Sustained colonoscopy quality improvement using a simple intervention bundle

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ABSTRACT
Background Unacceptable variation in colonoscopy quality exists. The Quality Improvement in Colonoscopy (QIC) study in 2011 improved quality by introducing an evidence-based “bundle” of measures into routine colonoscopy practice. The QIC bundle included: minimal cecal withdrawal time of ≥6 minutes; hyoscine butylbromide use; supine patient position for transverse colon examination; rectal retroflexion. Colonoscopy quality was measured by adenoma detection rate (ADR). The current study measured whether these effects led to a sustained change in practice 3 years following implementation.

Methods This observational study collected data from eight hospital trusts (sites) in the United Kingdom for a 6-month period, 3 years following QIC bundle implementation. Use of the antispasmodic, hyoscine butylbromide, was measured as a marker of bundle uptake. Bundle effectiveness was measured by ADR change. Comparisons were made between data before and immediately after implementation of the bundle.

Results 28,615 colonoscopies by 188 colonoscopists were studied. Hyoscine butylbromide use increased from 15.8% pre-implementation to 47.4% in the sustainability phase (P<0.01) indicating sustained engagement with QIC measures. ADR was higher in the sustainability period compared with pre-intervention, but only reached statistical significance among the poorest-performing colonoscopists.

Conclusions The introduction of a simple, inexpensive, pragmatic intervention significantly changed practice over a sustained period, improving colonoscopy quality as measured by ADR, particularly in poorer performers. QIC demonstrates that an easy-to-implement quality improvement approach can deliver a sustained change in practice for many years post intervention.
Introduction

Colonoscopy is the gold standard investigation of the lower gastrointestinal tract and is widely performed, with over 500,000 procedures performed annually in England and 15 million performed annually in the United States [1,2]. High quality colonoscopy is crucial to ensure adequate mucosal visualization and maximize detection of pathology. However, variation in quality of colonoscopy exists [3,4]. The adenoma detection rate (ADR) is the most widely used colonoscopy quality indicator and is defined as the proportion (%) of procedures where at least one adenoma is found in a patient [5–7]. Colonoscopists with low ADRs have significantly higher rates of post-colonoscopy colorectal cancers and poorer outcomes in their patients [8–10]. Approaches to improving ADRs have included enhanced optics, devices attached to the colonoscope tip, feedback, and leadership training.

Several studies aiming to improve ADR through practice change have been undertaken; however, only one study has demonstrated significant ADR improvement and this was among expert bowel cancer screening colonoscopists [11,12]. These results have not yet been replicated in a non-expert colonoscopist cohort. Multimodal approaches have been adopted to incorporate a number of measures to improve colonoscopy quality. The Endoscopic Quality Improvement Program (EQUIP) combined educational sessions with feedback and demonstrated ADR improvements; however, similar improvements were seen in control groups that received only passive monitoring [13].

Introducing evidence-based medicine into clinical practice is challenging, with multiple potential barriers including lack of time for training, perceived lack of time to implement change, and uncertainty regarding the impact of change [14]. Pronovost et al. demonstrated that a “bundle” of interventions could be successfully implemented by combining training, feedback, and support to reduce catheter-related bloodstream infections in intensive care units [15]. Using a similar approach, the Quality Improvement in Colonoscopy (QIC) study, previously published in Endoscopy, changed practice by introducing an evidence-based bundle of measures into routine colonoscopy practice (Fig. 1): colonoscopy quality, as measured by ADR, was improved [16]. This study is unique in its approach to implementing a bundle of measures in endoscopy.

QIC was a large, multicenter, pragmatic study undertaken within the Northern Region Endoscopy Group (NREG), a well-organized endoscopy research network in the North East of England [17]. The study consisted of central and local training, in addition to anonymized contemporaneous performance feedback. The bundle included a number of evidence-based measures: minimal cecal withdrawal time of ≥6 minutes; hyoscine butylbromide use; supine patient position for examination of the transverse colon; rectal retroflexion. Hyoscine butylbromide use (licensed in Europe as an antispasmodic) increased, as did ADR, the latter particularly among colonoscopists with low baseline ADRs, where ADR almost doubled in the lower quartile of performers.

Our hypothesis was that the effects of the pragmatic QIC intervention would lead to a sustained change in practice. We aimed to evaluate ongoing uptake of the bundle in addition to colonoscopy quality 3 years following implementation, without delivery of any further interventions or training during the 3-year period.

