Quality in screening colonoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE)

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Background

Many countries in Europe are now introducing screening for colorectal cancer [1]. This considerable investment adds to national economic burdens and must be audited to demonstrate that it is cost-effective, well-targeted and of high quality. Spending more money, having more doctors, admitting more patients or having a nearby "center of excellence" does not necessarily result in improved outcomes.

The provision of healthcare services is most effective when delivered in an organized and coordinated way [2]. Ad hoc screening for breast and cervical cancer has been shown to be less efficient and poorer value for money compared with screening delivered by an organized cancer screening program [3–12].

The International Agency for Research on Cancer defines an organized cancer screening program as having: (i) an explicit policy with defined methods including screening intervals; (ii) a clearly defined target population; (iii) a management team for implementation and to monitor uptake; (iv) a clinical healthcare team to decide on clinical matters; (v) a detailed quality assurance program; and (vi) a method for identifying cancer occurrence and death in both the target and the background populations [13].

Until recently, the only method of screening which had been tested in randomized prospective studies was the guaiac fecal occult blood test (FOBT) [14–18]. This screening method is therefore the only one that is recommended by the European Union [19]. Several European countries now have a FOBT-based organized screening program in place (Finland, France, Italy, Czech Republic, and the United Kingdom) and further countries are planning to introduce such a program. Several trials of flexible sigmoidoscopy have been recently reported or are due to report soon [20–22].

Methodology

The European Society of Gastrointestinal Endoscopy (ESGE) commissioned this Position Statement. A small working group was convened, with representation from Italy, France, the UK, Switzerland, Egypt, and Germany. The development process for this document included online discussions among members of the entire committee during 2009 and 2010.

A literature search was carried out on the Medline and Cochrane databases. Articles were first selected by title; their relevance was then confirmed by review of the corresponding abstract, and publications with content that was considered irrelevant were excluded. Additional articles were identified by manually searching the reference lists of retrieved papers. The evidence was not formally graded.

Searches were re-run in December 2010.

The recommendations are relevant to individuals and institutions involved in colorectal cancer screening, to ensure that screenees have access to screening with consistently reproducible high standards.

It is emphasized that this document does not consider the respective advantages of different screening modalities or quality assurance (QA) items related to flexible sigmoidoscopy. In addition, this document does not advise on QA issues outside the direct remit of screening colonoscopy, such as benchmarking the screening uptake, coverage, compliance, or timeliness of the screening service. Finally, this document does not address how screeners should be trained and accredited.

For a complete review of the merits of different methods of screening for colorectal cancer we refer to the recent guideline produced by the European Union [23]. This guideline also discusses the impact of different screening methodologies on endoscopic, histological, radiological, surgical, and oncological services.

Key quality indicators

Similarly to other screening programs, screening for colorectal cancer may directly harm its participants. Direct harm may for example be caused by oversedation, colonic perforation, or bleeding precipitated by polypectomy. Indirect harm may be caused by surgical intervention for neoplasia which would not have presented clinically if left in situ.

There are two principal reasons for collecting accurate data in an organized screening program. Firstly this enables QA indicators to be assessed and the addressing of suboptimal performance. Secondly, if there is no account for how the taxpayer's money is spent, continued funding may not be forthcoming [24].

Voluntary participation of screening centers in the QA process is not satisfactory. In the voluntary Norwegian Gastronet project, initially 73 endoscopists at 14 hospitals agreed to enter information on all their colonoscopies. At the initial analysis, complete datasets were available from only six institutions, and in these only 87 % of examinations appeared to have been fully captured [25]. In the follow-up phase of the study, the participation dwindled further and eventually only eight institutions entered any level of data. Furthermore, the authors concluded that it was the least experienced endoscopists who submitted the least data, particularly when the examinations were incomplete [26].

We recommend that national screening boards should monitor quality indicators and use them to license individual colonoscopists and endoscopy units. Our Position Statement document also proposes thresholds for acceptable colonoscopic practice. However, the precise QA thresholds will depend on the details of a country's screening program. Our list of recommendations is summarized in **Table 1**, and **Table 2** details the information that should be included in the screening colonoscopy report.

Consent

We recommend that the number of patients who decline colonoscopy on the day of the procedure, and the number of intraprocedural withdrawals of consent, should be recorded. Our proposed audit standards are withdrawal of consent on the day of the procedure in fewer than 5% of cases, and withdrawal of consent during the procedure in fewer than 1% of cases.

National screening boards have a duty to introduce robust systems to provide full information for screenees at all levels of the program. Individuals invited to an organized screening program deserve information about the potential benefits but also about the possible hazards intrinsic to colorectal cancer screening.

Organized screening programs should also ensure that there are policies guiding the consent process; this should include a clear explanation of the procedure and of the preparation required, and should have a realistic discussion of discomforts, risks, and benefits. Patients also need to be aware of the possibility that significant disease may be missed and of the possibility of early and late adverse events. After the procedure, patients should have direct access to advice 24 hours a day, in case of complications presenting after the procedure.

