Costs and benefits of a formal quality framework for colonoscopy: economic evaluation

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Angaben zur Veröffentlichung / Publication details:

Pakneshan, Sahar, Naomi Moy, Sam O'Connor, Luke Hourigan, Helmut Messmann, Ayesha Shah, Uwe Dulleck, and G. J. Holtmann. 2024. "Costs and benefits of a formal quality framework for colonoscopy: economic evaluation." Endoscopy International Open 12 (11): E1334–41. https://doi.org/10.1055/a-2444-6292.

Thieme

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Key words
Endoscopy Lower GI Tract, Colorectal cancer, CRC screening, Quality and logistical aspects, Performance and complications

received 17.4.2024
accepted after revision 23.9.2024

Bibliography
Endosc Int Open 2024; 12: E1334–E1341
DOI 10.1055/a-2444-6292
ISSN 2364-3722

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Supplementary Material is available at https://doi.org/10.1055/a-2444-6292

ABSTRACT

Background and study aims Reduction of colorectal cancer morbidity and mortality is one of the primary objectives of colonoscopy. Post-colonoscopy colorectal cancers (PCCRCs) are critical outcome parameters. Analysis of PCCRC rates can validate quality assurance measures in colonoscopy. We assessed the effectiveness of implementing a gastroenterologist-led quality framework that monitors key procedure quality indicators (i. e., bowel preparation quality, adenoma detection rates, or patient satisfaction) by comparing the PCCRC rate before and after implementation.

Patients and methods Individuals who had a colonoscopy between 2010 and 2017 at a single tertiary center in Queensland, Australia, were included and divided into two groups: baseline (2010–2014) and redesign phase (2015–2017). Data linkage of the state-wide cancer registry and hospital records enabled identification of subjects who developed colorectal cancers within 5 years of a negative colonoscopy. Costs associated with quality improvement were assessed for effectiveness.

Results A total of 19,383 individuals had a colonoscopy during the study period. Seventeen PCCRCs were detected. The PCCRC rate was 0.376 per 1,000 person-years and the average 5-year PCCRC risk ranged from 0.165% to 0.051%. The rate of PCCRCs was higher at the beginning (0.166%; 95% confidence interval [CI] 0.15%-0.17%) compared with the later period with full implementation of quality control measures (0.027%; 95% CI 0.023%-0.03%). The quality process determined an incremental cost-effectiveness ratio of -$5,670.53 per PCCRC avoided.

Conclusions This large cohort study demonstrated that a formal gastroenterologist-led quality assurance framework embedded into the routine operations of a clinical department not only reduces interval cancers but is also cost-effective regarding life years gained and quality-adjusted life years.

Introduction

Screening colonoscopy is the gold standard in colorectal cancer (CRC) detection and prevention [1]. However, a meta-analysis of studies on tandem colonoscopies has shown that a significant number of lesions are missed [2]. Missed lesions can result in CRC and those that are diagnosed post colonoscopy are likely to result in reduced survival rates [3] and increased costs to the healthcare system. Any instance of CRC that occurs after a negative colonoscopy falls under the umbrella term "post-colonoscopy colorectal cancers" (PCCRCs) [4]. A PCCRC diagnosed before the recommended colonoscopy surveillance interval is defined as an interval colorectal cancer [5, 6]. Non-interval PCCRCs are defined as cancers that occur at or after the recommended time interval or where no such follow-up period is recommended [4].

CRC is the second most prevalent cancer in Australia, and therefore, thus despite a low rate of incidence of interval cancers within the screening cohort, absolute numbers of PCCRCs that present can still be substantial [7]. PCCRC can arise from not only missed lesions but from incomplete resection [8], thus the PCCRC rate can be considered as a novel and overarching quality outcome measure of colonoscopy services [5, 6]. The interval cancer rate can be utilized to identify potential geographic differences in the effectiveness of colonoscopy services in relation to the effect on the CRC incidence. Worldwide PCCRC rates range from 0.1% to 9%, most likely because of non-standardized definitions of what constitutes PCCRC and differing follow-up periods utilized in the published literature [9, 10], as well as differing patient clinical, genetic, and lifestyle factors. Despite these differences, procedural and endoscopist factors contribute to the PCCRC rate; for example, proceduralists with low adenoma detection rates (ADRs) have higher rates of PCCRC [11, 12]. There is evidence that improvement in endoscopic quality may reduce the risk of PCCRC [12, 13, 14].

