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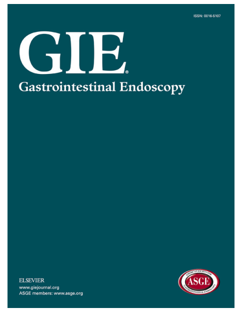

Performance Indicators in Colonoscopy after Certification for Independent Practice: Outcomes and Predictors of Competence

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PERFORMANCE INDICATORS IN COLONOSCOPY AFTER CERTIFICATION FOR INDEPENDENT PRACTICE: OUTCOMES AND PREDICTORS OF COMPETENCE

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ABSTRACT

Background: Robust real-world performance data of newly independent colonoscopists are lacking. In the United Kingdom, provisional colonoscopy certification (PCC) marks the transition from training to newly independent practice. We aimed to assess changes in key performance indicators (KPIs) such as cecal intubation rate (CIR) in the periods pre- and post-PCC, particularly regarding rates and predictors of trainees exhibiting a drop-in performance (DIP), defined as CIR <90% in the first 50 procedures post-PCC.

Methods: A prospective United Kingdom-wide observational study of JETS e-Portfolio colonoscopy entries (N=257,800) from trainees awarded PCC between July 2011-2016 was undertaken. Moving average analyses were used to study KPI trends relative to PCC. Pre-PCC trainee, trainer and training environment factors were compared between DIP and non-DIP cohorts to identify predictors of DIP.

Results: Seven hundred thirty-three trainees from 180 centers were awarded PCC after a median of 265 procedures and 3.1 years. Throughout the early post-PCC period, average CIR surpassed the national 90% standard. Despite this, not all trainees achieved this standard post-PCC, with DIP observed in 18.4%. DIP was not influenced by trainer presence and diminished after 100 additional procedures. On multivariable analysis, pre-PCC CIR and trainer specialty were predictive of DIP. Trainees with DIP incurred higher post-PCC rates of moderate-severe discomfort despite requiring higher analgesic dosages and were more likely to require trainer assistance in failed procedures.

Conclusions: The current PCC requirements are appropriate for diagnostic colonoscopy. It is possible to identify predictors of underperformance in trainees, which may be of value to training leads and could improve patient experience.

BACKGROUND

High-quality training is necessary to achieve high-quality endoscopy. Quality assurance (QA) refers to the monitoring and assessment of a process, to ensure that it is of sufficient quality.[1] Over the last decade, there has been increasing emphasis on QA in endoscopy, driven primarily by 2 factors: increasing evidence of variation in performance and the impact this has on patients,[2,3] and the requirement for bowel-cancer–screening programs to deliver high-quality colonoscopy.[4] The accumulating body of evidence that links endoscopy-based techniques with outcomes has led to the development of endoscopy key performance indicators (KPIs) by national bodies.[5,6] KPIs support QA of training by enabling trainee performance to be continuously monitored and, together with other measures such as competency assessments, gauge readiness for independent practice.[1]

Colonoscopy completion is fundamental to colonoscopy and is a proxy indicator of an endoscopist's technical skills. Failure of completion can result in additional investigations, missed pathology and patient inconvenience. Previous studies have explored the learning curve for competence in colonoscopy using a minimum cecal intubation rate (CIR) of 90% as a competency threshold.[7-10]

In the United Kingdom, certification of endoscopists is overseen by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG). Trainees are required to undergo certification in endoscopy for independent practice. Colonoscopy certification is awarded in 2 stages: provisional and full (**Figure 1**).[11] The process requires trainees to use the JAG Electronic Training System (JETS) e-portfolio, which serves as a procedural logbook with inputs from both trainees and trainers.

Trainees can apply for provisional colonoscopy certification (PCC) once they have met criteria set by JAG (**Figure 1**), ie, completing ≥200 procedures, achieving unassisted CIR ≥90% over the preceding 3 months, and demonstrating satisfactory performance in formative[12] and summative direct observation of procedural skills (DOPS)

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assessments[11,13] to objectively demonstrate competence. PCC is a transition period during which endoscopists progress from full-time supervised training to performing colonoscopy without direct supervision, providing there is available assistance within the department. During this period, trainees are required to continue to submit data into the e-portfolio to be eligible for full colonoscopy certification (**Figure 1**), which allows completely independent practice. Individuals may still receive training after PCC in therapeutic procedures (eg, polypectomy >10 mm). Assessing KPIs before and after PCC provides the novel opportunity to study performance during transition from full-time supervised training to newly independent practice.

There is a lack of data on performance or of factors that might influence performance during the early period of newly independent colonoscopy practice. Studying this performance is important for 3 reasons: it quality assures the performance of endoscopists; it can inform whether the process of certification is adequate; and it is indirectly a measure of quality of training. Such data may be used to quality assure training and identify training factors that may be improved.

AIMS AND OBJECTIVES

The study objective was to assess whether competence in colonoscopy, as measured using the CIR, was maintained after PCC. The PCC date was used to demarcate training and newly independent phases. The primary outcome was the proportion of trainees demonstrating a drop-in performance (DIP), defined as unassisted CIR of <90% during the first 50 post-PCC procedures. CIR was defined as the rate of colonoscopy completion at least to the extent of the cecum or ileo-colon anastomosis, without enlisting physical assistance (trainer manipulation of the endoscope at any point of insertion to the cecum), and included incomplete examinations for any reason, eg, poor bowel preparation or obstructive pathology.

Secondary objectives comprised:

1) Assessing the changes in other KPIs between the pre- and post-PCC periods, including rates of moderate-to-high discomfort scores, levels of sedation use exceeding those recommended in U.K. guidelines,[5] polyp detection rate (PDR), and serious adverse events (SAEs).
2) If a DIP were to exist:
    - Whether factors measured in the pre-PCC period could predict DIP.
    - Whether patient outcomes were affected in endoscopists with DIP.

METHODS

Subjects

We performed a national prospective observational study of trainee colonoscopy entries on the JETS e-portfolio and identified all endoscopists who obtained PCC between July 2011 and July 2016. To investigate KPIs in the early pre- and post-PCC period, data were collected from the first procedure recorded on JETS until the point of PCC, and for a minimum of 50 procedures and maximum of 100 procedures post-PCC. Procedures were limited to <100 post-PCC in order to focus on performance during newly independent colonoscopy practice.

Factors Analyzed

For each trainee, data were collected for every colonoscopy procedure recorded on the JETS e-portfolio. Trainee, trainer and procedural factors (**Supplementary Figure 1**) were retrieved, including the following: procedure date, trainee grade and specialty, nature of supervision (independent vs training), lifetime procedure count, trainer specialty, trainer course attendance, procedure extent, level of physical assistance, trainee limitation, certification date, use of magnetic endoscopic imaging (MEI), endoscopic diagnosis, sedation dosage, endoscopist and nurse reported discomfort scores, and SAEs (perforation, severe bleeding, unexpected admissions). With regard to polyps, trainees were exempt from colorectal cancer screening procedures and were asked to exclude rectal hyperplastic polyps. The outcome of unassisted cecal intubation was deduced from a trainee's extent and role for each procedure (**Supplementary Figure 1**). An independent procedure referred to a procedure performed without a trainer in the endoscopy room. A "training" procedure indicates in-room trainer presence, where a trainee procedure may be recorded as "observed" (unassisted with perhaps verbal assistance) or "assisted physically" (during cecal intubation). Training lists may be dedicated (predetermined ± adapted for a trainee) or ad hoc. Discomfort scores were rated using a validated 5-point Likert scale[14] by both the endoscopist and the attending nurse, with the greater of the 2 used in the case of discrepancies. Rates of moderate to severe discomfort were measured and compared against the U.K. standard of <10%.[5] Rates of intravenous sedation doses exceeding age-appropriate U.K. recommendations[5] were measured and defined as the per-procedure use of >50 mg pethidine (>100 µg fentanyl), >5 mg midazolam or equivalent drugs in patients aged <70, and use of >25 mg pethidine (>50 µg fentanyl), >2 mg midazolam or equivalent drugs in patients aged 70+.