Individuals should have the opportunity to withdraw consent during the examination. However, patients should also be told that there may be occasions, for example in the middle of a snare polypectomy, when the procedure cannot be halted immediately. Cases of withdrawn consent during colonoscopy should be recorded in any organized screening program. We propose that fewer than 1 % of patients who undergo colonoscopy can be expected to withdraw consent during the procedure.

Bowel cleansing

We recommend that the state of bowel cleansing should be audited and propose the standard that at least 90% of screening examinations should be rated as having "adequate" or better bowel cleansing.

Effective bowel cleansing is fundamental for high quality colonoscopy. Good bowel preparation allows the detection of neoplasia and optimizes cecal intubation, whilst poor bowel cleansing is associated with prolonged procedures and failure to detect disease [27 – 32]. There is also a need for careful pre-assessment to highlight issues such as renal or hepatic impairment, heart failure, and use of diuretics.

There is a lack of data on the impact of different bowel cleansing regimens in the context of an organized screening program, and no single agent appears to be superior. Preparations containing sodium phosphate may be better tolerated but there are safety concerns particularly when these are used in the elderly or in patients with renal impairment [33 – 35]. For this reason oral sodium phosphate solution has been withdrawn from the market in the United States. Tolerability, especially in the elderly, can be poor with high volume polyethylene glycol (PEG) solution [36 – 38]. Splitting the volume of PEG administered improves tolerability [39] and the quality of bowel preparation [40].

The timing of the bowel cleansing appears to be more important than the splitting of the dose. The degree of mucosal cleanliness appears to be best when the examination is commenced within hours of the bowel preparation [41]. Several studies have looked at the effect of taking the bowel preparation on the same day as the colonoscopy [42 – 45]. There is heterogeneity among the studies and the size of the effect varies. However, the direction of the effect is consistent: colonoscopy is best started within a few hours of finishing the bowel preparation.

As terms such as "poor," "good," or "excellent" are subjective, several scales to more formally assess bowel cleanliness have been published. However, these have mainly been devised for use in clinical trials [38, 46 – 49]. The Ottawa [50] and Boston [51] Bowel Preparation Scales are validated tools to record the state of bowel cleansing. They are both somewhat technical, requiring the endoscopist to numerically score the state of bowel cleansing in each colonic segment and then to add the values to obtain a total "bowel cleansing score." This value may then have to be translated into something that makes sense on an endoscopy report (e. g. "poor," "substandard," "adequate," "good," or "excellent" bowel preparation). Of note, the Boston scale takes into account the possibility of washing the mucosa.

Although there is no preferred method to assess the effectiveness of bowel cleansing, national screening boards should agree on a scale to standardize the reporting of bowel preparation. In addition, endoscopy reports should contain details of what bowel cleansing was used, patients' satisfaction with the regimen, and likely reason for inadequate bowel cleansing.

Of course more difficulties may be anticipated in achieving good bowel preparation for certain participant groups, such as those with poor reading skills, those who are socioeconomically disadvantaged, the very elderly, inpatients, immobile patients, or patients taking medications such as opiates. Nevertheless, all individuals presenting for screening deserve a fair chance of having

Table 1 Quality assurance in screening colonoscopy: summary of recommendations

Quality assurance item	Proposed standard
Consent and withdrawal of consent	Audit the number of patients who decline colonoscopy on the day of the procedure and the number of intraprocedural withdrawals of consent. Proposed standard: fewer than 5 % of cases to withdraw consent on the day of the procedure and fewer than1 % during the procedure
Experience of the screening colonoscopist	We recommend that a minimum lifetime colonoscopy experience together with a minimum number of annual screening colonoscopies should be agreed. Proposed standard: to be agreed by screening boards
Bowel cleansing	The state of bowel cleansing should be audited. Proposed standard: at least 90 % of examinations should be rated as "adequate" bowel cleansing or better
Sedation, analgesia, and comfort	Audit of sedation practices, including average doses used of medication together with comfort scores. Proposed standard: no more than 1 % of patients should become hypoxic (saturation below 85 % for more than 30 seconds) or for other reasons require administration of a reversal agent
Unadjusted cecal intubation rate	Audit the completion rate for all colonoscopies. Proposed standard: *unadjusted* cecal intubation rate of at least 90 %
Adenoma and cancer detection rates	The number of detected adenomas and cancers should be audited. Proposed standard: to be agreed by screening boards
Colonoscope withdrawal time	Average withdrawal times should be audited. Proposed standard: a minimum of 6 minutes in at least 90 % of purely diagnostic examinations
Polyp retrieval rate	Screening programs anticipate that all resected polyps are retrieved for histological analysis. Proposed standard: ≥ 90 % of resected polyps should be retrieved for histological analysis
Significant interval lesions	We recommend that screening programs monitor size, appearance, location, and histology of all polyps larger than 1 cm and cancers found between screening examinations as well as after the patient has been discharged from a screening program. Proposed standard: to be agreed by screening boards
Specialist referral for removal of larger polyps	We anticipate that the removal of larger polyps will be deferred to a dedicated clinical session, perhaps at a separate tertiary referral centre. Screening programs should record how larger polyps detected at screening are managed, together with details of outcomes. Proposed standard: to be agreed by screening boards
Cleaning and disinfection	Adoption of manufacturers', national, and European standards for disinfection. Proposed standard: routine microbiological testing at intervals not exceeding 3 months
Tattooing sites of larger polyps and cancers	We recommend that screening programs set standards regarding which polyp sites should be tattooed. Proposed standard: the placement of tattoos following the removal of all polyps 2 cm or larger outside of fixed colonic landmarks such as the cecum and rectum
Unscheduled readmissions	We recommend that screening programs record details of all emergency admissions within 30 days of the screening colonoscopy. Proposed standard: to be agreed by screening boards
Perforation rate	We recommend that details should be recorded of all perforations complicating diagnostic and therapeutic procedures, that require surgical repair and that occur up to 2 weeks after endoscopy. Proposed standard: fewer than 1:1000 diagnostic or therapeutic examinations should result in a perforation requiring surgical repair
Bleeding rate	All cases of immediate and late bleeding following polypectomy should be recorded. Proposed standard: fewer than 1:20 cases of bleeding should ultimately require surgical intervention

