

# **Accrediting for screening-related colonoscopy services: What is required of the endoscopist and of the endoscopy service?**

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**ABSTRACT**

Colorectal cancer (CRC) screening is widely implemented to reduce CRC incidence and related mortality. The impact of screening as well as the balance between screening burden and benefits strongly depends on the quality of colonoscopy. Besides quality, safety of the endoscopic procedure and patient satisfaction are important outcome parameters for a screening program. Therefore the requirements for both CRC screening endoscopy services and endoscopists focus on technical aspects, patient safety, and patient experience. Stringent quality assurance by means of routine monitoring of quality indicators for the performance of endoscopists and endoscopy units is recommended. This allows setting minimum standards, targeted interventions, and enhancement of the overall quality of population screening. This review deals with guidelines and quality standards for colorectal cancer screening, with focus on both endoscopist and endoscopy services.

## INTRODUCTION

In recent years, more than 50 countries have implemented organized or opportunistic population colorectal cancer (CRC) screening.<sup>1</sup> It has been convincingly demonstrated that CRC screening can reduce CRC-related mortality, as well as depending on the screening method, the incidence of the disease. Screening aims to lower the burden of cancer by discovering disease at an early, preclinical stage.<sup>2-5</sup> Population-based screening for CRC and precursor lesions can be effective provided that services and colonoscopies are of high quality.<sup>6</sup> Therefore, the European Union recommends to use evidence-based methods with quality assurance of the entire screening process.<sup>7</sup> To ensure that the experience is of high quality, safe and efficient, as well as people-oriented, services must take different domains of quality assurance into account. These are endoscopy/technical aspects, patients safety, and patients satisfaction.<sup>8</sup> The level of competency to perform high-quality endoscopy and to remove advanced lesions is not only dependent on the skills of the endoscopist, but also on the support team and the available facilities and equipment.<sup>9</sup> Screening enables known finite health gains, but also potential harms. Therefore, quality assurance of screening services and endoscopists is of utmost importance in CRC screening programs. This review describes the requirements for accrediting screening centers as well as individual endoscopists in a CRC screening program.

### Organized versus opportunistic screening programs

The organization of CRC screening differs between countries.<sup>1</sup> In some countries, such as the United States, opportunistic programs have been in place for a long time, and cover a significant proportion of the population with proven effects on CRC incidence and mortality.<sup>10</sup> In most settings however, opportunistic programs are characterized by low or unknown participation rates, simultaneous frequent overuse of services by those subjects who do undergo screening, and lack of impact on national CRC incidence and mortality data. For these reasons, the European Union recommends organized screening programs.<sup>11</sup> In contrast to case-finding or opportunistic screening, organized programs provide a comprehensive data collection structure, which ensures evaluation and quality assessment. Centrally organized screening programs follow a predefined protocol, which enables systematic monitoring of the effectiveness of the program and process quality.<sup>12</sup> Also, potential harms can be surveyed, both at individual and systemic levels. If flaws in the screening program are identified, measures can be taken to improve and optimize the proposed screening.

### Requirements for the endoscopy service

To ensure high-quality CRC screening programs, endoscopy services need to be efficient, safe, person-oriented and able to monitor key outcomes.<sup>9, 13</sup> In organized screening programs, accreditation of endoscopy services ensures that these conditions are met, in order to provide a minimum standard level of safety for participants.

The European guideline divides recommendations concerning endoscopy services into two categories. The first deals with planning and location of endoscopy services and the second with infrastructure and equipment.<sup>9</sup> Planning and location recommendations include that screening services be located in convenient locations for participants, that clinical services be accessible in a timely manner, and without compromising access to endoscopy services for symptomatic patients.<sup>9</sup> Infrastructure recommendations include proper facilities for pre-procedure assessment and post-procedure recovery with sufficient privacy to maintain dignity for the patient. The guideline also includes disinfection policies and procedures with the important remark that these should be compliant with national or international guidelines.