Statistical Analyses

Trends in CIR by trainee experience were first visualized by plotting the observed rates by procedure number relative to PCC using a 10-point moving average method. Changes in CIR around the point of PCC were then assessed using a generalized estimating equation model to account for the non-independence of repeated procedures by the same trainee. A binary variable specifying whether unassisted cecal intubation was achieved was set as the dependent variable, and the procedure number, grouped into blocks of 25, was entered as an independent variable. The trainee identifier and procedure number were set as the between- and within-subjects factors, respectively, and an autoregressive correlation structure applied.

To investigate predictors of post-PCC performance, the cohort was divided into groups at trainee-level of CIR <90% (DIP) and CIR ≥90% (non-DIP) in the 50 procedures post-PCC. Trainer-related factors were based on attributes of the trainers who were most frequently paired with the trainee in the 50 procedures pre-PCC. Continuous variables were reported as medians and interquartile ranges (IQRs) and compared between groups using Mann-Whitney tests, with Chi-square tests used for categorical variables. A multivariable binary logistic regression model was then produced to identify independent predictors of DIP.

Trends in the other KPIs considered were then assessed using segmented linear regression models. For the 200 procedures pre-PCC and 100 procedures post-PCC, the rate of each KPI was calculated across all trainees. Linear regression models were then produced with the KPI rate as the dependent variable, and 2 covariates, the first being the procedure number, and the second taking the value of zero for procedures pre-PCC, and the post-PCC procedure number subsequently. From these 2 covariates, comparisons were made between the gradients of the KPIs in the pre- and post-PCC periods.

Statistical analyses were performed using SPSS v22 (IBM Corp, Arkmont, Ill).

Study Approval

Users of the JETS e-portfolio agreed to a privacy statement declaring that trainee data may be used for audit and research purposes. Formal ethics approval was not required, as the data analyzed was anonymized and contained

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no patient identifiable data.

RESULTS

Study Population

Overall, 733 trainees from 180 U.K. training centers were included, contributing a total of 257,800 procedures (188,026 pre- and 69,744 post-PCC). Trainee specialties comprised the following: gastroenterology (N=376, 51.3%), gastrointestinal (GI) surgeon (N=235, 32.1%), non-medical endoscopist (N=117, 16.0%), and general practitioner (N=5, 0.7%). Trainee grades at PCC consisted of: associate specialist (N=68; 9.3%), consultant (N=36; 4.9%), senior trainees (specialist trainee years 6 to 8) [N=336; 45.8%], junior trainees (specialist trainee years 3 to 5) (N=119; 16.2%), non-medical (nurse) endoscopist (N=117; 16.0%) and clinical research fellow (N=57; 7.8%). PCC was achieved after a median of 265 (IQR 226-333) lifetime procedures, and after a median duration of 3.1y (IQR 2.2-4.2y) after the first recorded colonoscopy procedure.

CIR Relative to PCC

Initially, the CIR was plotted by procedure number relative to certification (**Figure 2**). This demonstrated a near-linear increase in CIR of the cohort in the pre-PCC period, from 62.7% 200 procedures before PCC, to 93.6% at PCC. After this point, the CIR dropped to a nadir of 90.9% (in the 16th procedure post-PCC), before increasing to 94.1% by the end of follow-up (100th procedure post-PCC).

To further assess this change, CIR was compared in blocks of 25 procedures relative to PCC (**Table 1**). This block size was selected in order to balance maximizing the within-block sample size, to have sufficient data to reliably estimate CIR, while maintaining the block width, to give greater granularity for identifying changes in CIR. The CIR declined from 94.7% in the 25 procedures pre-PCC to 92.7% for the 25 post-PCC procedures (p<0.001). The CIR then remained lower than the early pre-PCC period until 76-100 procedures post-PCC, where the difference became non-significant (94.7% vs 94.2%, p=0.076).

Predictors of DIP

Depending on the CIR in the 50 procedures post-PCC, trainees were categorized into DIP (<90%) and non-DIP (90%+) groups. One hundred thirty-five (18.4%) trainees fulfilled the DIP outcome, achieving a median CIR of 86% (IQR: 84%-88%). Univariable analysis was performed to compare various trainee and training factors between the 2 groups (**Table 2**). Trainees without DIP were found to have completed significantly more procedures before PCC than those with DIP, with a median of 266 versus 250 procedures (p=0.031). This association is illustrated in **Figure 3A**, with the proportion of trainees with DIP falling from 22.8% in those who had completed 200 to 224 pre-PPC procedures, to 15.3% in those completing 300+ pre-PPC procedures.

Trainees with DIP were found to have significantly lower terminal ileum intubation rates (p=0.003), CIR (p<0.001) and higher rates of moderate-severe discomfort in the 50 procedures pre-PCC (p=0.011). A difference was observed across trainer specialties (p=0.047), with DIP being least likely in those trained predominantly by gastroenterologists. No significant differences in trainee specialty (p=0.413), grade (p=0.793), predominant type of training (ad hoc vs dedicated lists, p=0.067) or breaks in training (maximum interval between consecutive

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procedures: p=0.573) were detected between groups. Furthermore, there were no significant differences in outcomes according to the degree of training supervision (p=0.432) or MEI use (p=0.616) in the post-PCC phase.

Multivariable analysis was then performed to identify independent predictors of DIP based on the factors considered in the 50 procedures pre-PCC (**Table 3**). The pre-PCC CIR (p<0.001) and main trainer specialty (p=0.025) emerged as significant predictors of DIP. The model suggested that, for those achieving the minimum target CIR of 90% in the pre-PCC period, 25% would miss this target in the 50 procedures post-PCC. However, for the 125 trainees that achieved a pre-PCC CIR of ≥98%, DIP was observed in only 8% (**Figure 3B**). Of those trained predominantly by a non-medical endoscopist, DIP was evident in 27%, compared with 16% of those trained by gastroenterologists (OR, 2.16’ 95% CI, 1.22-3.82; p=0.008) and 21% of those trained by GI surgeons (OR, 1.57; 95% CI, 0.85-2.89; p=0.148).

Trainer Effect Post-PCC

A total of 573 trainees (78.2%) received at least one training session (trainer present) during their first 50 post-PCC procedures. To assess the effect of trainer presence, trainees were divided into 3 groups according to the frequency of training in the 50 post-PCC procedures, namely those where this comprised 0% (N=160), 1-50% (N=299) and >50% (N=274) of procedures. Trainer presence during the post-PCC period was not associated with post-PCC CIR (p=0.636), with DIP rates of 20.0%, 18.1% and 17.9%, respectively (**Figure 4**).