a colonoscopy with a good exclusion value. For this reason, we propose the quality benchmark that no more than 10 % of the examinations should need to be repeated due to inadequate bowel preparation. This is likely to require a change in bowel cleansing regimens in some units. At the first analysis of data from the English national program, 8 /48 screening centers (17 %) did not meet this benchmark and had to make adjustments to their bowel cleansing regimens [C. Rees; personal communication on behalf of the English National Bowel Cancer Screening Evaluation Group].

Sedation, analgesia and comfort

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We recommend that sedation practices, including average doses and patient comfort scores, are audited for screening examinations. We recommend the standard that fewer than 1 % of patients should become hypoxic (saturation below 85 % for more than 30 seconds) or for other reasons require administration of a reversal agent.

Patients should be able expect a high quality, comfortable, and safe colonoscopy. Although colonoscopy without sedation is cheapest and safest [52 – 54], a higher risk of discomfort may impact adversely on screening uptake and colonoscopy completion rates.

In some European countries sedation is rarely used, whilst in others an opiate is combined with a benzodiazepine or propofol is used almost exclusively [55]. A review of the benefits and risks of sedation has not shown any clear advantage for a particular approach [56]. Recovery time is shortest with Entonox (nitrous oxide and oxygen). When Entonox is used, screenees can drive home after their procedure. If sedation with propofol alone is used, the ESGE recommends that patients may be able to drive after a minimum of 12 hours [57], compared with 24 hours following the administration of midazolam and opioids.

Table 2 Details to be included in the colonoscopy report.

Patient details	
Endoscope used	Manufacturer, model, and serial number
Name and position of endoscopist and ancillary staff	
Indication for the procedure	Number of screening round Details and interval to the recent screening investigation Follow-up polypectomy after previous screening colonoscopy
Bowel cleansing	Bowel cleansing regimen given Patient tolerance of bowel cleansing regimen Mucosal views obtained
Intubation	Limit of examination including reason why examination was incomplete Duration of intubation to limit of examination Duration of extubation
Disease detected and management	Site of each lesion Size of the lesion (as estimated by the endoscopist) Growth morphology (Paris classification) Crypt pattern of each lesion (Kudo's classification) Endoscopic diagnosis of each lesion Action taken for each lesion Success and complications in removing each lesion Diathermy settings used for cautery Final histological diagnosis

Naturally, sedation must be delivered in line with guidance produced by national screening boards. To allow comparisons of performance, national screening boards should agree a scoring system to monitor sedation practices, patient comfort, and level of sedation. The use of the following types of sedation practice should be recorded: (i) no sedation or analgesia; (ii) conscious sedation, including which drugs were used; (iii) propofol or general anesthesia; or (iv) Entonox.

Unfortunately, there is no validated score to record level of sedation and comfort, although a validation of a colonoscopy comfort score is underway. The American Society for Gastrointestinal Endoscopy (ASGE) has adopted a "continuous model" in which sedation ranges from simple anxiolysis to "conscious sedation," in which the patient responds to verbal commands and maintains adequate spontaneous breathing. This is followed by "deep sedation" when the patient is only responsive to pain and may stop breathing spontaneously [58]. Sedation is particularly hazardous in the elderly who are more likely to have co-morbidities that affect cardiorespiratory reserve and are more sensitive to the effect of sedation and analgesia [59, 60].

Evaluating patient comfort is more problematic. The endoscopist, the assistant, and the patient may have different opinions about the level of comfort during the procedure. We recommend that the patient's estimate of comfort should be recorded on a simple scale such as for example: 1, no or minimal discomfort; 2, mild discomfort; 3, moderate discomfort; or 4, severe discomfort.

A total of 14% of patients undergoing procedures in the Norwegian Gastronet program reported that the examination had been "severely painful" and a further 20% regarded the procedure as "painful." Patients undergoing colonoscopy performed by surgeons were more likely to report pain than patients examined by gastroenterologists. The authors of that study concluded that the proportion of patients reporting a painful procedure was unacceptably high [61].

