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# **CLINICAL/NARRATIVE REVIEW**

# **Colonoscopy: Quality Indicators**

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Effective endoscopic screening for colorectal cancer (CRC), one of the few preventable cancers, is dependent on the adequate detection and removal of potentially precancerous lesions. However, observed variation in colonoscopy performance in practice and outcomes has highlighted the need for consistent quality measures. Quality indicators or measures are tools that help to quantify health-care processes and can aid in providing high-quality health care. The primary colonoscopy quality indicator is the adenoma detection rate (ADR), which is defined as the proportion of an endoscopist's screening colonoscopies in which one or more adenomas have been detected. The risk of post-colonoscopy CRC is inversely correlated with an endoscopist's ADR. However, ADR is dependent on other quality measures, including cecal intubation rates, withdrawal times, and quality of bowel preparation. Achieving suggested benchmarks for these other quality measures will aid the endoscopist in achieving the recently updated ADR benchmark of 25% in their practice. In addition, beyond ensuring adequate ADRs, endoscopists should have high compliance rates with guideline-recommended and evidence-based screening and surveillance intervals. Compliance with quality measures will ensure effective and safe CRC prevention and better patient outcomes.

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#### INTRODUCTION

Colonoscopy is the most widely used colorectal cancer (CRC) screening tool and is recommended as the CRC test of choice by the recent American College of Gastroenterology CRC Screening Guidelines.<sup>1</sup> The effectiveness of CRC screening through the use of colonoscopy is dependent on the identification and complete removal of adenomas<sup>2</sup> and other potentially precancerous lesions.

The increased use of colonoscopy likely contributes to the declining CRC rates in this country,<sup>3</sup> with a 3.4% decrease per year in CRC incidence over the last decade. The National Polyp Study demonstrated a 76% reduction in CRC incidence and a 53% reduction in mortality in patients, who have had a colonoscopy and a polypectomy.<sup>2,4</sup> However, recent studies have demonstrated limitations in the effectiveness of colonoscopy, especially in the proximal colon.<sup>2,5-9</sup> Potential limiting factors can be divided into those that are biologically based and those owing to the technical performance of colonoscopy. It has been observed that protection from CRC death in patients in the United States who had a colonoscopy was associated with the endoscopist's specialty.<sup>10</sup> Variation among endoscopists in the performance of colonoscopy has also been well documented.<sup>11–13</sup> This variation demonstrates the importance of measuring quality in the performance of colonoscopy.

# website<sup>14</sup>), quality measures are tools that help us measure or quantify health-care processes that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care.<sup>14</sup> Quality measures are increasingly being used for reimbursement for colonoscopy, and may also affect patient utilization. A recent survey of 417 patients found that 20% researched their endoscopist's rating.<sup>15</sup>

The ideal outcome measure after colonoscopy would be prevention of CRC. Alternatively, the number of interval cancers, or those cancers diagnosed in a short interval (3–5 years) following colonoscopy, might also be a useful outcome measure. However, the infrequent occurrence of these cancers limits the use of this outcome as a quality measure for CRC prevention. More frequent findings, such as adenomas or advanced adenomas, are often used as surrogate measures to assess outcomes.

Adenoma detection rate (ADR), the primary quality indicator or outcome for an endoscopist, can be viewed as a function of the other quality measures.<sup>16</sup> These include cecal intubation rates, withdrawal times, and quality of bowel preparations. To maximize adenoma detection, an endoscopist needs to consistently and accurately intubate the cecum of an adequately prepared colon as well as use an adequate withdrawal time for mucosal inspection.