The purpose of this study was to determine the PCCRC rate at our large, publicly funded tertiary/quaternary center and assess the effectiveness of quality improvement measures by comparing two cohorts of patients: those with colonoscopies within the redesign and implementation phase (2010–2014) versus those after full implementation phase (2015–2017). Colonoscopy quality control measures were introduced in the redesign phase, then formalized and integrated into standard procedures during the full implementation phase. We hypothesize that formalization of quality monitoring of colonoscopies is cost-effective.

Patients and methods

Study population

This retrospective study was conducted at a large tertiary hospital in Brisbane, Queensland, Australia. Data were extracted from hospital records via the endoscopy proprietary reporting software (ProVation MD), for all colonoscopies performed between 2010 and 2017. Patients with a previous history of CRC, inflammatory bowel disease (IBD), or polyposis syndromes were excluded because of the increased risks of developing CRC in these populations. Incomplete procedures were excluded. The data included all relevant details such as date of colonoscopy procedure, age, name of proceduralist, indication for procedure, gastroenterology-related comorbidities, and colonoscopy findings. A data linkage process was performed through the state-wide regional cancer register, Cancer Alliance Queensland (CAQ), to determine any CRC occurrence post colonoscopy. Since 1982, the CAQ registry has been recording all cancer cases diagnosed in Queensland (excluding basal and squamous cell carcinomas [SCCs]). Cases were linked to subsequent CRC diagnoses up to and including June 2020 and verified by pathology review.

PCCRC calculation

A PCCRC was considered if the CRC diagnosis occurred between 3 months and 5 years after a negative colonoscopy. Rather than starting assessment of CRCs at 6 months or later after index colonoscopy, the 3-month period was chosen to ensure that any PCCRCs were not dismissed, despite the proportion of CRC being diagnosed this close to index procedure being expected to be very low [15]. The robust 5-year end term was chosen such that any missed lesions that naturally progressed to cancer were not excluded [16].

Intervention

Quality control measures were introduced in 2010, whereby select quality parameter monitoring was implemented, including cecal intubation rate (95% or better), polyp detection rate (25% or better), withdrawal time (6 minutes or longer), and quality of bowel preparation. This was expanded to a formalized system in 2014, whereby deidentified monitoring of colonoscopy quality indicators began and was provided at a department level to all endoscopists, an endoscopy quality monitoring group was introduced, and performance indicators were integrated into standard procedures. This coincided with implementation of other quality improvements, such as introduction of split bowel preparation for all patients and simplification of bowel preparation patient instructions with pictorial guides.

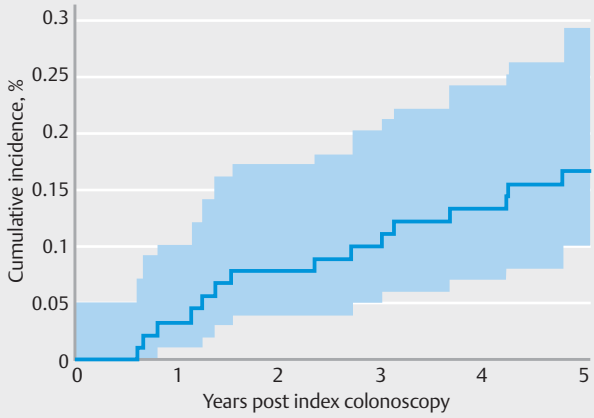
Statistical analyses

For confirmed PCCRC cases, we calculated the annual proportion of PCCRC and PCCRC-3yr and PCCRC-5yr risk rates. To define PCCRC rates in the population served by the hospital, the proportional confidence intervals (CIs) of PCCRC in each period were calculated. In addition, we estimated the probability of PCCRC occurrence using Kaplan-Meier cumulative incidence of PCCRCs within a 5-year period after colonoscopy, and the relative survival rate after PCCRC. Expected years of life lost following cancer diagnosis was calculated using the relative 5-year survival rate and the life expectancy based on gender, date of birth, and age at time of diagnosis for each patient [17].