Associations between DIP and other performance indicators

Associations between CIR and other performance indicators during the post-PCC period are presented in **Table 4**. By definition, trainees with DIP are less likely to achieve terminal ileal intubation (p<0.001). The DIP cohort incurred higher rates of moderate-severe discomfort (p<0.001), despite being more likely to exceed the age-appropriate recommended doses for intravenous analgesia, ie, pethidine/fentanyl (p<0.001). The U.K. recommendation threshold of <10% of procedures with moderate-severe discomfort scores[15] was exceeded by 25% of the DIP group, compared with 8% without DIP. The median PDR for the whole cohort in the first 50 procedures post-PCC was 22% (IQR 12%-32%), which was not affected by DIP (p=0.800). Where trainees had failed to achieve independent cecal intubation, trainers were more likely to provide physical assistance and advance the colonoscope proximally in the DIP group (39.4% vs 32.5%, p<0.001). Trainees with DIP were also less likely to document the reason for incomplete procedures (44.0% vs59.1%, p<0.001). In failed procedures where the procedure limitation was documented, there were no differences in reasons for incomplete procedures between groups (p=0.219). The SAE rate was 0.03% and was not affected by DIP (p=0.437).

Trends in Additional KPIs Relative to PCC

Trends in additional KPIs including discomfort scores (**Figure 5A**), PDR (**Figure 5B**) and sedation doses exceeding U.K. thresholds (**Figure 5C**) were also assessed. A segmented linear regression analysis (**Table 5**) found that each of these KPIs improved significantly with procedural experience as trainees approached certification. Over the 100 procedures post-PCC, this improvement continued for each KPI, albeit at a lesser gradient, except for PDR, which appeared to plateau.

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DISCUSSION

Colonoscopy performance metrics during the transition period between training and independent settings have not previously been studied. In this national study involving 733 trainees, the largest trainee colonoscopy cohort to date, we demonstrate that PCC is a reliable marker of competence in diagnostic colonoscopy, as measured by CIR. Despite a reduction in mean CIR from 93.6% to a nadir of 90.9% during the early post-PCC period, where 78% of all procedures were performed independently, overall performance remained above national standards for independent practice.[15]

Our results support the validity of PCC in determining competence for independent diagnostic practice. Certified trainees demonstrated practice that is safe and met national standards after PCC and thereafter, evidenced by trends in CIR, sedation use, procedural discomfort and SAE rates. Quality assurance of training not only involves demonstrating trainee progression to competence within a reasonable timeframe, but also ensuring that competence is maintained as training is withdrawn. This study has confirmed the latter requirement, but both the time (median 3.1 years, IQR 2.2-4.2) and procedural count (median 265) to achieve PCC raises questions about whether the training of colonoscopists in the United Kingdom is optimized. United Kingdom specialty training currently lasts 5 years, with most trainees attaining fewer than 50 procedures within their second year of specialist training.[16] More studies of training pathways (timing, duration, and case exposure), the impact of simulators and quality of training are required to appraise whether training can be delivered in a more effective and efficient manner. National databases such as the JETS e-portfolio are well placed to further evaluate these factors.

The primary outcome of DIP was observed in 18.4%, although this diminished after 100 post-PCC procedures. DIP occurred regardless of post-PCC trainer supervision (**Figure 4**), suggesting that ongoing improvement and refinement of technique are key during the newly independent period. There was no significant difference in DIP rate by trainee specialty or grade, certification in gastroscopy, breaks in training, or trainer TCT course or faculty attendance or use of MEI. Notably, pre-PCC CIR and predominant trainer specialty status were predictors of DIP in the multivariable analysis. Although significant on univariable analysis, neither the lifetime procedural count, nor the pre-PCC terminal ileal intubation rate were associated with DIP in the multivariable analysis because both these factors significantly correlated with, and were displaced by, the pre-PCC CIR in the regression model. DIP rates were higher in non-medical endoscopist versus gastroenterologist supervised trainees. One possible explanation for DIP and the variation by trainer specialty is case-selection bias. During the training period, trainees benefit from a protected training environment with potentially reduced caseload. Patients with previously difficult colonoscopy or high anxiety may refuse to consent to a trainee procedure. Trainers may differ in whether they deem cases as being inappropriate for training and may have differing thresholds in exposing their trainees to difficult or high-risk procedures. As some units implement vetting processes to limit patient selection to lower-risk indications based on trainer credentials, these case-selection biases may explain the higher DIP rates for their trainees when a change in caseload becomes apparent during newly independent colonoscopy. Although limited data suggest that endoscopist specialty may impact on patient outcomes such as CIR,[17] post-colonoscopy colorectal cancer rates,[17] and more recently, a composite outcome combining CIR, sedation and comfort,[18] the effect of trainer specialty on trainee outcomes and efficacy of training has not previously been evaluated and merits further study.

Trainees with DIP had significantly higher rates of adverse patient outcomes, which suggests a need for closer supervision. The DIP group was associated with higher rates of moderate-severe discomfort, while also being more likely to exceed the recommended age-appropriate analgesic dosages recommended in U.K. guidelines. This suggests that despite “trying harder,” trainees with DIP are still achieving lower rates of procedural completion and terminal ileal intubation. There were no significant differences in PDR, sedation-free procedure rates, SAE rates and the reasons given for incomplete procedures between groups. In procedures where trainees had failed to achieve colonoscopy completion, the DIP group were less likely to provide a valid limitation for procedural failure and were more likely to require physical assistance from a trainer to advance the colonoscope and complete the procedure. It is arguable that, without departmental trainer supervision, patients undergoing colonoscopies performed by trainees with DIP are at higher risk of requiring repeat colonoscopy or conversion to alternate

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investigations, in addition to the adverse outcomes discussed above. These may have implications on patient safety, patient satisfaction and healthcare costs. Hence, the ability to identify trainees likely to exhibit a DIP may be of practical value for trainers and training leads to identify and address specific support before PCC, and during the newly independent transition period, to the potential benefit of patients.

Several limitations should be discussed. First, our study was centered on PCC, and not full certification, as the objective was to assess newly independent endoscopists. This was not a comparison of distinct training versus non-training cohorts, as some trainees undergo ad hoc training to help complete difficult procedures and to further develop polypectomy competencies. However, 78% of all post-PCC procedures were performed without trainer observation, and adjustment for trainer frequency was performed (**Figure 4**), which did not demonstrate a trainer effect. Second, the choice of outcomes was specific to diagnostic colonoscopy and did not study polypectomy proficiency and polyp retrieval. PDR was used in place of adenoma detection rate (ADR), as polyp histology is not recorded on the JETS e-portfolio. United Kingdom guidelines recommend an aspirational ADR of 20+% and for PDR to be used as a marker of ADR where validated,[15] but this was not possible with the JETS e-portfolio. Comparisons with national data were also limited by the exclusion of rectal hyperplastic polyps and screening cases. Despite this, the post-PCC trainee PDR of 22% was comparable with the 20.3% reported for diagnostic colonoscopies in the 2011 United Kingdom audit.[19] However, the lack of significant increase in PDR in the early post-PCC period could indicate that, beyond CIR, the learning process in colonoscopy may continue long after independent practice begins. Third, the trainee-orientated JETS e-portfolio data has its limitations. As JETS does not hold trainer KPIs, it is possible that the trainer experience and performance metrics, eg, CIR, annual volume of colonoscopies, screening accreditation, may influence DIP rates. Fourth, our study does not address non-technical factors that may affect endoscopists during the transition period, such as the ability to adapt to the pressures of service lists and managing a less-selected patient caseload, which may not be assessed to the same effect during protected training. Finally, self-entered procedural entries risk trainee selection bias and entry error. However, trainee inputs on the JETS e-portfolio have previously been compared against endoscopy reporting software records and shown to be reliable.[10,20] The current development of the National Endoscopy Database (NED), which aims to export all U.K. trainer and trainee procedural data directly from endoscopy reports to the JETS e-portfolio, will enhance the reliability of future training data, but requires robust validation before implementation.