In addition, organized screening programs should record cases in which the oxygen saturation drops below 86% and when agents such as naloxone or flumazenil are used to reverse the sedation [62]. In an audit of sedation practices in a range of countries, hypoxic episodes were reported in 5% of procedures [63].

It may seem illogical to term the use of a potentially lifesaving measure, such as administration of reversal agents, a "negative outcome." Indeed, if the consequence of administration of a single dose of reversal agent is punitive to the endoscopist, this may become a disincentive to its use.

Nevertheless, the death of a patient from a respiratory arrest is the worst possible outcome. For this reason we propose the quality benchmark that fewer than 1% of patients should become hypoxic (saturation below 85% for more than 30 seconds) or for other reasons require administration of a reversal agent.

Cecal intubation rate

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We recommend that the completion rate for all screening colonoscopies is audited, and we propose a minimum standard of 90% for unadjusted cecal intubation rate.

A complete examination of the colon and rectum is fundamental to any colorectal cancer screening program. The medial wall of the cecum between the appendiceal orifice and ileocecal valve can not be visualized from a distance. Cecal intubation is defined as deep intubation into the cecum with the tip of the endoscope being able to touch the appendiceal orifice.

Failure to reach the cecum is expensive and inconvenient for patients as a new attempt at colonoscopy or a radiological examination is required.

Rapid and reliable cecal intubation is also a proxy indicator of colonoscopy skill. However, other factors also have an effect. The chances of successfully reaching the cecum are reduced in individuals with advancing age and increasing body mass index (BMI) [64, 65]. Colonoscopy in a young patient in good health is most likely to be complete [66, 67]. The use of technology such as the variable stiffness colonoscope [68] or endoscopic imaging can also improve the probability of successful cecal intubation [69].

The English National Health Service (NHS) Bowel Cancer Screening Programme (BCSP) has set a minimum, unadjusted cecal intubation rate of 90% [70]. The European Commission guideline also regards a 90% cecal intubation rate as acceptable but excludes cases with obstructive cancer requiring surgery [71].

The US Multi-Society Task Force on Colorectal Cancer recommends different benchmarks for "screening" and "symptomatic" populations (95% and 90%, respectively) [72, 73]. Similarly, Cancer Care Ontario Colonoscopy Standards set a minimum adjusted completion rate of 95% (excluding cases with poor bowel preparation and obstructing lesions) [74].

The appendiceal orifice should be photographed, preferably from a distance of 2 to 4 cm, so that the photograph encompasses the cecal strap fold or "crow's foot." A second photograph should be taken more distally to include the entire cecum and the ileocecal valve. The terminal ileum should be photographed if intubated. If resources are available, video recording provides the highest level evidence that the cecum has been intubated.

In the context of an organized screening program, variables such as the presence of an obstructing lesion are likely to be equally

distributed amongst all screening providers. For this reason, in the context of an organized screening program, we recommend that only completely unadjusted data are recorded, that is, based on intention to examine the complete colon. Not adjusting for cases with poor bowel cleansing makes the measure more objective and will allow national bowel cancer screening programs to detect endoscopy units that provide suboptimal bowel cleansing regimens.

Detection of adenomas and cancers

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We recommend that the number of adenomas and cancers is recorded for all screening examinations. As the number of lesions detected depends on the details of the screening program, the audit standard would have to be agreed by screening boards.

The detection of adenomas and early cancers is fundamental in any bowel cancer program. Data from the US National Polyp Study [75] and the UK Flexible Sigmoidoscopy Screening Trial [76] have shown that the removal of colonic adenomas reduces the risk of subsequent cancer.

When a primary FOBT-based organized population screening program is implemented, a secondary-test population "enriched" with adenomas and cancers is expected. Typically, screenees presenting for colonoscopy following a positive guiac-based FOBT have a 35% risk of detection of adenoma and a nearly 11% risk of cancer [77]. This compares with a 15%–25% risk of detection of benign adenoma by ad hoc case finding [78–80].

Unfortunately there is evidence that adenomas are missed at colonoscopy [81–83] and that some endoscopists miss more polyps than others [84]. A marked variation in adenoma detection rate (8%–16%) was found in the UK Flexible Sigmoidoscopy Screening Trial [85]. A recent meta-analysis of studies of colonoscopies performed by primary care physicians in the USA found an even greater range in adenoma detection (8.8% to > 50%) [86]. A tandem study demonstrated a miss rate for advanced adenomas (> 1 cm) of up to 6%, and a rate as high as 27% for adenomas less than 5 mm in size [87]. Such values have been confirmed by comparative studies between CT colonography and colonoscopy [88]. In a recent Polish study, screening colonoscopists with adenoma detection rates below 20% were more likely to have patients subsequently presenting with interval cancer [89].

It has been demonstrated that there is a good correlation between the polyp and adenoma detection rates (ADR) [90]. Nevertheless, adenoma detection is a more relevant QA item than polyp detection which would also include a number of non-neoplastic polyps. Although checking the histology of all polyps removed is a large task, it should be achievable within an organized screening program. In countries that are setting up bowel cancer screening programs, the national screening boards need to agree on minimum adenoma and cancer detection rates within their program.