Methods

Data were collected from original study sites on a per-endoscopist basis for a 6-month period (January 2014–June 2014), 3 years following implementation of the QIC bundle. The sites were all based in North East England and were part of the NREG network, including: South Tyneside District Hospital, South Shields; Sunderland Royal Hospital, Sunderland; Queen Elizabeth Hospital, Gateshead, Cumberland Infirmary, Carlisle; Northumbria Healthcare Trust; County Durham and Darlington NHS Foundation Trust; North Tees and Hartlepool NHS Trust; James Cook University Hospital, Middlesbrough. Patients undergoing bowel cancer screening procedures within the English National Health Service (NHS) have a much higher adenoma rate as they have all had a positive fecal occult blood test (FOBT). NHS Bowel Cancer Screening Programme (BCSP) colonoscopists were therefore excluded from the study, as it was not feasible to easily distinguish between BCSP and symptomatic procedures in this cohort, and higher ADR in FOBT-positve procedures would have influenced the data.

Procedural information was collected including total number of colonoscopies, cecal intubation rate, ADR, hyoscine butylbromide (Buscopan; Sanofi, Reading, UK) usage rate, colonoscopist specialty and grade, mean patient age, and proportion of male patients. All participating units used electronic endoscopy reporting systems, which enabled data collection.
All units recorded polyp detection rate and hyoscine butylbromide use; however, only one unit routinely reported ADR. Histopathology reporting systems were therefore interrogated to allow ADR calculation.

Comparisons were made across the three phases of data collection: 1) pre-intervention (pre-QIC) data were collected for 3 months prior to bundle implementation and demonstrated colonoscopists’ baseline performance; 2) post-intervention (post-QIC) data were collected for a duration of 9 months following completion of bundle implementation; 3) sustainability data were collected for a 6-month period, 3 years following implementation of the bundle (Fig. 2). The sustainability data were the only fresh data collected for the present study, and were compared with the first two phases of data collection as outlined in the original QIC study [16].

Outcomes
The primary outcome measure for this study was rate of hyoscine butylbromide use. This was used as a readily measurable and consistent marker of uptake of the bundle, and therefore of change in practice. It was not possible to measure uptake of other components of the bundle because of inconsistent reporting. Effectiveness of the bundle was measured by change in ADR, defined as the number of procedures in which at least one adenoma was found.

Statistical analyses
Data were compared across all procedures and by endoscopy unit. Colonoscopists for whom data were available across all three phases of data collection were ranked and analyzed by baseline ADR into four quartiles. The analysis was performed using multilevel logistic regression. When the data from all units were included in the analysis, three-level models were used, with individual patients contained within colonoscopists, who in turn were nested within units. When the data from each unit were analyzed separately, two-level models were used with individual patients nested within colonoscopists. The predictor variable was the time of measurement (pre-QIC, post-QIC, or QIC sustainability period).

Ethical approval
Sunderland Research Ethics Committee, UK, waived the need for full ethical review for the original QIC study as it was a service improvement initiative in which all participating units would receive the intervention. As the sustainability phase simply involved collecting data, ongoing local research and development and data access approvals were obtained.

Results
Sustainability data were collected from 1 January 2014 to 30 June 2014 inclusive (Fig. 2). All original QIC sites participated in the sustainability phase including 12 endoscopy units housed within eight institutions. All of these sites were district general (community) hospitals. A total of 188 colonoscopists performed procedures during the study period and were included in the overall analyses; however, only 50 colonoscopists performed colonoscopies across all phases of data collection. Colonoscopists performing procedures in all phases were ranked into quartiles according to their baseline ADR.

A total of 28615 colonoscopies were included for analyses at the level of the colonoscopist, unit, and overall: 4351 pre-intervention, 13158 post-intervention, and 11106 in the sustainability phase. A total of 14435 colonoscopies were included in the analyses at quartile level: 2556 pre-intervention, 7252 post-intervention, and 4627 in the sustainability phase. The mean patient age in each phase was 60, 61, and 60 years, respectively. The mean proportion of male patients in each phase was 46%, 45%, and 47%, respectively. Within the four quartiles, colonoscopists were comparable by specialty and experience level.

Uptake of the bundle: hyoscine butylbromide use
Overall, a significant increase in hyoscine butylbromide use was demonstrated, from 15.8% pre-implementation to 47.4% in the sustainability phase (P<0.01). This was replicated in all endoscopy units and all quartiles (Table 2). Overall, the odds of hyoscine butylbromide use were over 11 times higher in the post-intervention phase than in the pre-intervention phase, and the odds of hyoscine butylbromide use were over 9 times higher in the sustainability period than in the pre-intervention phase. The largest differences in rates of hyoscine butylbromide use were seen in the upper colonoscopist quartiles, where the odds of its use were over 16 times higher in the post-intervention and sustainability phases compared with baseline (P<0.001).