To measure the economic impact of the quality control measures, we assessed costs and health effects before and after the formalized monitoring process. Costs and health effects for each phase were then used to calculate the expected costs and effects per colonoscopy using a decision tree model. The health effects of the quality processes were represented by the impact

on interval cancer rates. These expected values for each phase were compared against each other in a cost-effective analysis.

The cost-effectiveness analysis was from the hospital perspective, using the direct costs of the quality measures and colonoscopy procedures calculated in 2014 Australian Dollars. The costs of a colonoscopy and the monitoring process were calculated using administrative costs provided by the department and the cost of a PCCRC was determined using existing literature about the cost of colorectal cancer in the 12 months after diagnosis [18]. A discount rate of 3% was applied [19] and a time horizon of 3 years. One-way sensitivity analysis was conducted on the decision tree model parameters for the cost and discount rate applied (**Supplementary Table 1**). An intervention would be recommended from a policy perspective and considered an efficient measure if the cost per PCCRC avoided were less than AUD$28,033 per quality-adjusted life year (QALY) [20].



▶ **Fig. 1** Kaplan-Meier cumulative incidence plot for 2010–2014. The black line increments represent an instance of an PCCRC (95% confidence interval is shown in grey).

Results

A total of 20,735 colonoscopy procedures were identified during the study period, with 17,573 eligible for inclusion according to our primary criteria. There were 19,383 patients who underwent a colonoscopy from 2010 to 2017 and 16,504 patients undertook an eligible colonoscopy. There were a number of patients in the cohort who underwent multiple colonoscopies, and thus, more colonoscopy procedures than eligible patients. Linkage to the cancer registry detected 373 CRCs between 1 and 7 days after the index colonoscopy and 135 cases within 5 years after the index colonoscopy. Of 135 cases, 43 possible PCCRCs for dates from 2010 to 2014 and 11 for 2015 to 2017 were extracted. Further verification of cases resulted in a total of 43 CRCs, of which 17 were classed as PCCRC (54% male, average age 71.5). There were two cases of patients originally linked to a CRC by CAQ that could not be verified upon examination of the patients' medical records and pathology results. These were reported, and it was confirmed that those entries had been removed. Fifteen of the 17 patients had a full 5-year follow up (for colonoscopies in 2010–2014) and five developed PCCRC at between 3 and 5 years. To allow for an equal-length period comparison, the 3-year PCCRC incidence for the two timeframes was compared, where the quality implementation between 2010 and 2014 revealed 15 PCCRCs compared with two for the 2015 to 2017 post implementation phase (▶ **Table 1** and **Supplementary Fig. 1**).

The calculated overall PCCRC incidence rate was 0.376/1,000 person-years and the average 5-year PCCRC risk was estimated as 0.108%. Because a maximum 3.5 years of follow-up was available for the data in 2017, the 3-year PCCRC rate was determined to allow for direct comparison for the two periods of the study. The 2010 to 2014 redesign and implementation phase had a PCCRC rate of 0.166% (95% CI 0.15%-0.17%), whereas the post-implementation phase of 2015 to 2017 had a rate of 0.027% (95% CI 0.023%-0.03%). The overall proportion of PCCRCs among all CRCs observed (N = 506) in our cohort was 3.36%.

A Kaplan-Meier cumulative incidence plot was used to visualize the 5-year PCCRC rate in patients undergoing colonoscopy procedures from 2010 to 2014 (▶ **Fig. 1**). Before the quality assurance processes were formalized, the probability of a PCCRC occurring increased over a 5-year incidence.

The quality rating for bowel preparation did not increase risk of PCCRC between the formalized processes (▶ **Table 2**). There was a steady increase in withdrawal time ($r^2 = 0.768$) over time. The same occurred for the rates of cecal intubation ($r^2 = 0.865$) and polyp detection ($r^2 = 0.774$), although the polyp detection rate showed a more prominent increase in the first few years of the quality program (▶ **Fig. 2a**). The quality of bowel preparation increased over time (▶ **Fig. 2b**). The average age of patients undergoing colonoscopy was lower as time progressed, with patients approximately 3 years younger in 2017 compared with 2010 ($r^2 = 0.712$).