National bodies, including the American Society for Gastrointestinal Endoscopy and European Society of Gastrointestinal Endoscopy, have set detailed frameworks for training and maintaining competence during independent practice.[6,21] However, none of them detail guidance regarding supportive interventions during early independent practice. Because there are trainees who experience a DIP, these could be targeted for a period of transition monitoring, with experienced endoscopists available in the department to provide support if required. Adopting transitional support in newly independent endoscopists with, or at risk of DIP could benefit the endoscopist and improve the experience and outcomes of patients. Our data suggest that DIP can potentially indicate whether training has been of sufficient quality to prepare trainees for independent colonoscopy. As such, rates of DIP could be considered as a quality metric which could be applied to training programs to quality assure colonoscopy training.

CONCLUSION

A DIP was demonstrated in 18.4% of trainees during newly independent colonoscopy practice. This was not influenced by trainer presence, but was associated with lower CIR and trainer specialty during the pre-PCC period. Trainees with DIP were associated with adverse KPI and patient experience. Identifying endoscopists who may perform less well during the post PCC period will allow more refined selection of patients for their lists and help training leads have the right support available for them during the critical period of early independent practice.

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References

1. Dunckley P, Elta G. Quality assurance of training. Best Practice & Research Clinical Gastroenterology 2011;25:397-407.
2. Kaminski MF, Wieszczy P, Rupinski M, et al. Increased Rate of Adenoma Detection Associates With Reduced Risk of Colorectal Cancer and Death. Gastroenterology 2017;153:98-105.
3. Corley DA, Jensen CD, Marks AR, et al. Adenoma detection rate and risk of colorectal cancer and death. N Engl J Med 2014;370:1298-306.
4. Gray JAM, Patnick J, Blanks RG. Maximising benefit and minimising harm of screening. BMJ 2008;336:480-83.
5. Rees CJ, Thomas Gibson S, Rutter MD, et al. UK key performance indicators and quality assurance standards for colonoscopy. Gut 2016;65:1923-29.
6. Kaminski MF, Thomas-Gibson S, Bugajski M, et al. Performance measures for lower gastrointestinal endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) quality improvement initiative. United European Gastroenterol J 2017;5:309-34.
7. Shahidi N, Ou G, Telford J, et al. Establishing the learning curve for achieving competency in performing colonoscopy: a systematic review. Gastrointestinal Endoscopy 2014;80(3):410-16.
8. Sedlack RE. Training to competency in colonoscopy: assessing and defining competency standards. Gastrointestinal Endoscopy 2011;74:355-66.e2.
9. Spier BJ, Benson M, Pfau PR, et al. Colonoscopy training in gastroenterology fellowships: determining competence. Gastrointestinal Endoscopy 2010;71:319-24.
10. Ward S, Mohammed M, Walt R, et al. An analysis of the learning curve to achieve competency at colonoscopy using the JETS database. Gut 2014;63:1746-54.
11. Joint Advisory Group. JAG trainee certification process: Colonoscopy (provisional and full). [cited 15th January 2018]; Available from: https://www.thejag.org.uk/Downloads/JAG%20Certification%20for%20trainees/Colonoscopy%20application%20criteria%20and%20process.pdf.
12. Siau K, Dunckley P, Valori R, et al. Changes in scoring of Direct Observation of Procedural Skills (DOPS) forms and the impact on competence assessment. Endoscopy 2018 Published Online First: 2018/04/04. doi: 10.1055/a-0576-6667.
13. Barton JR, Corbett S, van der Vleuten CP. The validity and reliability of a Direct Observation of Procedural Skills assessment tool: assessing colonoscopic skills of senior endoscopists. Gastrointest Endosc 2012;75:591-7.
14. Ekkelenkamp VE, Dowler K, Valori RM, et al. Patient comfort and quality in colonoscopy. World Journal of Gastroenterology : WJG 2013;19:2355-61.
15. Rees C, Thomas Gibson S, Rutter M, et al. UK key performance indicators and quality assurance standards for colonoscopy. Gut 2016;65:1923-29.
16. Biswas S, Alrubaiy L, China L, et al. Trends in UK endoscopy training in the BSG trainees' national survey and strategic planning for the future. Frontline Gastroenterology 2017.
17. Baxter NN, Sutradhar R, Forbes SS, et al. Analysis of administrative data finds endoscopist quality measures associated with postcolonoscopy colorectal cancer. Gastroenterology 2011;140:65-72.
18. Valori RM, Damery S, Gavin DR, et al. A new composite measure of colonoscopy: the Performance Indicator of Colonic Intubation (PICI). Endoscopy 2018;50:40-51.
19. Gavin DR, Valori RM, Anderson JT, et al. The national colonoscopy audit: a nationwide assessment of the quality and safety of colonoscopy in the UK. Gut 2013;62:242.
20. Ward ST, Hancox A, Mohammed MA, et al. The learning curve to achieve satisfactory completion rates in upper GI endoscopy: An analysis of a national training database. Gut 2017;66:1022-30.
21. American Society for Gastrointestinal Endoscopy (ASGE). Ensuring Competence in Endoscopy. [cited 15th January 2018]; Available from: http://s3.gi.org/physicians/EnsuringCompetence.pdf.

TABLES

Procedure Number*	Procedures (N)	Cecal Intubation (N, %)		*P* Value
		N (%)	**Odds Ratio (95% CI)**	
-49 to -25	18325	16835 (91.9%)	0.64 (0.58 - 0.70)	**<0.001**
-24 to 0	18325	17348 (94.7%)	1 (Reference)	-
1 to 25	18325	16987 (92.7%)	0.72 (0.65 - 0.78)	**<0.001**
26 to 50	18325	17099 (93.3%)	0.79 (0.72 - 0.86)	**<0.001**
51 to 75	17545	16414 (93.6%)	0.82 (0.75 - 0.90)	**<0.001**
76 to 100	15579	14679 (94.2%)	0.92 (0.84 - 1.01)	0.076

Table 1: CIR by procedure number relative to provisional certification. *Procedure numbers are relative to the time of provisional certification, with negative values being pre-provisional certification. Odds ratios and *P* values are from a generalized estimating equation model performed on a procedure level, which accounted for the correlations between repeated procedures performed by the same trainee. The 25 procedures performed immediately before provisional certification (-24 to 0) were set as the reference category. Bold *P* values are significant at *P* < .05

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Table 2: Characteristics of trainees with CIR<90% (DIP) and CIR90%+ in the 50 procedures post-provisional certification.