To perform high-quality endoscopy, remove advanced lesions and deal effectively with adverse events, a competent team and adequate equipment are required. Carbon dioxide insufflation is recommended for colonic endoscopic procedures since this has been proven to improve safety and reduce post-procedural discomfort. The available equipment needs to undergo regular safety checks and its use needs to be regularly trained. The risk of adverse events should be routinely assessed with every patient. In case of serious adverse events, which cannot be managed locally, the patient needs to be transferred safely for further care. The endoscopist and supporting staff must be competent to deliver high quality endoscopy. Patient comfort score and satisfaction should be monitored and periodically evaluated, followed by targeted measures where needed.<sup>14</sup> Examples of quality requirements for the screening endoscopy service and endoscopist are depicted in Table 1.

### **Requirements for the endoscopist**

Colonoscopists are required to meet predetermined standards before involvement in a screening program, and to become subject to ongoing quality assurance. Several surrogate parameters have been developed to measure efficacy and professional quality on the level of the individual endoscopist. Commonly used parameters, which directly relate to detection of adenoma and cancer, are the quality of the bowel preparation, cecal intubation rate, colonoscopy withdrawal time, and adenoma detection rate (ADR).<sup>15-17</sup> In recent years, several studies have shown that adenoma detection rates directly relate to the risk of post-colonoscopy colorectal cancers (PCCRCs).<sup>18,19</sup> In a Polish trial involving 45,026 individuals followed for an average four years after screening colonoscopy performed by 186 individual colonoscopists, 42 PCCRCs were diagnosed.<sup>18</sup> The hazard ratio for PCCRC was more than ten if the colonoscopy had been performed by an endoscopist with an ADR <20% compared to ≥20%. In a very similar trial from the US, 314,872 individuals underwent a colonoscopy performed by 136 gastroenterologists.<sup>19</sup> During follow-up up to 10 years, 712 patients were diagnosed with a PCCRC. The adjusted hazard ratio for interval cancer

**Table 1** Examples of required quality indicators for screening endoscopy services and endoscopists with according minimum standards and targets.

Colonoscopy quality indicator	Examples	Minimum standard	Targets
<b>Infrastructure</b>			
	Proper facilities for pre-procedure assessment and post-procedure recovery.	Demonstrable	According to (inter)national guidelines
	Contamination policies and procedures.	Demonstrable	According to (inter)national guidelines
	Adequate equipment for high quality colonoscopies.	Safety checks and regular training of the available and new equipment	Documentation on safety checks and regular training performed
	Percentage of colonoscopies where CO <sub>2</sub> insufflation is used.	100% use of CO <sub>2</sub>	–
	Capable to record, monitor and deliver quality and auditable indicators [9], [13]	Demonstrable	Full registration of all quality indicators in 100% of the colonoscopies performed
<b>Performance</b>			
<i>Documentation of quality standards</i>	Percentage of colonoscopies with adequate bowel preparation [8], [28], [29]	≥90%	≥95%
	Percentage of colonoscopies with complete visualization of the cecum [9]	≥90%	≥97%
	Percentages of colonoscopies where at least one adenoma is found (ADR) [8], [18], [19]	≥30–35%	≥40%
	Percentages of negative colonoscopies with a withdrawal time ≥6 min [17]	90%	95%
	Percentage of patients with discomfort [14]	100% monitoring of comfort scores per every colonoscopy	–
<i>Documentation of auditable outcomes</i>	Number of colonoscopies performed per endoscopist per year [9]	≥300 per year	–
	Recording colonoscopic findings, procedural methods and interventions [49]	MAP/MAP+/Polyp retrieval ≥90%	Polyp retrieval ≥95%
<i>Documentation of auditable outcomes</i>	Percentage of patients with discomfort [14]	100% monitoring of comfort scores per every colonoscopy	–
<b>Fundamental outcomes</b>			
	Recording of adverse events [9], [13]	–	Post polypectomy bleeding rate <1 per 100
	Registration of interval cancers	–	Perforation rate <1 per 1000
		–	–

was 0.52 for patients of endoscopists with adenoma detection rates in the highest quintile compared to those in the lowest quintile. Every stepwise 1% increase of ADR reduced the risk for PCCRC with 3%.<sup>19</sup>

These and similar trials strongly emphasized the need for quality assurance in screening colonoscopy. This is further enhanced by the fact that the procedure is associated with risks of serious complications.<sup>20</sup>

Quality standards are measurable outcomes for which there is an evidence base that supports a minimum standard.<sup>8</sup> They drive quality to higher standards while setting limits to identify suboptimal performance. There is a range of accepted quality standards for the individual endoscopist performing screening colonoscopy.