Effectiveness of the bundle: ADR
A significant increase in ADR was observed, from 16.0% to 18.0% (P=0.02) in the first two phases of the study, with a sustained increase in ADR to 18.2% 3 years following implementation of the bundle (P=0.09). At the endoscopy unit level, only one

<table>
<thead>
<tr>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<tbody>
<tr>
<td>Oct</td>
<td>Nov</td>
<td>Dec</td>
<td>Jan</td>
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<tr>
<td>Pre-QIC Implementation Post-QIC Sustainability Phase</td>
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</table>

Fig. 2 The Quality Improvement in Colonoscopy (QIC) data collection timeline.
endoscopy unit demonstrated a statistically significant change in ADR in the pre-QIC compared with the post-QIC analysis; however, this was not sustained (Fig. 3).

Where data were available at endoscopist level across all phases of the study, ADR significantly increased from 16.3% pre-intervention to 19.3% post-intervention ($P=0.003$) and 18.2% in the sustainability phase ($P=0.14$). Although ADR was higher in the sustainability period compared with pre-intervention, this only reached statistical significance in the lowest colonoscopist quartile. Improvement in ADR was most marked in the lower ranking colonoscopist quartiles (Fig. 4).

### Discussion

Changing practice and implementing evidence-based procedures is a challenge. This study reports a simple, pragmatic, inexpensive approach, which led to a major change in practice with sustained results 3 years after the training intervention. First, uptake of the bundle and therefore change in practice, as measured by the use of hyoscine butylbromide antispasmodic, was sustained 3 years following implementation, without the need for further study promotion or training sessions. This effect was seen in all units and among all colonoscopist quartiles. Hyoscine butylbromide was included as a component of this bundle as it is widely available in Europe and is used as an antispasmodic to improve mucosal views [18]. As documentation of medication usage is mandatory in endoscopy reporting systems, documentation of hyoscine butylbromide use was the most obvious measure of bundle uptake.

Second, this study evaluated the effect of the intervention on ADR. Although, overall, ADR significantly increased immediately following implementation of the bundle, the ongoing improvement in ADR seen in the sustainability phase did not reach statistical significance. Where data were present for all three study periods, a significant, sustained improvement in ADR was seen in the poorest-performing colonoscopists was seen, (i.e. those with the lowest baseline ADRs and therefore those more strongly associated with post-colonoscopy colorectal cancer). Although ADR fell in the upper colonoscopist quartile between pre-QIC and post-QIC phases, this did not reach statistical sig-

### Table 1 Hyoscine butylbromide usage rate per endoscopy unit.

<table>
<thead>
<tr>
<th>Endoscopy unit</th>
<th>Hyoscine butylbromide use rate, %</th>
<th>Hyoscine butylbromide use, OR (95%CI)</th>
<th>$P$ value pre- vs. sustainability phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-QIC</td>
<td>Post-QIC</td>
<td>Sustainability</td>
</tr>
<tr>
<td>A</td>
<td>11.9</td>
<td>49.0</td>
<td>41.3</td>
</tr>
<tr>
<td>B</td>
<td>2.6</td>
<td>38.8</td>
<td>28.9</td>
</tr>
<tr>
<td>C</td>
<td>13.3</td>
<td>56.3</td>
<td>54.2</td>
</tr>
<tr>
<td>D</td>
<td>25.4</td>
<td>66.7</td>
<td>39.6</td>
</tr>
<tr>
<td>E</td>
<td>14.4</td>
<td>44.8</td>
<td>57.1</td>
</tr>
<tr>
<td>F</td>
<td>24.1</td>
<td>50.7</td>
<td>40.2</td>
</tr>
<tr>
<td>G</td>
<td>19.5</td>
<td>71.8</td>
<td>57.5</td>
</tr>
<tr>
<td>H</td>
<td>12.8</td>
<td>59.6</td>
<td>45.0</td>
</tr>
<tr>
<td>All</td>
<td>15.8</td>
<td>54.4</td>
<td>47.4</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; QIC, Quality Improvement in Colonoscopy.