	N	CIR in 50 Procedures post-PCC <90% (DIP) N=135	90%+ N=598	*P* value
Pre- Provisional Certification Factors				
Trainee				
Lifetime Procedural Count (Pre-PCC)	733	250 (221 - 311)	266 (228 - 336)	**0.031**
Pre-PCC Duration (Days) [a]	733	1096 (743 - 1566)	1132 (810 - 1532)	0.581
Maximum interval between procedures [b]	733	95 (49 - 217)	100 (52 - 216)	0.573
Trainee Grade [c]	733			0.793
Associate Specialist		12 (8.9%)	56 (9.4%)	
Clinical Research Fellow		7 (5.2%)	50 (8.4%)	
Consultant		6 (4.4%)	30 (5.0%)	
Non-medical Endoscopist		20 (14.8%)	97 (16.2%)	
ST3-5		25 (18.5%)	94 (15.7%)	
ST6-8		65 (48.1%)	271 (45.3%)	
Trainee Specialty	733			0.413
Gastroenterologist		65 (48.2%)	311 (52.0%)	
GI Surgeon		50 (37.0%)	185 (30.9%)	
GP		0 (0.0%)	5 (0.8%)	
Non-medical Endoscopist		20 (14.8%)	97 (16.2%)	
Certification in gastroscopy	732	76 (56.3%)	349 (58.5%)	0.646
Training in the 50 procedures before provisional certification				
Procedures on Training Lists [d]	733	98% (82% - 100%)	98% (78% - 100%)	0.465
Proportion of Training on Dedicated Lists [d]	712	60% (24% - 86%)	51% (13% - 83%)	0.067
Number of Procedures per Week [d]	733	2.4 (1.8 - 3.5)	2.6 (1.8 - 3.8)	0.163
Main Trainer Specialty [e]	710			**0.047**
Gastroenterologist		67 (50.0%)	348 (60.4%)	
GI Surgeon		44 (32.8%)	165 (28.6%)	
Non-medical Endoscopist		23 (17.2%)	63 (10.9%)	
Trainer TCT attendance [e]	712	67 (50.0%)	297 (51.4%)	0.755
Trainer Faculty attendance [e]	712	34 (25.4%)	137 (23.7%)	0.736
DOPS	733	27 (18 - 42)	31 (19 - 48)	0.062
DOPyS	733	7 (5 - 9)	7 (5 - 9)	0.590
KPI in the 50 procedures before provisional certification				
CIR [d]	733	92% (88% - 94%)	94% (92% - 96%)	**<0.001**
Unassisted Terminal Ileal Intubation Rate [d]	733	20% (12% - 40%)	30% (16% - 46%)	**0.003**
Polyp Detection Rate [d]	733	24% (12% - 32%)	22% (12% - 32%)	0.660
Rate of Sedation Doses > Recommended [d]	733	4% (2% - 8%)	4% (2% - 8%)	0.574
Rate of Moderate-Severe Discomfort [d]	733	2% (0% - 6%)	2% (0% - 4%)	**0.011**
After provisional certification training factors				
Procedures on Training Lists [f]	733	22% (2% - 68%)	29% (4% - 74%)	0.432
Proportion of Training on Dedicated Lists [f]	573	46% (0% - 79%)	28% (0% - 82%)	0.458
Magnetic endoscopic imaging usage [f]	305	62% (31% - 92%)	72% (16% - 96%)	0.616

Data are reported as median (IQR), with p-values from Mann-Whitney tests, or as N (Column %), with p-values from Chi-square tests, as applicable. Bold p-values are significant at p<0.05. PCC: Provisional colonoscopy certification, DOPS: Direct Observation of Procedural Skills, DOPyS: Direct Observation of Polypectomy Skills, TCT: Training-Colonoscopy-Trainers Course, GP: General Practitioner, ST: Specialist Trainee

[a] The number of days from the first recorded procedure on JETS to PCC.

[b] The maximum number of days between 2 consecutive procedures performed by a trainee in the pre- provisional certification period

[c] At the point of PCC

[d] In the 50 procedures, pre-PCC

[e] Because trainees could have multiple trainers, the trainer present at the most of the 50 pre-provisional certification procedures was used. Where there were ties, the trainer closest to provisional certification was used

[f] In the 50 procedures, post-provisional certification

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Table 3: Multivariable analysis of pre-PCC factors predictive of post-PCC CIR<90%.

Factor (Pre-PCC)	**Odds Ratio (95% CI) for CIR<90% Post-PCC**	***P* value**
Main Trainer Specialty		**0.025**
Gastroenterologist	-	**-**
GI Surgeon	1.38 (0.88 – 2.14)	0.158
Non-medical Endoscopist	2.16 (1.22 – 3.82)	**0.008**
CIR (per Percentage Point)	0.85 (0.81 – 0.89)	**<0.001**

Results are from a multivariable binary logistic regression model, using a forwards stepwise variable selection procedure. All factors from **Table 2** that were measured pre-PCC were considered for inclusion in the model. All of the factors selected for inclusion in the final model related to the 50 procedures pre-PCC. CIR was treated as a continuous covariate, hence the odds ratios represent the increase in the likelihood of a trainee having a CIR<90% in the 50 procedures post-PCC per percentage point increase in the factor. Bold p-values are significant at p<0.05.

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Table 4: Trainee and procedural-level differences in performance indicators according to DIP status. Data are reported as median (IQR), with p-values from Mann-Whitney tests, unless stated otherwise. *In procedures where unassisted CI was not achieved, where a trainer progressed to a more proximal colonic segment than the trainee extent. **In procedures where unassisted CI was not achieved, this was the overall failure rate even after trainer assistance.

	CIR in 50 Procedures Post-PCC		
	<90%	**90%+**	***P* value**
Trainee-Level (KPI) Outcomes	***N*=135**	***N*=598**	
Unassisted Terminal Ileal Intubation Rate	24% (10% - 38%)	34% (16% - 50%)	**<0.001**
Rate of Polyp Detection	24% (10% - 32%)	22% (14% - 32%)	0.800
Rate of Moderate-Severe Discomfort	4% (0% - 10%)	2% (0% - 4%)	**<0.001**
Sedation-Free Procedure Rate	24% (10% - 36%)	20% (8% - 36%)	0.168
Procedure-Level Outcomes	***N*=6750**	***N*=29900**	
Midazolam Doses > Recommended	114/4798 (2.4%)	523/22198 (2.4%)	0.921
Pethidine/Fentanyl Doses > Recommended	227/4901 (4.6%)	753/22067 (3.4%)	**<0.001**
Serious Adverse Events	3 (0.04%)	8 (0.03%)	0.437
Unassisted Cecal Intubation Not Achieved	1035/6750 (15.3%)	1529/29900 (5.1%)	**<0.001**
Trainer Assistance*	408/1035 (39.4%)	465/1529 (32.5%)	**<0.001**
Overall Failure of Completion**	718/1035 (69.4%)	1173/1529 (76.7%)	**<0.001**
Reason Given for Failure	316/718 (44.0%)	693/1173 (59.1%)	**<0.001**
Procedure Limited By			0.219
Patient Discomfort	108/316 (34.2%)	188/693 (27.1%)	
Inadequate Bowel Prep	57/316 (18.0%)	136/693 (19.6%)	
Stricture	54/316 (17.1%)	145/693 (20.9%)	
Unresolved Loop	56/316 (17.7%)	125/693 (18.0%)	
Other	41/316 (13.0%)	99/693 (14.3%)	

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Table 5: Changes in KPIs in the periods pre- and post-PCC

	Pre-PCC		**Post-PCC**		**Change in Gradient**
KPI	***Gradient (95% CI)****	***P* value**	***Gradient (95% CI)****	***P* value**	***P* value**
Moderate/Severe Discomfort	-1.41 (-1.55, -1.28)	**<0.001**	-0.61 (-1.02, -0.21)	**0.003**	**0.002**
Polyp Detection	3.31 (3.07, 3.54)	**<0.001**	-0.50 (-1.20, 0.20)	0.165	**<0.001**
High Sedation Doses	-1.66 (-1.81, -1.50)	**<0.001**	-2.05 (-2.52, -1.59)	**<0.001**	0.167

Results are segmented linear regression models, based on the data in **Figure 5**. For each procedure number, the rates of each KPI were calculated across the cohort of trainees. Linear regression models were then produced, allowing for separate gradients in the periods pre- and post-provisional certification. The p-value in the Change in Gradient column is a comparison of these to regression lines. *Gradients represent the percentage point change per 100 procedures. Bold p-values are significant at p<0.05.