#### QUALITY MEASURES

Quality measures can be used to maximize the effectiveness of colonoscopy by guiding consistent, high-quality practice. As defined by the Center for Medicare and Medicaid Services (CMS

#### ADENOMA DETECTION RATE

ADR is defined as the proportion of screening colonoscopies that detect at least one adenoma.<sup>17</sup> The rationale for using

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ADR as a quality measure was based on three assumptions.<sup>17</sup> Clearing the large bowel of neoplasms is the goal of endoscopic screening and surveillance for CRC. Adenoma as opposed to advanced adenoma detection is considered a superior measure, as it allows tracking of endoscopist variation owing to the higher frequency of the former. At last, it seemed reasonable to assume that adequate detection of smaller adenomas would ensure the detection of the larger advanced adenomas. The first recommended ADR benchmark for patients undergoing a screening colonoscopy<sup>17</sup> was 20%. This recommendation was based on several studies that showed that the prevalence of adenomas in asymptomatic adults ranged from 25 to 40%.<sup>18–21</sup> Sex-specific recommendations were 25% for men older than 50 and 15% for women in the same age group.<sup>17</sup>

The recommended ADR of 20% was validated by a large screening study from Poland that included data from nearly 50 thousand patients who were followed for a median of 52.1 months after a screening colonoscopy.<sup>12</sup> There were 42 interval CRCs that were diagnosed. When a 20% ADR was used as a reference, there was an increased interval cancer risk for ADR <11% (hazard ratio (HR) = 10.9; 95% confidence interval (CI); 1.4–87.0). In addition, there was also an increased risk for ADR of 11–14.9% (hazard ratio = 10.8; 95% CI; 1.4–85.1) and an ADR of 15–19.9% (hazard ratio = 12.5; 95% CI; 1.5–103.4). There were no interval cancers diagnosed over a 4-year period in patients with exams performed by endoscopists with ADRs of 20% or greater. However, this study was limited by the inclusion of a relatively small number of interval cancers (n=42).

Recently, a larger study, using data from nearly a guarter of a million patients who were enrolled in an integrated healthcare delivery organization in the state of California, examined the impact of higher ADRs on interval cancers.<sup>22</sup> This study investigated exams performed by 136 gastroenterologists; 712 interval cancers were identified. For each 1% increase in ADR, there was an associated 3% reduction in the risk of cancer. The lowest risk for interval cancers was for those endoscopists with ADRs of at least 33.5%. Although the ADRs in this study include exams with all indications rather than screening only, these data suggest that the benchmark of 20% might not offer optimal protection from cancer. On the basis of these data, a recent joint task force of the American College of Gastroenterology and the American Society of Gastrointestinal Endoscopy recommended ADR benchmarks of 25% for all patients and sex-specific rates of 30% for men and 20% for women.23

There have been several studies that examine potential interventions to increase endoscopists' ADRs.<sup>24</sup> Most interventions, such as those that used education or feedback to the endoscopists,<sup>25</sup> education on inspection techniques,<sup>26</sup> or financial penalties,<sup>27</sup> did not have a positive impact on ADR.

One successful educational intervention involved the use of two 1-h training sessions.<sup>28</sup> These sessions covered basic topics such as bowel preparation and withdrawal technique as well as more advanced topics such as polyp morphology, polyp pit pattern, and dye staining.<sup>28</sup> Endoscopists randomized to the educational group had a significant increase in their ADR from the baseline (36 to 47%) as compared with the other endoscopists' ADR (35%). The investigators followed

the endoscopists for 5 months and observed that the ADR for endoscopists in the intervention group was stable (46%), suggesting durability of the training.<sup>29</sup>

In the statewide New Hampshire Colonoscopy Registry, endoscopists are provided with periodic feedback reports on their quality indicators, including comparison with aggregate data for the endoscopist's site and to the state. Feedback information on performance quality is essential for improving performance and therefore ADRs. Similarly, a quarterly "report card" was shown to increase the ADRs for endoscopists performing colonoscopies in tertiary-care, academic, Veterans Affairs, and other university affiliated centers.<sup>30</sup> These report cards contained endoscopist-specific data for bowel preparation quality, pre-procedure patient assessment, cecal intubation, withdrawal times, and ADRs. Although the overall ADR increased post intervention (44.7% pre vs. 53.9% post; P=0.013), the largest increase in detection was for proximal adenomas (29.3% vs. 39.8%; P=0.003).