The English Bowel Cancer Screening Programme defines "adenoma detection rate" as "the number of colonoscopies at which one or more histologically confirmed adenomas is found divided by the total number of colonoscopies performed." Perhaps a more useful alternative would be the "adenoma detection index" (ADI) which signifies the total number of adenomas detected divided by the total number of colonoscopies performed.

The benchmarks set for minimum detection rates would depend on the details of the country's colorectal cancer screening program, such as the age of those screened [91, 92] and the sensitivity and specificity of the primary stool test used [93–98]. In addition, the adenoma and cancer detection rate will vary greatly between men and women. Finally, when an organized screening program is introduced in a country with widespread ad hoc case finding for bowel cancer, fewer polyps and cancers may be detected.

In the English screening program a surprisingly wide range of adenoma detection was found at the first analysis [C. Rees; personal communication on behalf of the English National Bowel Cancer Screening Evaluation Group]. It is of concern that some screening colonoscopists only detected an adenoma at 22% of examinations whilst others found adenomas in 60% of cases. As adenomas are more common in men (mean adenoma detection rate [ADR] 52.9% in men vs. 36.5% in women), a predominance of women in the screening population might have explained part, but not all, of this variation.

Withdrawal time

We recommend that the average withdrawal time is audited during screening colonoscopies and propose a minimum of 6 minutes in at least 90% of purely diagnostic examinations.

Colonoscopy withdrawal time and polyp detection are closely related. Two large studies have supported a minimum withdrawal time of 6 minutes in diagnostic colonoscopies [99, 100]. As the finding of polyps, followed by their removal increases the average duration of the colonoscopy, this figure only applies to examinations in which no polyps are found.

In the study by Barclay et al., there was a threefold difference (9.4%–32.7%) in adenoma detection rate depending on the duration of withdrawal (which ranged from 3.1 to 16.8 minutes). Colonoscopists with withdrawal times of greater than 6 minutes had higher detection of any neoplasia (28.3% vs. 11.8%). In addition, the detection of advanced neoplasia was also significantly different (6.4% vs. 2.6%). A recent analysis of the English screening program showed that withdrawal times of 10 minutes were associated with the best adenoma detection rate [101].

As there is a correlation between withdrawal time and the detection of adenomas we recommend that withdrawal time is audited. A minimum of 6 minutes for withdrawal time is recommended in cases when no therapy is undertaken. However, speed of withdrawal is not the only factor affecting polyp detection.

In addition to withdrawal time, factors such as aspiration of liquid, careful examination behind folds [102], position change, the use of buscopan, fitting a shallow cap on the tip of the endoscope [103], or technology such as high resolution or "the third-eye retroscope" can also improve polyp detection [104, 105].

The use of blue dye sprayed onto suspicious mucosal areas improves the detection of smaller lesions or polyps with a flat growth pattern [106, 107]. Furthermore, dye-spraying techniques allow prediction of histology [108] particularly when used together with a magnifying endoscope [109]. Image processing technologies such as Olympus narrow band imaging (NBI), Fuji Intelligent Chromo Endoscopy (FICE) and the Pentax i-scan have been developed to provide quicker assessment of suspicious areas and to allow differentiation between hyperplastic and adenomatous polyps [110].

Retrieval of polyps

We recommend that the number of resected and retrieved polyps is audited for all screening colonoscopies, and propose the standard that at least 90% of resected polyps are retrieved for histological analysis.

Retrieval of resected polyps for histological examination is important. In the UK pilot demonstration of colorectal screening, 16.6% of all cancers were "polyp cancers" [81]. As expected, the risk of polyp-cancer increases with the size of the polyp (**Table 3**). After piecemeal resection, or when histological analysis of adenomas larger than 10 mm cannot confirm complete excision, early follow-up is recommended (e.g. within 3 – 6 months). Interestingly, when polyps are resected using Endocut current, microscopic evaluation of resection margins is better than if coagulation current is used for polypectomy [111].

In organized screening programs it is expected that resected polyps will be retrieved for histological analysis. However, recently, a "resect and discard" policy for smaller polyps has been proposed. At an expert center, optical diagnosis has been found to be accurate in more than 90% of polyps up to 10 mm in size [112]. Such a policy would result in substantial cost savings for screening programs [113].

As the effect of a "resect and discard" policy has never been tested outside tertiary referral centers, we recommend that national screening boards monitor the retrieval rate for all resected polyps. Successful retrieval of at least 90% of excised polyps seems a reasonable standard.

Significant interval lesions

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We recommend that the size, appearance, location and histology of all polyps larger than 1 cm should be recorded in screening programs, as well as all cancers found between screening examinations and those found after the patient has been discharged from a screening program.