Cancer stage and relative 5-year survival rate based on sex, cancer stage, and age at diagnosis were calculated (▶ **Table 3**) [21, 22, 23, 24, 25]. Expected years of life lost following cancer diagnosis were calculated using the relative 5-year survival rate and life expectancy based on gender, date of birth. and age at time of diagnosis for each patient. This ranged from 11.5% to 99.7%, with the expected years of life lost ranging from 0.01 to 14.19 years with an average of 2.94 (95% CI 1.06–4.82). Since the full implementation of the quality improvement program, two PCCRCs were detected at index colonoscopy that occurred between 2015 and 2017. Cumulative expected years lost for the 17 cases of interval cancer was 50.09 years between 2010 and 2017 (48.27 years before and 1.82 years after implementation) for 17,614 patients over the study period.

Finally, based on administrative data, cost-effectiveness of the quality processes was calculated, and an incremental cost-effectiveness ratio (ICER) was determined (▶ **Table 4**). The estimated cost to the hospital of the formal process per patient was AUD$1.27, and the average annual cost for quality monitoring over the formalized observation was AUD$4294.50. The aver-

▶ **Table 1** Raw data and PCCRC (patients at increased risk of CRC excluded).

Year of index colonoscopy	No. colonoscopies/ patients	No. suitable index colonoscopies/patients*	No. PCCRCs	% PCCRC (95% CI)	Withdrawal average ± SD (mm:ss)	3-year average per 10,000 patients
2010†	1,516/1,427	1,266/1,192	5	0.42 (0.15–1.04)	13:23 ± 6:39	41.9¶
2011	1,842/1,728	1,536/1,446	1	0.07 (0.00–0.44)	12:45 ± 5:51	22.7¶
2012	2,752/2,571	2,375/2,229	5	0.22 (0.08–0.55)	13:49 ± 5:34	22.6
2013	2,533/2,381	2,120/2,001	4	0.20 (0.06–0.55)	13:23 ± 5:19	17.6
2014‡	2,833/2,602	2,360/2,178	0	0.00 (0.00–0.22)	14:15 ± 6:00	14.0
2015	2,939/2,723	2,472/2,306	2§	0.09 (0.02–0.35)	14:04 ± 5:55	9.3
2016	3,125/2,932	2,686/2,529	0§	0.00 (0.00–0.19)	15:07 ± 7:35	2.9
2017	3,195/3,019	2,758/2,623	0§	0.00 (0.00–0.18)	14:52 ± 5:54	2.7

*This number removes procedures as per the exclusion criteria (polyposis syndromes, previous CRC, and IBD).
†Monitoring of quality parameters started in the department.
‡Further formal monitoring of colonoscopy quality parameters and revised bowel preparation. Instructions rolled out in the department.
§Full 5-year follow-up unavailable at time of data linkage.
¶1- and 2-year average, respectively.
CI, confidence interval; CRC, colorectal cancer; PCCRC, post-colonoscopy colorectal cancer.

age cost of a colonoscopy procedure with quality monitoring during the formalized process was AUD$238.34, and during the informal period it was AUD$215.59. Compared with no formalized process, formalizing the process had an ICER of -$5670.53 per PCCRC avoided. The calculated ICER based on one-way sensitivity varied between -$5781.32 and -$5,565.31 for adjusted discount rates ranging from 0% to 5% in 1% increments and an increase in monitoring costs of 13% or 14% returned ICERs of -$4,683.07 and -$4,221.91 per PCCRC avoided.