### ***Bowel preparation***

Adequate colon cleansing is mandatory to the endoscopic visualization of the colonic mucosa. The quality of bowel preparation thus influences endoscopy efficacy, and directly affects both cecal intubation rates and polyp detection rates.<sup>21-24</sup> In addition, inadequate bowel preparation can result in longer procedure times, increased screenee burden, additional costs, shorter surveillance intervals, re-scheduled procedures, and alternative diagnostic investigations [25]. A recent prospective study showed that bowel preparation together with detection of advanced neoplasia, were the only two independent significant predictors of the need for a second-look colonoscopy in a CRC screening program.<sup>25</sup> In this study involving 1250 screenees with a positive faecal immunochemical test, 8.6% underwent a second-look colonoscopy within 1 year, of which 13% was due to poor bowel preparation at the initial investigation. This finding highlights the impact that poor colon cleansing can have on colonoscopy resources. Finally, patient's (dis)comfort and (in)convenience with regards to bowel preparation may have an effect on attendance rates of endoscopy in CRC screening programs. A randomized study showed that the proportion of individuals complaining of serious adverse events from the bowel preparation was higher (odds ratio 5.17) in those undergoing a colonoscopy than in individuals undergoing flexible sigmoidoscopy.<sup>26</sup> In this study screenees prepared for sigmoidoscopy by means of a self-administered enema (133 ml, 22% sodium phosphate) at home two hours before the procedure; for colonoscopy, an oral preparation with sodium phosphate solution (2L), starting in the afternoon preceding the scheduled appointment, was used. The most common complaints were abdominal distension and pain.

It is recommended that at least 85% of patients referred for colonoscopy and at least 90% of those who do so for screening purposes should present with an adequately cleansed colon.<sup>8, 27, 28</sup> In order to achieve adequate colon cleansing, the United States Multi-Society

Task Force (USMSTF) and the European Society of Gastrointestinal Endoscopy (ESGE) both recommend split-dose bowel preparation regimens.<sup>27, 28</sup> A split-dose regime implies that the bowel cleansing dose is given in two portions either on the day before and the day of the exam, or a same day split-dose regimen in the case of afternoon procedures. Preferably, the intake of the second dose should start 4–6 hours before the procedure time, and is completed two hours before the procedure.<sup>27</sup> The efficacy of split-dose versus day-before bowel cleansing regimens were assessed in more than 40 randomized trials. Two meta-analyses concluded that split-dose regimens lead to a significantly higher proportion of patients with adequately cleansed bowels compared with day-before regimens (odds ratios 2.5 – 3.7).<sup>29, 30</sup> As a result, split-dose compared to day-before regimens lead to higher adenoma detection rates (ADR) and potentially higher detection rates of flat polyps.<sup>17, 30, 31</sup> Split dosing also significantly decreased the proportion of patients that complained of nausea (odds ratio 0.55) or who were unable to complete the bowel preparation (odds ratio 0.53).<sup>32</sup> This increases the willingness to repeat the preparation and exam when needed (odds ratio 1.8).<sup>28</sup>

Complications need to be taken into account, when prescribing bowel cleansing medication. The ESGE advises against the routine use of sodium phosphate for bowel preparation because of safety concerns. Sodium phosphate compounds can lead to significant fluid and electrolyte shifts and are thus particularly contra-indicated in patients with hypertension, those taking diuretics or renin-angiotensin blockers, or who suffer from heart failure, chronic kidney disease, or liver failure.<sup>33</sup> In these patients, PEG is the only recommended bowel preparation.<sup>28</sup> Screening units should record and report on the bowel cleansing regimen used, and the proportion of screenees with adequately cleansed bowels.