The US National Polyp Study suggested that polypectomy can prevent up to 90% of subsequent cancers. In a study by Imperiale et al. [114] no interval cancers were found 5 years after a negative colonoscopy in 1256 individuals. However other studies have demonstrated a lower protective effect [115]. In a study by Farrar et al. [116] 5.4% of all cancers detected were interval lesions. A pooled analysis of North American studies that had followed patients with previous adenomas for a median of 4 years put the risk of subsequent cancer at 0.6% [117] (the risk of developing an "advanced neoplasia" was 11.8%). In a retrospective Dutch study the sensitivity of colonoscopy to detect a colorectal cancer was estimated at 90% [118]. In a Canadian study, between 2% and 6% of patients who developed colorectal cancer had undergone a colonoscopy in the previous 3 years [119].

It appears that colonoscopy offers better protection against future cancer arising in the left hemi-colon (80% protection) than the right hemi-colon (12% – 33% protection) [120 – 124]. One explanation for why colonoscopy might offer better protection against distal cancers is that the right side of the colon tends to be less well cleaned than the left side. Indeed, miss rates are consistently two- to threefold higher in the proximal than the distal colon [125 – 127]. An alternative explanation is that right-sided lesions are more aggressive [128] or that they arise from inconspicuous flat lesions [129] that are easily missed particularly as the right hemi-colon is more difficult to clean [130].

National screening boards need to agree clear definitions for "interval lesions." For example, they may be defined as adenomas larger than 1 cm or cancers, that are detected between a screening episode and the scheduled next screening (surveillance) episode. Data on interval lesions are an important tool for assessing the quality of screening colonoscopies. Capturing data on adenomas larger than 1 cm or cancers that are detected after the patient has left a screening program would also be important, for example to identify a need to extend the screening age range.

We recommend that national screening bodies record the details (size, appearance, location, and histology) of all lesions detected, not just during screening examinations but also outside the screening program. By cross-referencing data with national cancer registries, it should be possible for national cancer screening programs to obtain accurate data on interval cancers.

Table 3 Risk of malignancy versus size of polyp in the English Bowel Cancer Screening Programme (BCSP)

	Polyp-cancers, n	Total polyps, n	Polyp-cancers, %
Size range			
0 – 9 mm	103	34 959	0.29%
10 – 19 mm	370	8 425	4.39%
20 – 29 mm	240	3 008	7.98%
≥ 30 mm	174	1 705	10.2%
Size not recorded	34	957	–
Total	921	49 054	1.88%

Removal of larger polyps

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We recommend that screening programs audit how larger lesions detected at screening are managed, together with details of outcomes. In particular, the number of benign lesions referred for surgical resection should be recorded and outcomes monitored.

The purpose of colorectal cancer screening is to detect early cancers and remove precursor lesions safely and effectively, thereby potentially reducing cancer incidence. However, screening colonoscopists may not have the expertise to remove the largest polyps. In addition, the removal of larger polyps is associated with greater risks and the informed consent process must reflect this.

Unfortunately, referring patients with larger benign lesions for surgery rather than polypectomy may be associated with higher risks of adverse outcomes [131, 132]. There is evidence from the French screening program that up to 10% of entirely benign polyps are removed surgically rather than endoscopically [133].

Colonoscopists providing an enhanced therapeutic referral service may not wish to provide conventional screening. Nevertheless, in order to provide a therapeutic referral service, we recommend that individuals should register as "screening colonoscopists" and collect QA data on their activities. There is little published data on advanced therapy complication rates that can be used to establish benchmarks for such a tertiary referral service [134]. Moss et al. reviewed the outcomes following resection of 479 polyps, 2 cm or larger in size. A total of 1.5% of patients presented with a post-polypectomy serositis, 2.1% were admitted with pain following the procedure, 2.9% of patients suffered delayed bleeding, and perforation complicated 1.3% of resections [135]. It seems clear that the risks are greater with larger polyps.

Tattooing the sites of suspected malignant polyps and cancers

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We recommend that screening programs introduce guidelines on the use of ink tattoos and recommend the placement of tattoos fol-

lowing the removal of all polyps 2 cm or larger situated outside of the cecum or rectum.

The sites of larger polyps, suspected malignant polyps, and cancers should be marked with an indelible compound such as India ink or a pure carbon-based alternative, if they are situated outside of an unmistakable colonic landmark such as the rectum or cecum. This assists identification at follow-up colonoscopies or at the time of surgery (especially for laparoscopic resections).

India ink is a marker which requires dilution and sterilization in contrast to pre-packed sterile pure carbon-based preparations. Concerns have been raised about the safety of tattooing, with reports of fever, abdominal pain, and abscess formation [136]. However, prior injection with saline followed by injection of the ink into the saline bleb appears safe [137].

National screening bodies should agree guidelines on which lesions detected at screening should have the site marked with a tattoo. Furthermore, agreement with local colorectal surgeons should be sought regarding the preferred number and position of tattoos. In most cases, it is preferable to place more than one tattoo just distal to the lesion. The placement of 2 or 3 tattoos ensures that at least one tattoo is visible on the antemesenteric border of the colon, allowing the distal resection margin to be clear of neoplasia.

The risk of unexpected cancer increases with the size of the polyp, approaching 10% for lesions 2 cm in diameter or larger (**Table 3**). For this reason, we recommend the placement of tattoos following the removal of all polyps 2 cm or larger situated outside of the rectum or cecum.