Discussion

Principal findings

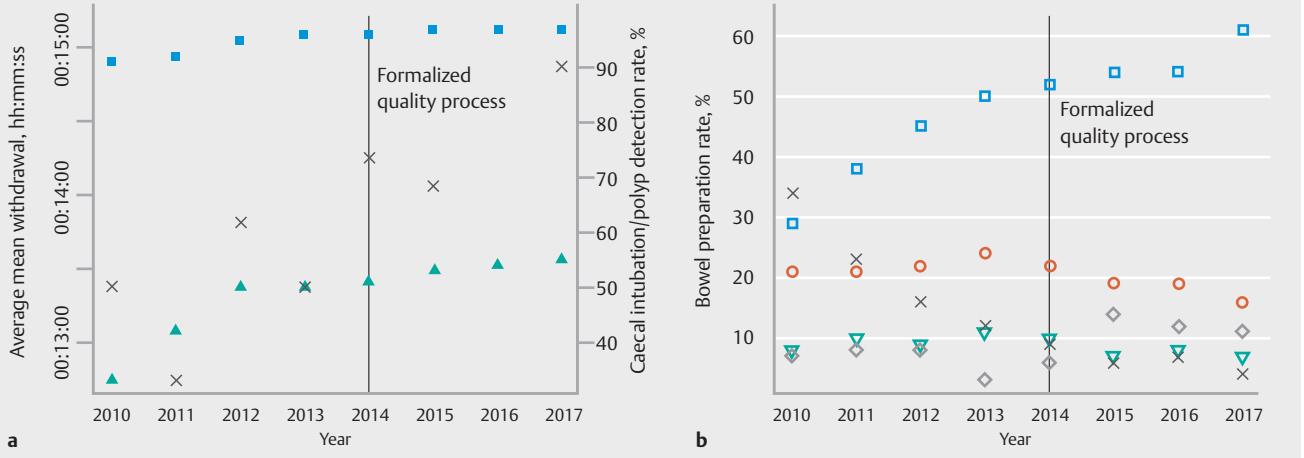
To the best of our knowledge, this is the first study that has evaluated the cost-effectiveness of quality assurance measures in the context of endoscopic services. It is already well established that risk of interval cancers after a colonoscopy is related to specific quality indicators [12], and a high-quality colonoscopy increases the benefits for patients undergoing screening colonoscopy. This study provides a health economic evaluation of staged implementation of a quality framework for colonoscopy. While this approach has been described elsewhere [26], this study provides further information about the clinical effectiveness and complements it with a comprehensive health economic assessment.

Consistent with other studies [26], incidence of PCCRC in our cohort was low, but implementing a formal clinician-led colonoscopy framework further reduced this rate. The actual rate of interval cancers in the redesign phase might be even lower because the interval cancers in 2015, 2016, and 2017 were anal SCC and neuroendocrine tumors, and the quality programs were designed to increase monitoring of adenocarcinoma precursors. Cecal intubation rates, colonoscopy withdrawal times, polyp detection rates, and bowel preparation quality improved due to implementation of a formal quality framework. The key feature of the quality framework was that at the level of a large hospital (and later at the level of all hospitals in Queensland, Australia), quality groups were established and supported by

▶ **Table 2** Patients with interval cancer versus bowel preparation quality.

Bowel preparation quality	Total colonoscopies	No. patients with interval cancer	% patients with interval cancer	95% CI
2010–2014				
Excellent	729	0	0.00%	0.00%-0.00%
Good	5,124	10	0.20%	0.07%-0.32%
Fair	2,564	3	0.12%	-0.02%-0.25%
Poor	1,129	1	0.09%	-0.08%-0.26%
Not specified	1,925	1	0.05%	-0.05%-0.15%
2015–2017				
Excellent	1158	0	0.00%	0.00%-0.00%
Good	5219	0	0.00%	0.00%-0.00%
Fair	1,649	2	0.12%	-0.05%-0.29%
Poor	699	0	0.00%	0.00%-0.00%
Not specified	536	0	0.00%	0.00%-0.00%

CI, confidence interval.