### ***Cecal intubation rates***

Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve so that the entire cecal cap is visible. Cecal intubation rates (CIRs) reflect the proportion of patients in whom the entire colon has been reached with the colonoscope.<sup>34, 35</sup> It is recommended that CIRs be reported as unadjusted rates, i.e. rates that are not corrected for incompleteness due to luminal obstruction or poor bowel preparation. Unadjusted rates are preferred because the corrections could be applied differently and adjusted rates can therefore be difficult to compare.

When combined with measures of bowel cleansing and withdrawal time, CIR serves as a measure of the completeness of inspection of the colonic surface. Cecal intubation rates of 96% and higher have been reported in CRC screening programs.<sup>35-39</sup>, hence the

target of  $\geq 95\%$  (unadjusted) cecal intubation rate is required in colonoscopy screening.<sup>9</sup> In symptomatic patients a slightly lower target level of  $\geq 90\%$  is generally used.<sup>34</sup>

Complete colonoscopy to the cecum is sometimes difficult and cannot be performed due to patient discomfort, looping, colonic redundancy, severe diverticulosis, or adhesions. Adjunct endoscopic techniques such as water immersion, abdominal pressure, patient positioning and use of magnetic endoscopic imaging can overcome many of these challenges.<sup>40</sup> Screening units and endoscopists should record CIRs, and report the reason for not reaching the cecum.

### ***Adenoma detection rates***

Multiple studies have shown that polyp and adenoma detection rates (ADR) vary between endoscopists.<sup>41-45</sup> ADR is defined as the number of colonoscopies in which at least one adenomatous lesion is identified divided by total amount of colonoscopies.<sup>46</sup> The variation in ADR between endoscopists and the demonstration that ADRs inversely correlate with the risk for PCCRC have become the rationale for the creation of targets for adenoma detection.<sup>18, 19, 34, 43</sup> Interval cancers are defined by the World Endoscopy Organization as cancer diagnosed after a screening test or examination in which no cancer is detected and before the date of the next recommended examination.<sup>47</sup> Two large studies formed the basis for the current ADR target recommendation, being 30% in men and 20% in women in an average risk population aged  $\geq 50$  years undergoing primary screening colonoscopy.<sup>18, 19</sup> These targets should be set higher in screening programs that are based on faecal occult blood testing as primary tests, followed by colonoscopy after a positive fecal test. In the UK screening program with guaiac faecal occult blood testing, minimal adenoma detection rates are set at 35%, with a preferred target ADR  $>40\%$ .<sup>8</sup>

Since adenoma detection rates do not take the number of adenomas per positive screenee into account, and the presence of an advanced adenoma is the most important predictor for adenoma recurrence, some programs also assess the mean number of adenomas per procedure and the mean number of adenomas per positive procedure (respectively MAP and MAP+).<sup>48</sup> These measures are thought to provide additional information about colonoscopy performance in addition to ADR, and have also been shown to differ between endoscopists.<sup>8</sup>

### ***Colonoscopy withdrawal time***

In 2006, a first study showed an association between colonoscopy withdrawal time (WT) and detection of advanced neoplasia.<sup>42</sup> Colonoscopists with a mean WT of more than 6 minutes had 2.5 times higher detection rates of advanced neoplasia compared to colonoscopists with WT less than 6 minutes. This finding has been confirmed in other



studies. A multicenter randomized trial assessing the association between multiple parameters and ADR in a colorectal cancer screening program, showed that WT was the only factor related to ADR.<sup>17</sup> In another recent Canadian cohort study involving more than 18,000 asymptomatic individuals, WT and CIR were associated with the detection of screen-relevant lesions (defined as CRC, serrated and adenomatous polyps).<sup>16</sup> In this study, both an average WT over 6 minutes and a >20% detection rate of screen-relevant lesions were associated with an almost 6- to 8-fold decreased risk of PCCRCs.