Minimum experience for screening colonoscopists

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We recommend that screening programs agree a minimum lifetime experience for their screening colonoscopists and set a minimum benchmark for their annual number of screening examinations.

There is a link between the experience of the endoscopist and the time to reach the cecum, as well as with polyp detection rate and with outcomes following polypectomy [138 – 140].

A population-based study from Canada found that the risk of complications such as perforation and bleeding was increased threefold with colonoscopists who performed fewer than the threshold of 300 colonoscopies per year [141]. For this reason, the setting of a minimum annual number of screening colonoscopies is fundamental to all other QA audits. For example, the English NHS Bowel Cancer Screening Program set requirements of a minimum lifetime experience of 1000 examinations and a minimum annual number of 150 screening colonoscopies. This annual figure was set in order to allow meaningful analysis of QA data from all screening colonoscopists [142].

To ensure that screeners are of sufficient caliber, all national screening boards should consider setting minimum standards for lifetime experience and annual number of procedures.

Recording early and late adverse outcomes

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We recommend that full details of all complications, including unscheduled re-admissions following screening examinations are recorded. We propose the quality standard that fewer than 5% of bleeding complications should require surgical intervention and that fewer than 1:1000 screening colonoscopies should be complicated by a perforation requiring emergency surgery.

Colonoscopy with polypectomy is a high risk endeavor with the potential for life-threatening complications. Screening for colorectal cancer therefore has a real risk of directly harming its participants.

It is difficult to draw firm conclusions from the literature on the incidence of complications. Most published series come from single centers with extensive experience in colonoscopy, without separation of symptomatic and screening patients. Results may therefore not reflect standard practice. Differences among authors in the definitions of complications has also hampered the setting of firm benchmarks for screening. Recently the American Society for Gastrointestinal Endoscopy (ASGE) sponsored a workshop that devised a useful classification system of adverse events to incorporate into our current Minimal Standard Terminology (MST version 3.0) lexicon [62]. We encourage national screening boards to use the current MST terminology together with the recent ASGE classification of adverse events.

Many adverse events are obvious direct complications of the endoscopic procedure, e.g. bleeding, perforation, or cardiorespiratory complications. However, at other times it can be more difficult to decide whether an adverse event should be attributed to the colonoscopy. Examples could include phlebitis at the site of the intravenous cannula, abdominal discomfort that resolves spontaneously soon after the colonoscopy, development of a chest infection within a week of the procedure.

As it is important not to miss adverse outcomes that may have been caused by the endoscopic procedure, we propose that all events should be recorded that result in: (i) an unscheduled admission; (ii) a lengthening of the hospital stay; (iii) an unscheduled further endoscopic procedure; (iv) emergency intervention, including blood transfusion; (v) emergency surgery; or (vi) death of the patient.

The capture of "late events" up to 30 days after the patient has left the endoscopy unit is difficult. Nevertheless it forms a benchmark which allows comparison between screening programs. Full details of all readmissions should be sought including reason for admission, length of stay, medical/surgical intervention, and outcomes.

Perforation

In study series from both Nottingham in the UK [14] and Minnesota in the USA [16] there were approximately 7 perforations per 10 000 colonoscopies. In the UK pilot program, 5 perforations per 10 000 colonoscopies were reported. In the smaller Norwegian Colorectal Cancer Prevention (NORCCAP) study, there were no reported perforations following diagnostic examinations; however 1 perforation per 336 polypectomies was reported [143].

The British Society of Gastroenterology (BSG) audit of colonoscopy in the UK also demonstrated that the risk of perforation approximately doubles when polypectomy is carried out [144]. The risk of perforation at diagnostic examinations was 1:923 compared with 1:460 following polypectomy. A review of a larger dataset (39 286 colonoscopies carried out in the US Medicare program) also reported a perforation rate of 1:500 examinations but did not report on the influence of polypectomy [145]. The above figures are not dramatically different from that of a German review of colonoscopies carried out in the late 1970s. This study from 40 years ago reported 1 perforation complicating every 300 polypectomies [146].

A colonic perforation is usually defined as evidence of air, luminal contents, or instrumentation outside the gastrointestinal tract. Nevertheless a small, contained perforation into the omental re-

flection of the colon or a microperforation which is immediately closed by the application of clips may also be regarded as a perforation. On occasion, perforations are suspected in patients who develop abdominal discomfort following simple mucosal biopsies or smaller polypectomies. In these cases abdominal X-rays may disclose the presence of a small amount of intramural gas or pericolonic edema; this can be difficult to interpret when the patient has no clinical signs of a perforation.

Most perforations complicate therapeutic procedures and some polypectomies are more hazardous than others. The risk of perforation appears to be greatest with the removal of larger, sessile, or right-sided polyps [147]. Provided that such therapeutic microperforations are immediately recognized and managed with the application of clips and systemic antibiotics, no harm will ensue.

A pragmatic endpoint, which will capture all significant cases, is to only record perforations which require surgical repair. We propose the quality benchmark that fewer than 1:1000 screening examinations should result in a perforation requiring emergency surgery.