### **OTHER DETECTION RATES**

Although a higher ADR has been shown to be correlated with a lower risk for interval cancers,<sup>12,22</sup> there are some limitations in the practical use of ADR. As it requires a diagnosis of adenoma, the histology of the removed lesion must be known to accurately calculate the ADR. This may add an extra step for calculation in clinical practice, as many endoscopic electronic databases do not have linked endoscopy and histology data. For measurements involving location, size, or number of polyps, there may be challenges to matching polyp characteristics and histology, especially in those instances where multiple polyps are in one jar.<sup>31</sup> Therefore, some studies have examined the potential use of polyp detection rate instead of ADR as a measure. One analysis derived an adenoma to polyp detection rate quotient to calculate ADRs from polyp detection rates.<sup>32</sup> They calculated the adenoma to polyp detection rate quotient in their sample to be 0.64 and observed a strong correlation between actual and calculated ADRs. Another study calculated a colon segment-specific adenoma to polyp quotient for each endoscopist.<sup>33</sup> The correlation between calculated and actual ADR was excellent in the proximal colon (r=0.95) but modest in the left colon (r=0.59).<sup>33</sup> These data were supported by another study that also observed a stronger correlation between the polypectomy rate and ADR in the proximal as compared with the distal colon.<sup>34</sup> The correlation was also stronger in men than for women.

However, there are concerns regarding the use of polyp detection rate or polypectomy rate as a quality measure. Even if the polyp detection rate was limited to use in the proximal colon, where it may correlate better with ADR, there are still potential ways to "game the system".<sup>35</sup> For example, to achieve a higher polypectomy rate, an extra biopsy could be taken.<sup>36</sup> Incorporation and linking of histology data into commonly used electronic medical records might facilitate measurement of ADR.

Appropriate sample selection for calculation of ADR is also essential. What number of exams constitutes an adequate number for which a meaningful ADR can be derived? One study calculated 95% CIs for the ADRs of their endoscopists.<sup>37</sup> They concluded that at least 500 exams were

required to have narrow CIs and thus provide a reliable assessment of an endoscopist's ADR. Thus, endoscopists who perform very few procedures per week might need several years of data to assess their quality. Another important issue is the selection of cases by indication. As it may be easier to analyze all of an endoscopist's exams, can surveillance and screening exams be included together? The ADR was originally developed for asymptomatic screening patients over 50, which has been the basis for benchmark standards. An analysis of the New Hampshire Colonoscopy Registry demonstrated that the ADR for surveillance exams was higher than that for the screening exams.<sup>38</sup> Thus, an endoscopist who performs more surveillance might have a falsely elevated ADR. Therefore, for appropriate comparison with benchmark standards, ADR calculation should be derived from screening exams only.

Another concern with the use of ADR is that this measurement does not include the total number of adenomas detected. A suggested new measure, called ADR-plus, is calculated as the mean number of additional adenomas, which were detected after the first lesion.<sup>39</sup> One study compared the ADR and ADR-plus for two different groups of patients.<sup>39</sup> Although the ADRs for the groups were similar, there was a difference for the ADR-plus calculation. The group with the higher ADR-plus also had a higher rate of advanced adenomas that were detected. Finally, another study showed that the ADR for an endoscopist did not correlate with the advanced ADR.<sup>35</sup>

Despite potential flaws, ADRs have been shown to be inversely correlated with interval cancers and thus remain the most important process measure at this time. Additional possible detection rates that have been proposed include those for serrated polyp detection rate<sup>13</sup> or proximal serrated polyps.<sup>40</sup> Serrated polyps—which include proximal hyperplastic polyps, sessile serrated adenomas/polyps and traditional serrated adenomas-are part of the serrated pathway that may be implicated in interval cancers. Factors that support the use of serrated polyp detection rate or proximal serrated polyps as quality measures include the observation that there may be substantial variation in detection rates among endoscopists;<sup>41,42</sup> therefore, interventions to promote consistent performance are needed. A tight correlation between ADR and proximal serrated polyps detection rates has been noted. More data are needed to clarify how this measure may add additional information regarding quality to existing measures such as ADR.40