Colonoscopy WT is thus an important parameter to measure when performing a screening colonoscopy. The ESGE guidelines recommend a mean WT  $\geq 6$  minutes in negative colonoscopies performed in average risk subjects for CRC screening.<sup>49</sup>

### ***Endoscopy volumes***

In contrast to colonoscopies in symptomatic patients, screening endoscopies involve healthy individuals. This further emphasizes the need for attention to the potential benefits to risks ratio. Several studies have shown that low numbers of examinations per endoscopist are associated with an increased risk of complications.<sup>20, 50</sup> In a large retrospective study from Canada, patients had a 3-fold higher odds of bleeding or perforation if their colonoscopy was performed by endoscopists with the lowest annual volume of examinations compared to patients who had their colonoscopy performed by endoscopists with the highest annual volume.<sup>20</sup> This risk of complications was increased below a threshold of 300 colonoscopies per year. As a result, current European guidelines recommend that each endoscopist participating in a colorectal cancer screening program should perform at least 300 procedures per year to maintain adequate competence.<sup>9</sup> This also ensures sufficient sample size to reliably assess quality indicators as mentioned above.

## **Screening accreditation and strategies for suboptimal performance**

### ***Accreditation of screening endoscopists***

To outline the service and quality indicators expected and in order to ensure that a high standard of service is provided, (organized) screening programs provide accreditation processes for screening endoscopists and endoscopy units. These accreditation processes lead to a certificate of competency to perform screening colonoscopy. There is a considerable disparity between countries in accreditation practice for screening endoscopists. All have different criteria for accreditation that vary in the methods of assessment, minimum number of procedures, and key quality criteria.<sup>51</sup> The responsibility for accreditation for colonoscopy also differs between countries. Responsibility for accreditation for colonoscopy can be the responsibility of the national gastroenterology society such as in Canada, or of the national screening program such as in the Netherlands. In the USA, training in gastrointestinal endoscopy is outlined in the Gastroenterology

Core Curriculum, while England has one of the most rigorous accreditation processes. Here, a Joint Advisory Group for GI Endoscopy (JAG) manages the Screening Assessor Accreditation System (SAAS) process with defined parameters for endoscopy training and national endoscopy standards<sup>52, 53</sup>.

### ***Accreditation of endoscopy services***

The Global Rating Scale (GRS) is a quality assurance program that was developed in England to assess patient-centered care in endoscopy.<sup>54</sup> The development of the GRS was prompted by the introduction of the national colorectal cancer screening program and by shortcomings in the quality of endoscopy.<sup>55</sup> The GRS is suitable to assess patient experiences, and can be used as a benchmark tool for quality and safety in endoscopy departments. More countries are of have implemented the UK Global Rating Scale in an effort to improve and maintain high standards of endoscopy service.<sup>56</sup>

Besides measuring quality indicators, it is also important to consider how suboptimal performances ought to be managed. A systematic review showed that interventions targeting endoscopist performance have generally been ineffective for improving adenoma or polyp detection rates.<sup>57</sup> However, studies included in this systematic review had small sample sizes and a lack of randomized designs. Recently, a large trial randomized endoscopy screening centers with suboptimal performance (with the centre leader having an ADR  $\leq 25\%$ ) to either a Train-Colonoscopy-Leaders programme (assessment, hands-on training, post-training feedback) or feedback only (individual quality measures). It showed that leadership training led to a significant 7.1% higher increase in ADR compared to feedback only.<sup>58</sup> These kinds of solutions to increase endoscopist performance will help to optimize CRC screening programs by decreasing the variation in quality between screening centers, and increase colonoscopy quality without decreasing colonoscopy resources by excluding centers that did not reach quality benchmarks.

### **SUMMARY**

In recent years, more than 50 countries worldwide have implemented CRC screening programs. Colorectal cancer screening can lead to significant population health gains, but can also harm healthy subjects. High quality colonoscopies are required in order to achieve CRC screening efficacy and reduce CRC-related mortality. Centrally organized screening and accreditation of screening services are recommended by the European Union and provide the possibility of systematic monitoring and quality assessment. An important parameter at the endoscopist's level is the ADR. Multiple studies have shown that ADR differs between endoscopists, and recent evidence convincingly showed an inverse correlation between ADR and risk of PCCRC, emphasizing the importance of high quality endoscopies. Future research is needed to address current practice in the identification

of early endoscopically resectable CRCs and endoscopic resection techniques used to remove them accurately in a CRC screening setting in order to improve screening program, increase quality and prevent unnecessary surgery.

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