An example interpretation for this table is as follows: before PCC, the rates of moderate/severe discomfort were declining significantly (p<0.001) by 1.41 (95% CI, 1.28-1.55) percentage points for each additional 100 procedures of experience per trainee. At the point of PCC, this rate of improvement slowed significantly (p=0.002), to only 0.61 (95% CI, 0.21-1.02) percentage points per 100 procedures, although this trend was still significant (p=0.003).

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FIGURES

Figure 1: Trainee status in relation to JAG colonoscopy certification.[11] *PCC: provisional colonoscopy certification, DOPS: direct observation of procedural skills, DOPyS: direct observation of polypectomy skills, KPI: key performance indicator, CIR: Cecal intubation rate.*

Figure 2: CIR by procedure number relative to PCC. *Points represent the observed CIR for each procedure number, and lines are 10-point moving averages. Procedure 0 refers to the point of PCC. Inset plot has truncated axes to highlight the changes around the time of PCC.*

Figure 3: Proportion of trainees with DIP according to pre-PCC lifetime procedural count (**Figure 3A**) and CIR (**Figure 3B**).

Figure 4: Association between CIR and degree of post-PCC training. *Lines represent 10-point moving averages over the observed CIRs for each procedure number.*

Figure 5: Rates of moderate/severe discomfort (**Figure 5A**), polyp detection (**Figure 5B**) and sedation doses exceeding JAG recommendations (**Figure 5C**) relative to PCC. *Points represent the observed CIR for each procedure number, and lines are 10-point moving averages. The broken line is plotted at the point of PCC.*

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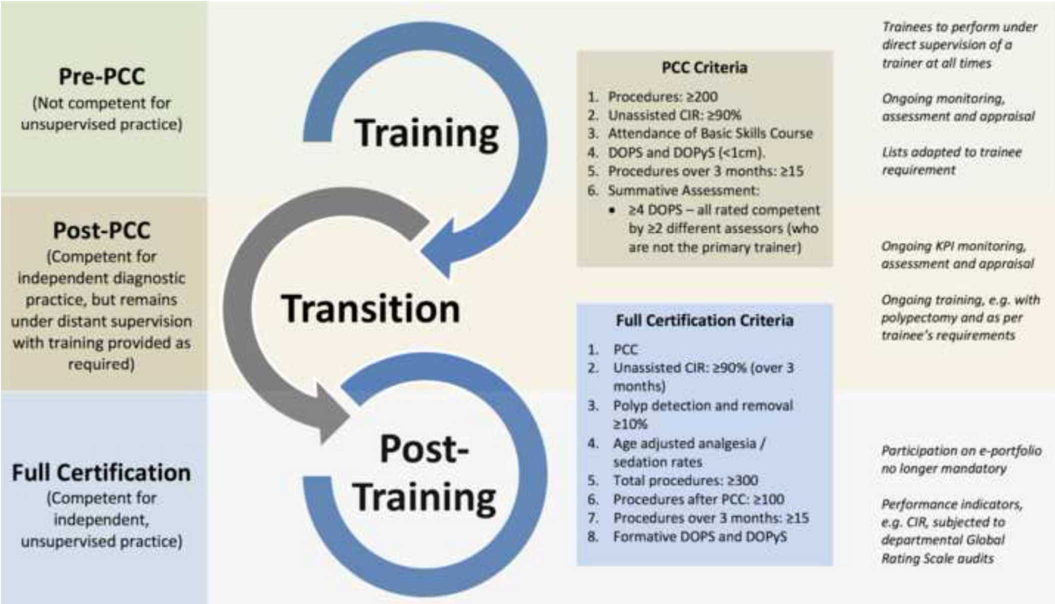
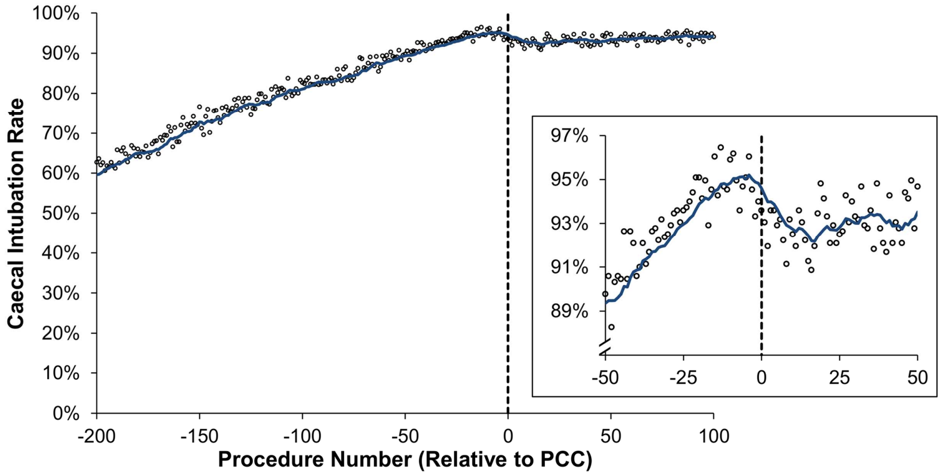

Pre-PCC
(Not competent for unsupervised practice)
Post-PCC
(Competent for independent diagnostic practice, but remains under distant supervision with training provided as required)
Full Certification
(Competent for independent, unsupervised practice)
Training
Transition
Post-Training
PCC Criteria
1. Procedures: ≥200
2. Unassisted CIR: ≥90%
3. Attendance of Basic Skills Course
4. DOPS and DOPyS (<1cm).
5. Procedures over 3 months: ≥15
6. Summative Assessment:
• ≥4 DOPS – all rated competent by ≥2 different assessors (who are not the primary trainer)
Full Certification Criteria
1. PCC
2. Unassisted CIR: ≥90% (over 3 months)
3. Polyp detection and removal ≥10%
4. Age adjusted analgesia / sedation rates
5. Total procedures: ≥300
6. Procedures after PCC: ≥100
7. Procedures over 3 months: ≥15
8. Formative DOPS and DOPyS
Trainees to perform under direct supervision of a trainer at all times
Ongoing monitoring, assessment and appraisal
Lists adapted to trainee requirement
Ongoing KPI monitoring, assessment and appraisal
Ongoing training, e.g. with polypectomy and as per trainee's requirements
Participation on e-portfolio no longer mandatory
Performance indicators, e.g. CIR, subjected to departmental Global Rating Scale audits



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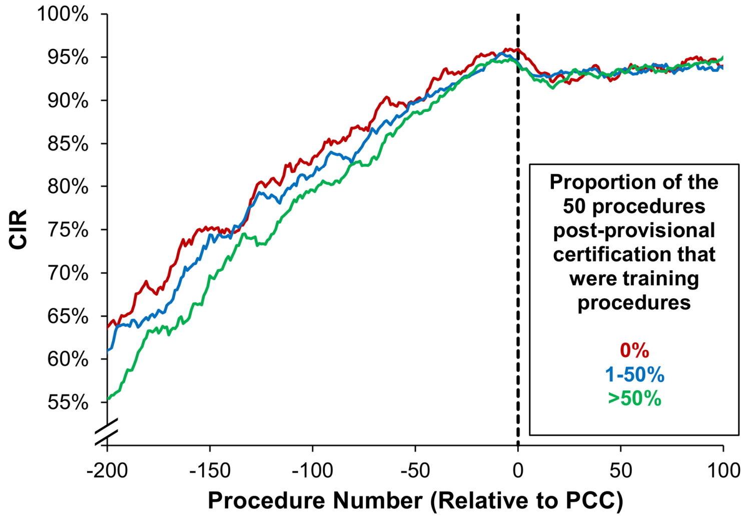

