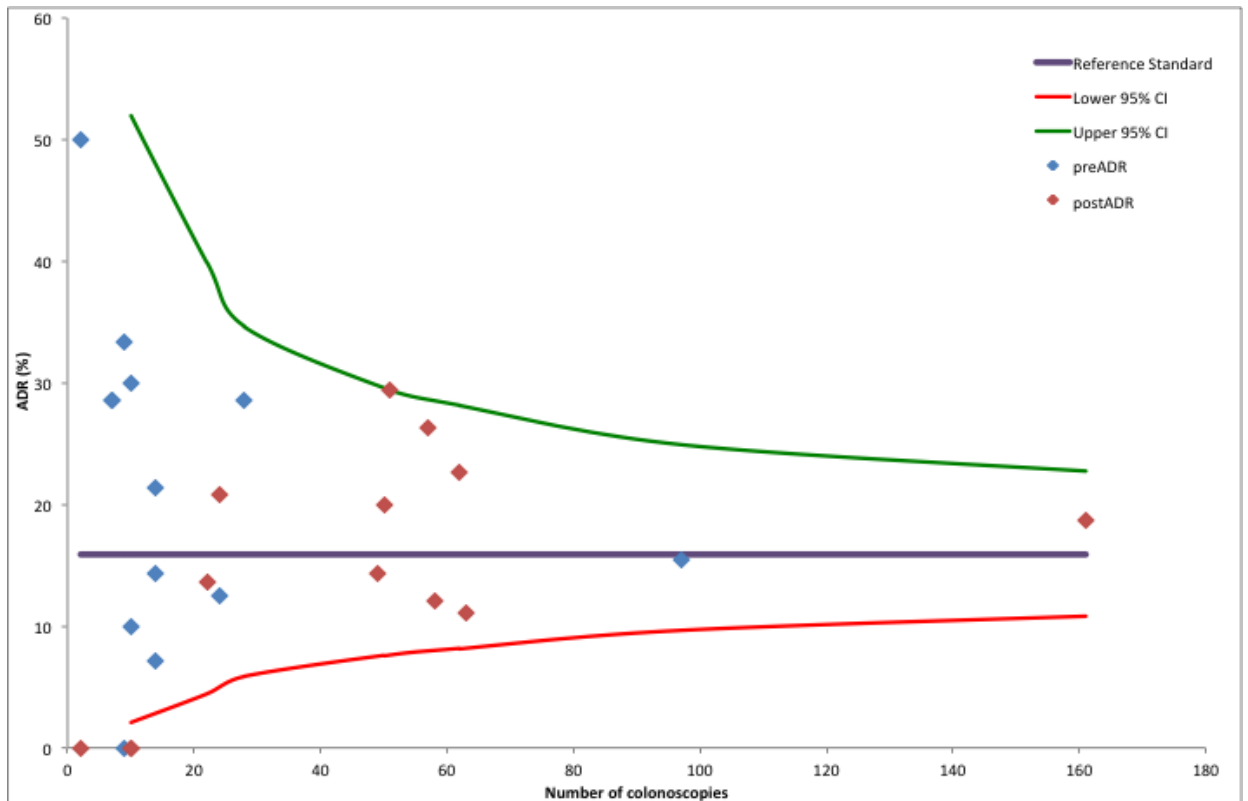
Unit H



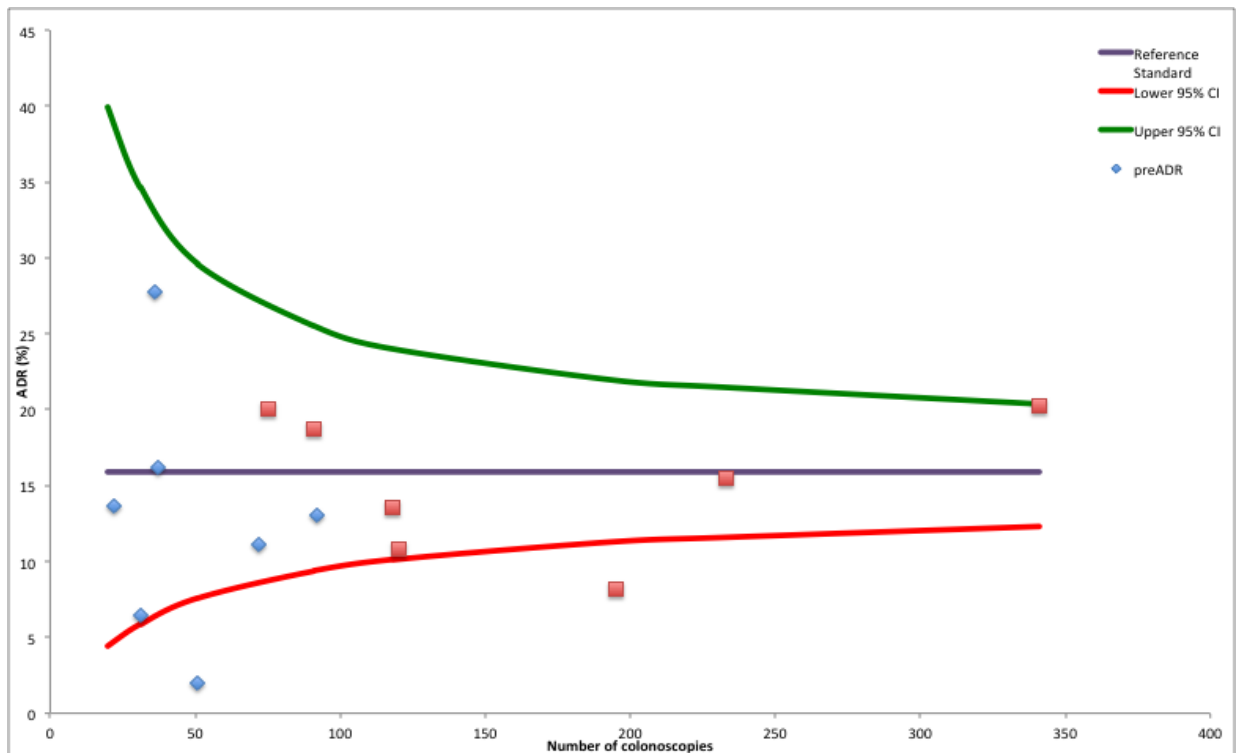
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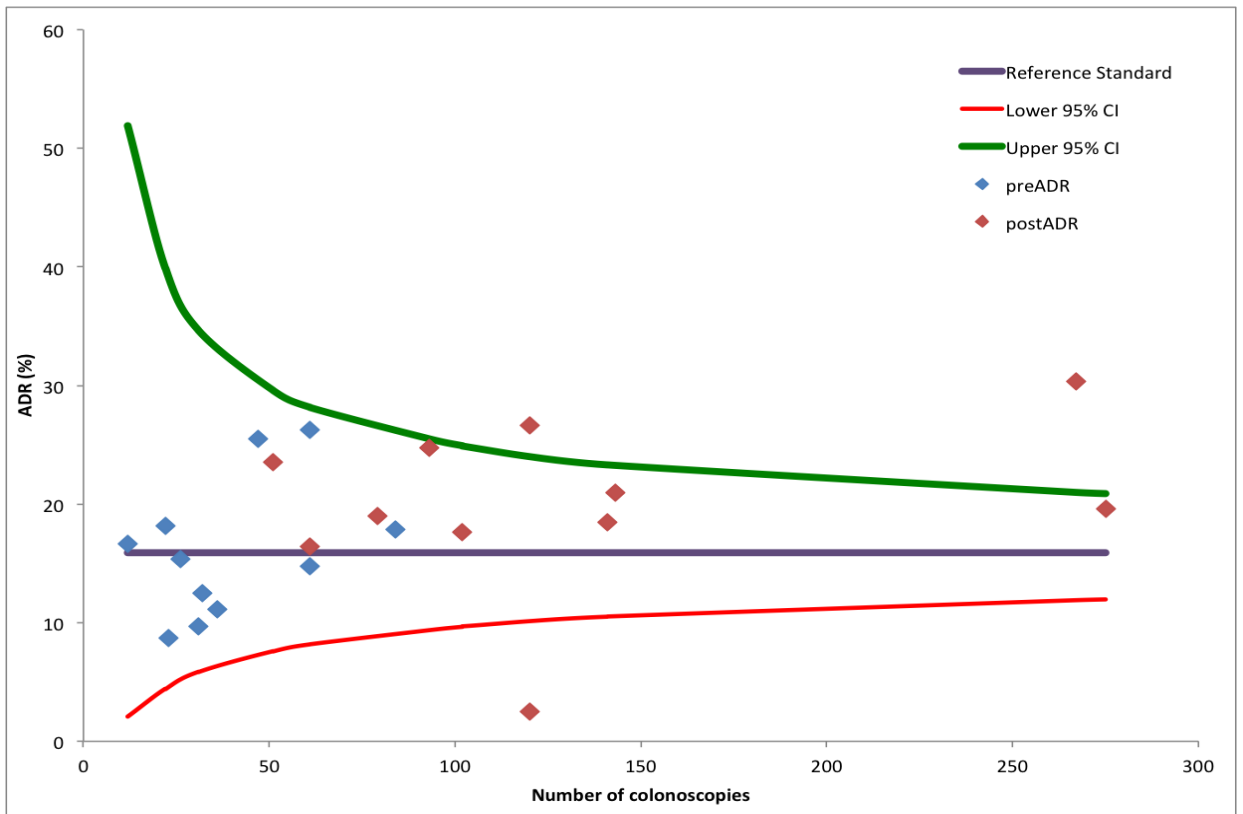
Unit J



Unit K



Unit L



Appendix N



Wolfson Research Institute
Improving health and well-being

Rebecca Maier (nee Perrett)
NHS Engagement Manager, Wolfson Research Institute
Chair, School of Medicine and Health Ethics Sub- Committee
Tel: 0191 334 0425
Email: Rebecca.Perrett@durham.ac.uk

Dr Sally Brown
School of Medicine and Health
The Wolfson Research Institute
Durham University Queen's Campus
Stockton-on-Tees
TS17 6BH
United Kingdom

10th January 2012

Dear Sally,

Re: Ethics Application ESC2/2011/24
**Factors affecting uptake of an evidence based intervention bundle amongst colonoscopists:
a qualitative analysis of the Quality improvement in Colonoscopy (QIC) study.**

Thank you for sending your revisions to the above application to the School of Medicine and Health ethics sub-committee.

I am satisfied that all of the changes requested by the SMH ethics sub-committee at the meeting have been made. I can therefore confirm Durham University ethical approval for you to conduct this study.

Please note that as custodian of the data generated for this study you will be responsible for ensuring it is maintained and destroyed as outlined in this proposal and in keeping with the Data Protection Act.

Please do not hesitate to contact me should you have any questions. Good luck, I hope that the study goes well.

With best wishes

A handwritten signature in purple ink that reads "R Maier".

Rebecca Maier