# **CECAL INTUBATION RATES**

Cecal intubation rate is another important quality measure. The completion of the insertion process by fully intubating the cecum allows the endoscopist to perform a complete examination of the colon mucosa upon withdrawal. By definition, cecal intubation is achieved when the tip of the colonoscope is passed beyond the ileocecal valve lip into the caput, allowing effective visualization of the medial wall of the cecum lying proximal to the ileocecal valve. Variation in cecal intubation rates exists in practice and may explain the proximal location of some interval cancers.<sup>6,43–45</sup> One study at a

university hospital showed wide variation in cecal intubation rates, ranging from 63 to 97% for 10 endoscopists.<sup>46</sup>

The US Multi-Society Task Force on Colorectal Cancer (USMSTF) and the ACG/ASGE task force have recommended benchmarks of 90% for cecal intubation rates for all exams and 95% for screening exams.<sup>23,47</sup> These rates should be calculated after subtracting those exams, which were incomplete owing to a poor bowel preparation, severe colitis, or an obstructing lesion such as a tumor. For many gastroenterologists in the United States, cecal intubation rates are in the 97–99% range for both men and women.<sup>18,19,48,49</sup>

What is the impact of cecal intubation rates on interval cancer rates? An analysis of a British screening program observed an adjusted cecal intubation rate that ranged from 76.2 to 100%,<sup>50</sup> and noted a correlation between the cecal intubation rate and an endoscopist's ADR. A study from Japan observed that 4 out of 15 interval cancers were diagnosed after an incomplete colonoscopy.<sup>51</sup> One study of 14,064 patients from Ontario, Canada examined the impact of an endoscopist's completion rate on the occurrence of interval cancers.<sup>52</sup> When compared with patients whose exams were performed by endoscopists with a <80% completion rate, those whose exams were performed by endoscopists with higher completion rates had a lower risk for interval cancers. This rate appeared to be stable above a completion rate of 85%, lower than the recommended benchmark of 90%. This study confirmed the importance of adequate completion rates to minimize the occurrence of interval cancers.

Photo-documentation is also important to confirm that the cecum was intubated. A recent review of 12 Dutch endoscopy departments found that the compliance rate for photo-documentation of having reached the cecum ranged from 44.8 to 97.1%.<sup>53</sup> Photo-documentation of the cecum is vital for subsequent physicians who may alter treatment or diagnosis if there is any doubt that a complete exam was performed. It has been suggested that the optimal photograph should be taken distal enough from the cecum so that it contains an image of the appendiceal orifice with the ileocecal valve.<sup>47,54</sup> An image of the ileum with villi may be helpful in confirming cecal intubation.<sup>17</sup> The recent recommended benchmarks from the ACG/ASGE task force for successful cecal intubation rates with photo-documentation of appropriate landmarks are 90% for all exams and 95% for screening exams.<sup>23</sup>

#### WITHDRAWAL TIME

To maximize adenoma detection, adequate mucosal inspection is required to ensure complete examination. Studies of tandem colonoscopies have revealed that endoscopists may miss adenomas larger than 1 cm.<sup>55,56</sup> To ensure adequate adenoma detection, studies have suggested that an endoscopist's withdrawal time, not including polyp resection, should be on average at least 6–9 min.<sup>13,17</sup> A paper published in 2006 by the ASGE/ACG Taskforce on Quality in Endoscopy recommended that the withdrawal time should be measured as an aggregate of an endoscopsist's practice rather than based on an individual patient given the variation in anatomy such the prominence of colonic folds.<sup>47</sup>

The 2006 recommendation for a 6 min withdrawal time was supported by a community-based study of 12

gastroenterologists who performed nearly 8000 procedures.<sup>57</sup> The authors observed a wide variation in ADRs, which ranged from 9.4 to 32.7%. In addition, there was a wide variation in withdrawal times for normal exams where no polyps were removed (3.1–16.8 min). The investigators observed that compared with endoscopists who had mean withdrawal times of 6 min or longer, those who had a shorter withdrawal time had lower detection rates of any adenoma as well as advanced adenomas.