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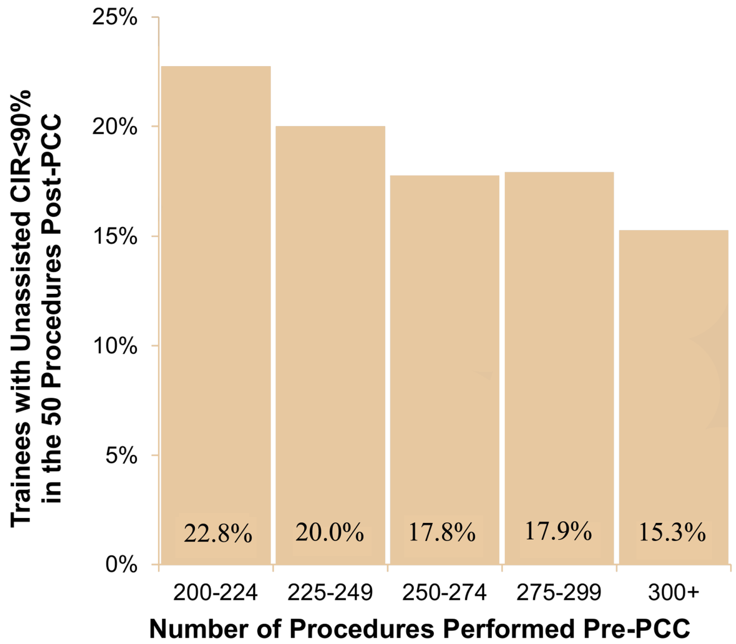

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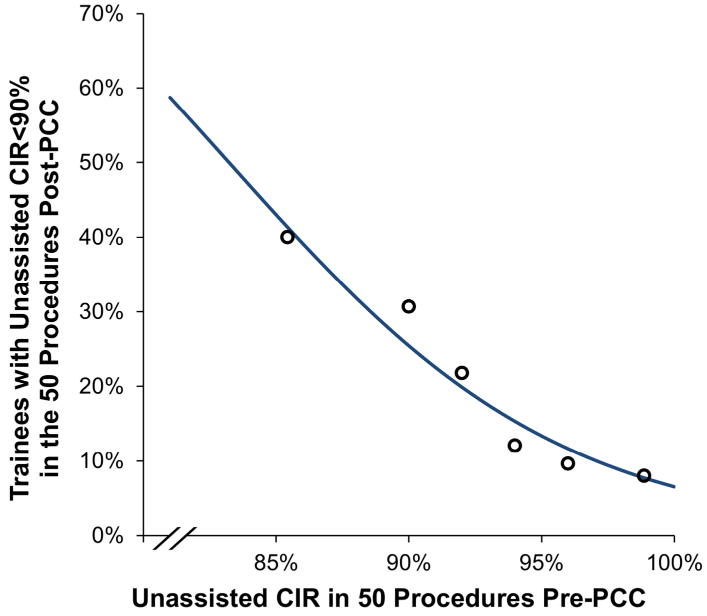

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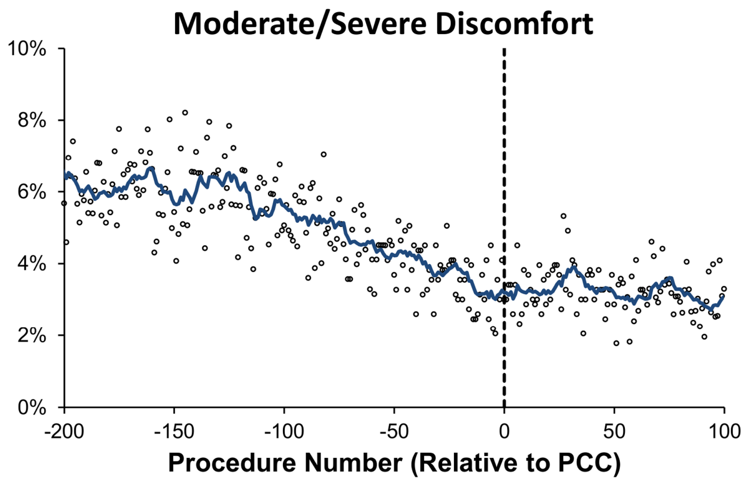

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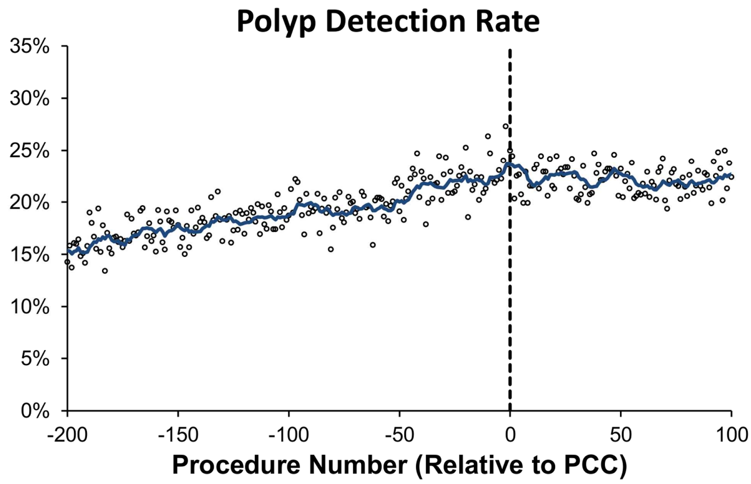

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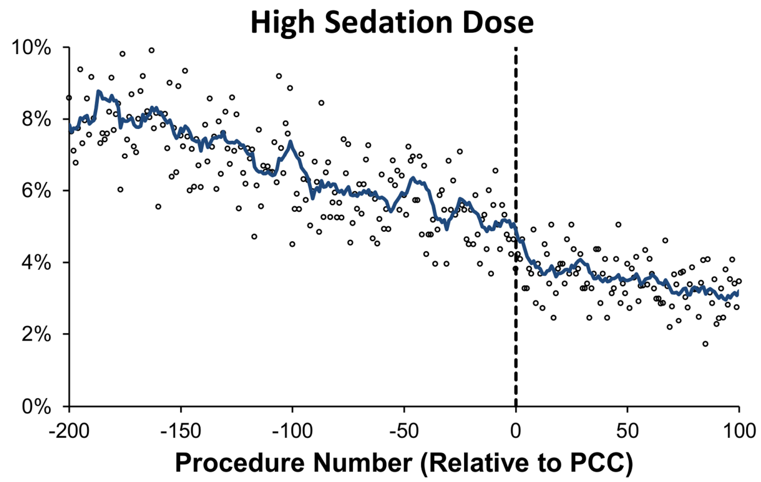