▶ **Fig. 2** Trends of colonoscopy quality parameters over time. **a** Demonstrates clinical led quality indicators. **b** Indicates patient led quality indicators. Clinical indicators: ■, cecal intubation; ▲, polyp detection; X mean withdrawal time. Bowel preparation score: ◇, Excellent; □, Good; ○, Fair; ▽, poor; X, not specified.

dedicated staff to perform standardized monitoring of relevant quality parameters. The groups, chaired by a gastroenterologist, carefully analyzed the respective quality parameters against established benchmarks at the individual and hospital level. For interpretation of performance data, the specific patient cohorts (e.g., age, the proportion of iFOBT-positive subjects, and proportion of patients with IBD) were considered. Every endoscopist had access to their performance data and de-identified data from their peers. Corrective actions were planned, initiated, and monitored by the quality group as required. Further, the effects of development and implementation of the quality framework regarding the ICER revealed that the outlined gastroenterologist-led formalized quality control process is a cost-effective strategy.

The overall rate of PCCRC in our cohort before the intervention was similar to that reported in other studies; for example, a study conducted at the Canberra Hospital quoted a rate of 0.192% [27]. Comparison with other cohorts is difficult: A review of the literature presents highly variable rates of PCCRC, alongside highly variable criteria for defining what constitutes a PCCRC [9, 10, 12, 13, 17, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38]. Another confounding factor is gradual incremental improvement in endoscope and imaging technology over time. For this reason, only studies with cohorts in the 2000s were

▶ **Table 3** Relative 5-year survival at diagnosis and expected years of life lost following cancer diagnosis in 17 PCCRC patients.

Year of cancer diagnosis	Stage at diagnosis	Relative 5-year survival for CRC by stage at diagnosis, age, and sex	Expected years of life lost following cancer diagnosis
2012	1	96.9%	0.47
2012	3	64.4%	2.81
2012	4	13.6%	6.3
2013	3	72.7%	3.35
2013	1	99.7%	0.01
2013	1	99.7%	0.01
2013	4	13.2%	6.85
2013	4	11.5%	3.89
2014	1	97.1%	0.37
2014	4 (metastatic anal adenocarcinoma)	34.0%	14.19
2015	3	74.7%	2.88
2015	2 (SCC of anal canal)	82.0%	1.49
2016	3B (locally advanced anal SCC)	66%	5.1
2016	1	98.3%	0.15
2017	1	97.1%	0.4
2017*	3C (locally advanced anorectal SCC)	66%	1.46
2017*	1 (Grade 2 neuroendocrine tumor in rectum)	97%	0.36

*Interval cancers with index colonoscopy post full implementation of the quality measures in the department in 2014.
CRC, colorectal cancer; PCCRC, post-colonoscopy colorectal cancer; SCC, squamous cell carcinoma.

considered for comparison with this cohort. These studies reported the PCCRC rate as a proportion of total CRC cases [9, 13, 17, 29, 30, 31, 35], whereas several used a cumulative incidence calculated per patient year [12]. Compared with other cohorts, the rate of PCCRC detected as a proportion of all CRCs in our cohort was 3.36% (N = 506), which is lower than the rates observed in other populations and demonstrates the effects of our quality intervention (**Supplementary Table 2**).

▶ **Table 4** Results of cost-effectiveness analysis.

Outcomes	Informal process	Formal process
Cost ($)	$1,122.59	$1,118.31
Incremental cost ($)	-	-$4.28
Effectiveness, PCCRC avoided	0.5790	0.5798
Incremental effectiveness (PCCRC avoided)	-	0.0008
ICER ($/PCCRC avoided)	-	-$5,670.53

Costs and effects are the expected value of the decision tree per patient with a time horizon of 3 years and a discount of 3%.
Costs are in Australian dollars.
ICER, incremental cost-effectiveness ratio.

Factors associated with PCCRC

This study did not determine factors associated with risk of PCCRC, due to its retrospective nature and the large volume of data collected. Nevertheless, it was noted that over the period examined, ADR, withdrawal time, and the cecal intubation rate all increased, suggesting an association. This is in line with observations that higher adenoma and proximal sessile serrated adenoma detection in screening colonoscopies could reduce PCCRC cancer mortality [39]. Quality of bowel preparation did not appear to be a crucial factor in our cohort, despite poor bowel preparation being a risk factor [36]. However, it is important to consider when the quality of the bowel preparation is documented. If quality of preparation is documented upon insertion of the colonoscope after appropriate distension but without cleansing maneuvers, or during withdrawal, after cleansing maneuvers such as washing and suctioning of fluid have been completed, the ability to fully inspect the mucosa after cleansing will be linked to adenoma detection and subsequent interval cancers, whereas the former is an assessment of the appropriate method of colonic preparation and may guide personalized approaches to bowel preparation [40, 41]. Lack of correlation in this study might be explained by the fact that quality of the bowel preparation was assessed by the Aronchick scale [42] before any efforts to clean the bowel by the endoscopists during the procedure.