However, the same group showed that endoscopists with a mean withdrawal time of 8 min or longer had a higher ADR than those endoscopists with shorter times.<sup>58</sup> Conversely, another group demonstrated no effect on polyp detection of an institution wide policy mandating 7 min withdrawal times for all procedures.<sup>59</sup> One German study found no correlation between ADRs and mean withdrawal times that were between 6 and 11 min.<sup>60</sup> A study performed in the United States that examined 10,955 colonoscopies observed an increase in polyp detection for those endoscopists with a withdrawal time of 7 min or greater.<sup>61</sup>

Many of the studies that have examined this issue were performed in single centers with relatively few endoscopists. Many have also examined polyp detection rather than adenoma detection. The New Hampshire Colonoscopy Registry is a statewide, population-based registry that prospectively collects data from diverse endoscopy centers throughout NH,62 with participating endoscopists from a variety of specialties (gastroenterology, general surgery, colorectal surgery, and family practice). A recent analysis of the New Hampshire Colonoscopy Registry database examined the median withdrawal times for normal exams of 42 endoscopists across 14 centers.13 Results of this analysis suggested that a median withdrawal time for normal colonoscopies of 9 min is needed to maximize adenoma and proximal serrated polyp detection. Whereas withdrawal times of 6 min had an ADR of 23.8%, a withdrawal time of 9 min was associated with an ADR of 33.6%. There was also a nearly 30% increase in serrated polyp detection rate detection with an increase in withdrawal time to 9-10 min. These data, from a large registry, which includes diverse settings and endoscopists, suggest that a mean withdrawal time of >9 min for normal exams may be required for optimal polyp detection.

# **BOWEL PREPARATION QUALITY**

Another quality measure that affects adenoma detection is the quality of the bowel preparation. An adequate colon preparation is vital to ensure complete mucosal inspection. It has been reported that only three quarter of colonoscopies have an adequate colon preparation.<sup>63</sup> High rates of missed adenomas and advanced neoplasia have been observed in patients with suboptimal colon preparations.<sup>64,65</sup>

A recent paper from the USMSTF have reiterated a prior recommendation that exams with an inadequate colon preparation should be repeated with a more aggressive bowel regimen within 1 year.<sup>66,67</sup> Poor or inadequate bowel preparations appear to decrease the detection of adenomas and thus should be repeated at a short interval. More controversial are follow-up intervals for bowel preparations that are rated as fair. One study observed an adenoma miss

rate of 28% in a small sample of 39 patients who had a fair preparation on the index colonoscopy exam and a follow-up exam within 3 years.<sup>68</sup> These data suggest that colons with fair preparations could harbor undetected adenomas. Conversely, another study observed that exams with fair preparations had similar rates of adenomas and advanced lesions as those with adequate preparations, either excellent or good.<sup>69</sup> Evidence to support a follow-up recommendation for fair preparation is currently limited; furthermore, many studies do not standardize preparation scores or include withdrawal times in their analyses.