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ACRONYMS

CIR: caecal intubation rate

DIP: Drop in performance

JAG: Joint Advisory Group on Gastrointestinal Endoscopy

JETS: JAG Endoscopy Training System

KPI: Key performance indicator

PCC: Provision colonoscopy certification

PDR: Polyp detection rate

QA: Quality assurance

SAE: Serious adverse event

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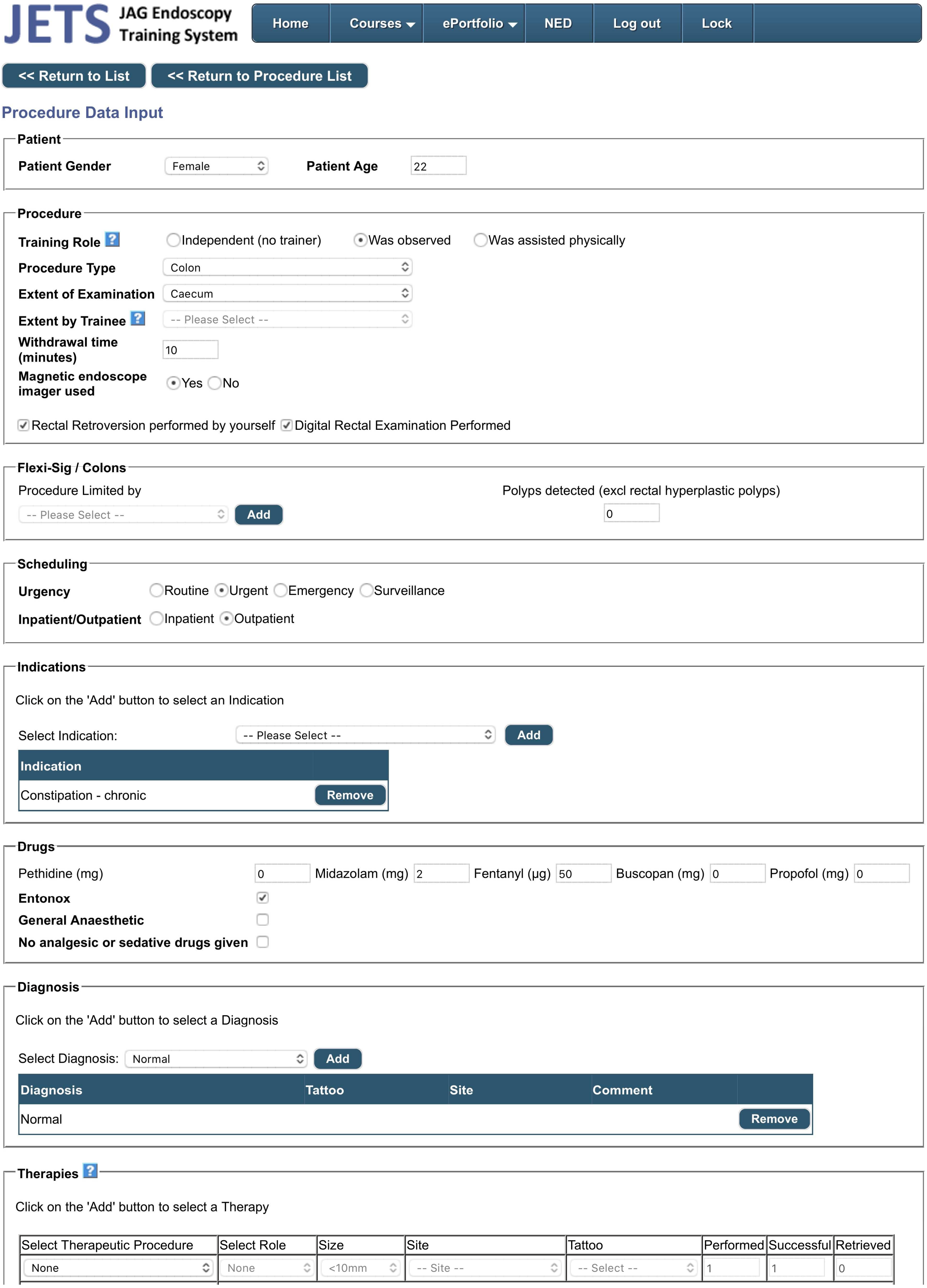

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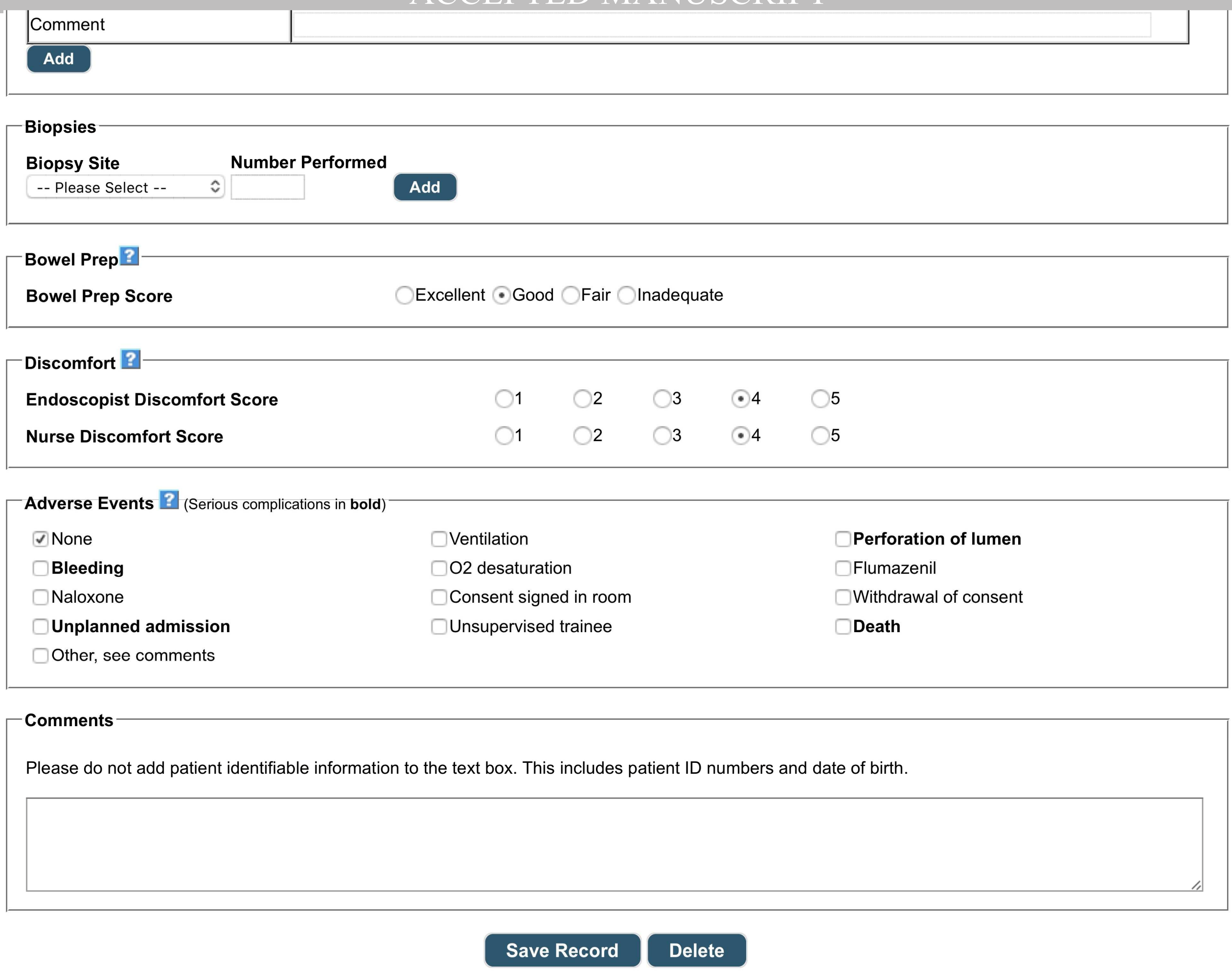

Supplementary Figure 1: Procedural factors recorded within the JETS e-portfolio interface for colonoscopy. *The question mark symbol represents a hover point which provides definitions to standardise user entry for each field. In this example, the training procedure was performed under trainer observation and achieved the outcome of unassisted caecal intubation.*

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