There was a trend toward a decrease in average age of the cohorts with each year that was studied (59.4 ± 14.5 in 2010, compared with 56.5 ± 15.5 by 2017), which corresponded with a steady fall in incidence of PCCRC in the 3-year rolling average (▶ **Table 1**). Therefore, the fall in PCCRC could be explained by earlier screening and prevention of CRC at a population level, confounding our results. The reduction in PCCRC may be attributed to constantly improving scope and imaging technology. However, the magnitude of change in PCCRC strongly suggests the benefit of quality assurance within the department.

Strengths and limitations

The PCCRC rate can validate quality improvement interventions and determine their cost-effectiveness. We estimate that implementation of formalized quality standard monitoring and revision of patient instruction materials regarding bowel preparation for a colonoscopy resulted in prevention of eight PCCRCs (based on a 3-year follow-up timeframe) and could reduce expected years of life lost due to cancer.

Not only is there clinical benefit in quality monitoring of colonoscopy indicators for patients, but there is a demonstrated economic benefit to the healthcare system. This benefit was observed at higher cost levels in the one-way sensitivity analysis, suggesting that the findings are relevant for a wide spectrum of clinical settings. Monitoring of colonoscopy quality indicators is mandatory for all public hospitals in Queensland, Australia, and has been integrated into certification and recertification processes for Australian endoscopists. However, by focusing on a single site, this study allowed for a controlled comparison of the formalized process for colonoscopy quality monitoring. In addition, having the quality assurance process embedded in the operations of a clinical department delivers other tangible and non-tangible benefits [43, 44, 45].

Although this study included a rich dataset that covered the improvements and formalized approach for quality in colonoscopy procedures, it was limited because it was a causal study, indicating that the linear relationship between the formalized quality assurance process was underexplored [39]. However, there are few studies examining the effects of quality assurance processes on interval cancer rates and this research begins to fill the gap [46]. In addition, the best methodology to determine the PCCRC rate would be to conduct a prospective study in patients who are negative for CRC. Nevertheless, good record-keeping and a suitable linking process with a reliable data source from a cancer registry (e. g., CAQ in our study) provide results immediately and is considered as close as possible to a complete dataset. Future work should consider transition probabilities or associated costs with any PCCRCs that go into remission. It needs to be noted that endoscopist ADR does not rest exclusively on competence in spotting adenomas. It equally hinges on pathologist skill in identifying adenomatous tissue from biopsy or resection specimens. Thus, ADR also reflects how adept the pathologist is. In a setting of close monitoring of ADR, situations can also improve pathologist ADRs. Although this health economic assessment focused on PCCRC, other benefits (e. g., concerning patient satisfaction) have not been quantified.

Conclusions

This is the first study that provides evidence from a large patient cohort treated in a routine clinical setting that introduction of a formal quality improvement program – embedded in the operations of a large tertiary/quaternary Department of Gastroenterology and Hepatology – not only reduces the PCCRC rate but is cost-effective concerning life-years gained and QALY. From a policy perspective, these data suggest that quality colonoscopy quality assurance should be a requirement for hospital accreditation.

Acknowledgement

The authors would like to acknowledge the support from the Cancer Alliance Queensland by providing data from the cancer registry for this project.

Conflict of Interest

HM has previously received grants from Olympus and Satisfai. Speaker fees from Dr Falk Pharma, Olympus, Norgine, IPSEN, medupdate and Erbe. Consultation fees from Olympus, Ambu, Boston Scientific, Covidien and Takeda. All other authors have no conflicts of interest to disclose.

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