The New Hampshire Colonoscopy registry includes data regarding bowel preparation for each colonoscopy. Endoscopists are instructed to grade the preparation according to the worst prepared segment after clearing, using a consistent rating that is described in detail on the colonoscopy report form. A recent analysis of 13,022 colonoscopies showed that 11,620 (89%) were judged to have an optimal (excellent or good) preparation, 1,201 (9%) had a fair preparation and 201 (2%) had a poor preparation.<sup>70</sup> The calculated ADR for the bowel preparation groups were similar for the fair (27.1%) and optimal (26.3%) groups. There was a significant decrease in ADR for the poor bowel preparation group (20.9%). The results were similar when the analysis was restricted to the proximal colon. A multivariable analysis which included age. sex, body mass index, smoking, family history of CRC, indication for examination, withdrawal time, and endoscopist characteristics showed that only poor preparation was associated with a reduced ADR. These data support other studies that suggest that fair preparation may not significantly reduce adenoma detection.69

A recent meta-analysis examined the results of 11 studies.<sup>71</sup> The preparation quality scores were grouped into three groups: high quality (excellent/good), intermediate quality (fair), and low quality (poor / insufficient). Although low-quality preparation scores were associated with a lower ADR, intermediate preparation ADRs were not significantly different than the exams with high-quality preparations. These data support previous published reports regarding fair colon preparation scores.<sup>69,70</sup> Longitudinal data-examining outcomes and miss rates for fair preparation in a large population with standardized preparation scores are needed to address whether patients with fair preparations can be given the same follow-up intervals as guideline recommendations for high-quality preparation.<sup>67</sup>

The recent USMSTF guidelines for optimizing bowel preparation include other important recommendations for endoscopists.<sup>66</sup> The task force recommends that bowel preparation ratings should be based on the adequacy to detect polyps 5 mm or larger. Further, an adequate preparation should allow the endoscopist to adhere to recommended surveillance intervals. Finally, the bowel preparation should be rated after the endoscopist has cleared the fecal debris.

The task force also included recommendations for optimizing bowel preparations. The USMSTF recommends that endoscopists achieve an 85% adequate bowel preparation rate in their practice.<sup>66</sup> If the rate is lower than this benchmark, endoscopists should take steps to optimize their patients' bowel preparation scores. A split-dose regimen has been shown to be the most effective and should be used in all patients if possible.<sup>72–74</sup> The task force also states that "health-care professionals should provide both oral and written patient education instructions for all components of the colonoscopy preparation and emphasize the importance of compliance" with bowel cleansing. In addition, trained patient navigators can aid in compliance with instructions and bowel cleansing,<sup>75,76</sup> and instructional videos to explain the preparation, available online, have also been used effectively.

#### ADHERENCE WITH SURVEILLANCE GUIDELINES

The quality measures outlined above are essential to ensure adequate adenoma and other precancerous polyp detection. Another critical component of effective colonoscopy for CRC prevention is using appropriate evidence-based screening and surveillance intervals for follow-up. Recently published USMSTF guidelines reinforce a previous version that divided colon findings into those that are low risk such as one to two small adenomas and those that are high risk such as advanced neoplasia.67 Whereas intervals for high-risk adenomas should be shorter (usually 3 years, although shorter for piecemeal resection), those for low risk should be longer (5-10 years). Overuse of colonoscopy through shorter than guideline-recommended intervals can lead to increased complications, whereas intervals that are too long can undermine the ability for prevention. Therefore, appropriate screening and surveillance intervals are an integral part of colonoscopy quality. The recent ACG/ASGE paper on quality indicators recommended that endoscopists maintain a 90% adherence rate with surveillance guidelines.<sup>23</sup>

#### CONCLUSION

How should endoscopists ensure quality colonoscopy for CRC screening in their practice? Despite some limitations, the ADR should be calculated for each endoscopist based on data from screening examinations. If an endoscopist's ADR is lower than the benchmark of 20%, quality improvement efforts are needed to increase this rate. Endoscopists should aim to achieve cecal intubation rates of 95% or greater in screening colonoscopies. Techniques for mucosal examination with a focus on mean withdrawal time should be assessed. The quality of bowel preparation in the endoscopy practice should also be determined and optimized. Finally, in adequately prepped and carefully examined colons, compliance with screening and surveillance guidelines for future exams is strongly recommended. These steps will ensure that colono-scopy is maximally effective in preventing CRC.

# CONFLICT OF INTEREST

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