### Table 2 Hyoscine butylbromide usage rate per endoscopist quartile.

<table>
<thead>
<tr>
<th>Quartile*</th>
<th>Hyoscine butylbromide use rate, %</th>
<th>Hyoscine butylbromide use, OR (95%CI)</th>
<th>$P$ value pre- vs. sustainability phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-QIC</td>
<td>Post-QIC</td>
<td>Sustainability</td>
</tr>
<tr>
<td>Q1: Upper</td>
<td>19.1</td>
<td>71.7</td>
<td>77.2</td>
</tr>
<tr>
<td>Q2: Upper middle</td>
<td>25.6</td>
<td>58.9</td>
<td>57.3</td>
</tr>
<tr>
<td>Q3: Lower middle</td>
<td>7.6</td>
<td>36.4</td>
<td>34.3</td>
</tr>
<tr>
<td>Q4: Lower</td>
<td>9.3</td>
<td>45.9</td>
<td>39.9</td>
</tr>
<tr>
<td>All</td>
<td>15.5</td>
<td>52.9</td>
<td>52.2</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; QIC, Quality Improvement in Colonoscopy.

* Colonoscopists were divided into four quartiles according to their baseline adenoma detection rate.
**Fig. 3** Adenoma detection rate per endoscopy unit.

**Fig. 4** Adenoma detection rate per endoscopist quartile.
nificance. A potential explanation for this is regression to the mean as the post-intervention dataset was larger, and similar performance is seen in post-QIC and sustainability phases.

The main limitation of this study was lack of a control group. The rationale for this methodology was that as a pragmatic service improvement project, it was considered important that all units and colonoscopists had access to the intervention, which was based upon evidence for efficacy. Hyoscine butylbromide is used in Europe as an antispasmodic and although it is not available globally, for example in the USA, it is reported in this context as a marker of engagement with the QIC bundle. The benefits of hyoscine butylbromide on ADR are inconclusive, owing to heterogeneity within current studies [19]. Notably, within the UK there have been recent cautions issued regarding the routine use of hyoscine butylbromide [20], particularly in patients with pre-existing cardiac disease. In light of this, the authors repeat the guidance that contraindications to the use of hyoscine butylbromide should be carefully considered and accept that in future the raised anxiety regarding its use may influence ongoing uptake of aspects of the QIC bundle. Other components of the bundle are not routinely recorded within the study region and therefore it was not possible to comment on uptake of these components. Some colonoscopists may not have implemented all parts of the bundle but it is an accepted limitation of this study that it was not a randomized trial but a pragmatic study to explore whether practice could be changed easily. Furthermore, owing to limitations in reporting systems across the region, it was not possible to explore potential confounding variables, such as procedure indication, bowel preparation, equipment used, or endoscopist technique. These factors were not explored in the original QIC study [16]. As this was a “before and after” study and not a randomized controlled trial, some caution should be taken when interpreting the results; the possibility cannot be excluded that some other event may have caused the change (e.g. change in practice or different populations). It was stated in the original paper, but is worth repeating, that hyoscine butylbromide use was taken as a marker of bundle compliance and should not be misinterpreted as directly correlating with the change in ADR.

Service improvement projects are often targeted at poorly performing groups. This study demonstrated sustained improvement in ADR, driven by the poorest-performing colonoscopists. Within the lowest colonoscopist quartile, ADR was sustained at 15.9%, compared with 8.0% pre-intervention, an almost doubling in performance, which would have moved these endoscopists into the lower middle quartile pre-QIC. Corley et al. previously demonstrated that each 1.0% absolute increase in ADR is associated with a relative 3.0% decrease in the risk of interval cancer [9]. More recently Kaminski et al. demonstrated that improving ADR through benchmarking and feedback translates into lower post-colonoscopy cancer rates [10]. With this in mind, introducing this bundle into routine colonoscopy practice should improve outcomes by reducing variation in colonoscopy quality [4].

It is important that evidence-based interventions are included within the bundle to maximize the effect on ADR. Potential barriers to introduction of the bundle into routine practice may include reluctance to change, individual uncertainty as to the effect or necessity of such an intervention, and perceived lack of time to introduce the bundle. One way to overcome this may be to introduce the approach into basic colonoscopy training courses, which are mandatory to achieve complete colonoscopy accreditation in the UK. It is possible that the improvement in the poorest-performing endoscopists in the current study was not simply limited to bundle implementation and may have occurred due to changes in practice prompted by feedback given in the original QIC study. However, hyoscine butylbromide use in these groups did increase, suggesting that implementation of the bundle had a role.

The intervention bundle was viewed positively by endoscopists, and the simple study posters (Fig. 1) were reported to be a useful reminder [14].