Bleeding

Bleeding at the time of polypectomy is common and is usually of no significance when immediately managed endoscopically. However, if further intervention such as an unscheduled admission is required, the bleeding should be recorded as an adverse event. Pragmatically, post-polypectomy bleeding (PPB) may be defined as visible blood loss or melena for up to 2 weeks following the procedure that requires transfusion, surgery, or further endoscopic therapy. This definition excludes the smaller amount of post-polypectomy bleeding that most patients experience following the removal of large lesions.

It is difficult to draw conclusions from published PPB rates as a huge range (1:10 to 1:300) has been reported [148, 149]. The reason for the wide range is that the risk of bleeding is affected by numerous factors. Elderly patients, or those taking antithrombotic medication (apart from aspirin) appear to be at greatest overall risk [150, 151]. Lesion-specific factors also affect the risk of bleeding. The risks are greater with larger and sessile lesions, particularly in the right hemi-colon [147]. Finally, the diathermy settings can also influence bleeding rates [152]. The use of a "pure cut" diathermy is associated with a higher risk of immediate bleeding [153, 154] whilst "blended" and "pure coagulation" electrocautery are associated with a similar risk of PPB [155], with a trend to more immediate versus delayed (up to 8 days) PPB with blended versus coagulation current, respectively.

The topic of PPB has recently been reviewed by the ESGE [156]. The review concluded that endoscopic interventions that are effective in preventing PPB include placement of a detachable loop ligating device for large pedunculated polyps and submucosal injection of diluted adrenaline for sessile polyps. The efficacy of other measures, including endoclip placement, injection of saline, and argon plasma coagulation, has not been definitively demonstrated.

Finally, it is perhaps not surprising that the experience of the colonoscopist also affects the risk. A study of outcomes following almost 100 000 outpatient colonoscopies showed that the risk of complications was 3-fold greater when the polypectomy was carried out by a "low volume" colonoscopist [145]. However, it is likely that it is the annual number of polypectomies that is of importance rather than the annual number of diagnostic examinations. The German quality assurance program has set a modest annual minimum of 10 snare polypectomies to maintain accreditation.

In almost all instances of immediate and delayed bleeding, it should be possible to manage the bleeding with supportive care and endoscopic therapy. As the rate of PPB is affected by a large number of factors, it is difficult to set an arbitrary benchmark. However, in all cases of late bleeding in which the patient is hemodynamically compromised or has ongoing bleeding, an attempt at endoscopic management should precede surgery. We propose that less than 5% of patients suffering a post-polypectomy bleed, as defined above, should ultimately require surgical intervention

The colonoscopy report

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The report is an important record of the screening examination and we recommend that it contains a minimum dataset documenting the procedure.

It is important that the endoscopy report is complete, with details of all abnormalities. In particular, details of each lesion detected should be recorded together with information on method of removal. For a complete colonoscopy report, the ESGE recommend a set of eight photographs to be taken from standard locations [157]. A ninth photograph of the low rectal mucosa with the endoscope in a retroverted position should also be taken whenever possible. In addition, reasons for any failed cecal intubation should be recorded.

An outline of information which should be included in the screening colonoscopy report is detailed in **Table 2**. In many countries the patient is provided with a copy of the report immediately after the procedure and the endoscopist is obliged to immediately forward a copy to the patient's primary care physician. Nevertheless, most would consider the endoscopy report to be incomplete before it has been updated with the final histological analysis.

Cleaning and disinfection of equipment

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We recommend that standards for disinfection set by manufacturers and by national and European bodies are actively audited in screening programs, and recommend routine microbiological testing at intervals not exceeding 3 months.

Appropriate cleaning of endoscopes and accessories is a core requirement of endoscopy. Naturally, individuals attending for screening must be able to be confident that all equipment has been effectively cleaned.

The Guideline Committee of ESGE and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) has published detailed guidelines relating to hygiene and disinfection in endoscopy [158, 159]. In addition to these there may be local regulations, national laws [160], and manufacturers' instructions to follow.

There are also published European Standards (EN 14885) and guidelines on how the efficacy of the cleaning process should be assessed [161 – 163] at intervals not exceeding3 months. National screening boards should ensure that relevant guidelines are followed.

Conclusion

Our guidance has been produced under the auspices of the ESGE with the aim of providing clear and simple advice for countries setting up organized screening programs, to allow assessment of safety and quality relevant to screening colonoscopy.

Colonoscopy is fundamental to most screening programs and the success of screening programs is closely related to the prompt provision of a high quality, patient-centered colonoscopy service. To minimize risks and maximize benefit, all countries need to put robust quality assurance frameworks in place.

The adoption of our quality assurance items lays the foundation for meaningful comparisons among individual endoscopists, different endoscopy units, and even the services provided by different countries, to achieve better outcomes for patients.

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This ESGE position statement is intended to assist National Bodies developing Quality Standards for Colorectal Cancer Screening Programmes. The recommendations are not rules and should not be constructed as establishing a legal standard of care or as encouraging, advocating, requiring or discouraging any particular treatment.