There is a growing body of evidence for other interventions to improve ADR through improved mucosal visualization, such as water exchange colonoscopy [21]. Optimizing bowel preparation to ensure adequate visualization is important; however, split-dose preparations have not shown significant improvements in ADR [22, 23].

Recent approaches to improving ADR have also focused on technology and devices, as well as endoscopist characteristics. In addition to high definition colonoscopes, wide-angle colonoscopes have been developed to increase the field of view [24]. Full Spectrum Endoscopy (FUSE; Endochoice inc., Alpharetta, Georgia, USA) is one such example; however, a randomized controlled trial, systematic review, and meta-analysis have shown no significant difference in polyp or adenoma detection rates compared with standard colonoscopy [25-27].

Devices that attach to the tip of the colonoscope have been devised to improve colonic visualization. The Endocuff Vision (Arc Medical Design Ltd. Leeds, UK) is a second-generation, plastic device with backward-pointing projections that open colonic folds on withdrawal [28]. Studies have reported a significant increase in ADR (40.9% vs. 36.2%) when the Endocuff Vision was used, largely driven by improvements in colorectal cancer screening patients [29, 30].

Providing feedback on colonoscopist performance has also been shown to significantly improve ADR and cecal intubation rates, as has public reporting of ADRs [31-34]. Within the colorectal cancer screening setting, a Polish study introduced leadership training to screening centers with suboptimal performance [35]. When compared with providing feedback alone, those centers that were randomized to leadership training demonstrated larger improvements in ADR [35]. The EQUIP-I, -II, and -III studies showed that simple educational interventions and feedback improve ADR [36, 37]. The benefit of our approach is that only clinical leads for each site were required to attend training sessions and the effects of the study were ongoing at 3 years following the intervention, without the need for further training or feedback.

The bundle approach to changing practice has been used successfully in other areas of clinical medicine, most notably in reducing catheter-related bloodstream infections in the intensive care unit setting [15, 38]. A sustained response was also seen in this setting. The current study is the first within the field
of endoscopy to introduce a bundle of evidence-based measures to change practice, and furthermore is the first to assess the sustainability of an intervention designed to improve ADR over the medium term [11]. The bundle delivered in this study was based upon the best evidence available at the time of the intervention. Future interventions should consider the most up-to-date evidence in order to decide the components of the bundle, taking account of the complexity and cost of the interventions and the ease with which they can be implemented.

This was a large, multicenter, multi-endoscopist study undertaken in a community-based, non-budget setting and is therefore generalizable to routine colonoscopy practice. NHS BCSP colonoscopists were excluded, as screening procedures could not be differentiated and these colonoscopists undergo accreditation exams and are required to demonstrate consistently high quality colonoscopy. It should be noted that ADR in the reported population is lower than in many published colonoscopy series. Bowel cancer screening cases in which all patients are FOBT positive and therefore have a high incidence of adenomas were excluded, and the study included all other indications, hence the lower overall ADR. The factors associated with sustained practice change were not individually evaluated and therefore measures that had the greatest impact cannot be investigated within this study design. Data collection in the sustainability phase was undertaken without ongoing study promotion and therefore reflected true current practice.

The results of this study demonstrate that introducing an evidence-based bundle of measures is an effective way of introducing change into routine colonoscopy practice. Future research in this area should focus on whether the bundle could be modified by introducing further evidence-based measures, in addition to studying which educational approaches most readily change practice. Additional study of poorer performers and non-engagers, a particular challenge for quality improvement initiatives, would be of value.

In conclusion, this simple, inexpensive, pragmatic intervention was able to significantly change practice over a sustained period. While accepting that the effect on change in ADR is modest, there is evidence for sustained improvement, particularly in poor performers, and improving ADR in these colonoscopists has been demonstrated to improve patient outcomes. The primary goal of changing practice was achieved and taking this further to change outcomes is a matter of choosing the best evidence-based interventions to be included within a bundle. Multimodal interventions that target endoscopist, patient, procedure, and unit factors will be needed to maximize ADR and minimize post-colonoscopy colorectal cancer.

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Competing interests

Dr. East has served on clinical advisory boards for Lumendi and Boston Scientific, and has received speaker fees from Olympus and Falk. Prof. Rees has received research grants from ARC Medical, Olympus Medical, Aquilant Endoscopy, and Norgine, and has received travel grants from Boston Scientific and Cook Medical. He is also an advisory board member for AIAGI. All other authors declare that they have no conflict of interest.

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