

European guidelines for quality assurance in colorectal cancer screening and diagnosis. First Edition

Quality assurance in endoscopy in colorectal cancer screening and diagnosis

Authors

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Institutions

Institutions are listed at the end of article.

Keywords

- mass screening
- colorectal neoplasms
- endoscopy
- colonoscopy
- flexible sigmoidoscopy
- evidence-based guidelines
- multidisciplinary population-based programmes

Multidisciplinary, evidence-based guidelines for quality assurance in colorectal cancer screening and diagnosis have been developed by experts in a project coordinated by the International Agency for Research on Cancer. The full guideline document covers the entire process of population-based screening. It consists of 10 chapters and over 250 recommendations, graded according to the strength of the recommendation and the supporting evidence. The 450-page guidelines and the extensive evidence base have been published by the European Commission. The chapter on quality assurance in endoscopy includes 50 grad-

ed recommendations. The content of the chapter is presented here to promote international discussion and collaboration by making the principles and standards recommended in the new EU Guidelines known to a wider professional and scientific community. Following these recommendations has the potential to enhance the control of colorectal cancer through improvement in the quality and effectiveness of endoscopy and other elements in the screening process, including multidisciplinary diagnosis and management of the disease.

Background

According to the most recent estimates by the International Agency for Research on Cancer [33] colorectal cancer (CRC) is the most common cancer in Europe with 432 000 new cases in men and women reported annually. It is the second most common cause of cancer deaths in Europe with 212 000 deaths reported in 2008. Worldwide CRC ranks third in incidence and fourth in mortality with an estimated 1.2 million cases and 0.6 million deaths annually. The European Union (EU) recommends population-based screening for breast, cervical and colorectal cancer using evidence-based tests with quality assurance of the entire screening process including diagnosis and management of patients with screen-detected lesions [25]. The EU policy takes into account the principles of cancer screening developed by the World Health Organization [103] and the extensive experience in the EU in piloting and implementing population-based cancer screening programmes [99]. Screening is an important tool in cancer control in countries with a significant burden of CRC, provided the screening services are high quality [100]. The presently reported multidisciplinary, evidence-based guidelines for quality assurance in colorectal cancer screening and

diagnosis have been developed by experts and published by the EU [81].

Methods

The methods used are described in detail elsewhere in this supplement [60]. Briefly, a multidisciplinary group of authors and editors experienced in programme implementation and quality assurance in colorectal cancer screening and in guideline development collaborated with a literature group consisting of epidemiologists with special expertise in the field of CRC and in performing systematic literature reviews. The literature group systematically retrieved, evaluated and synthesized relevant publications according to defined clinical questions (modified Patient-Intervention-Comparison-Outcome-Study method). Bibliographic searches for most clinical questions were limited to the years 2000 to 2008 and were performed on Medline, and in many cases also on Embase and The Cochrane Library. Additional searches were conducted without date restrictions or starting before 2000 if the authors or editors who were experts in the field knew that there were relevant articles published before 2000. Articles of adequate quality recommended

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by authors because of their clinical relevance were also included. Only scientific publications in English, Italian, French and Spanish were included. Priority was given to recently published, systematic reviews or clinical guidelines. If systematic reviews of high methodological quality were retrieved, the search for primary studies was limited to those published after the last search date of the most recently published systematic review, i.e. if the systematic review had searched primary studies until February 2006, primary studies published after February 2006 were sought. If no systematic reviews were found, a search for primary studies published since 2000 was performed.

In selected cases references not identified by the above process were included in the evidence base, i.e. when authors of the chapters found relevant articles published after 2008 during the period when chapter manuscripts were drafted and revised prior to publication. The criteria for relevance were: articles concerning new and emerging technologies where the research grows rapidly, high-quality and updated systematic reviews, and large trials giving high contribution to the robustness of the results or allowing upgrading of the level of evidence.

The methodological quality of the retrieved publications was assessed using the criteria obtained from published and validated check lists. Evidence tables were prepared for the selected studies. The evidence tables, clinical questions and bibliographic literature searches are documented elsewhere [59]. In the full guidelines document prepared by the authors and editors [81] over 250 recommendations were formulated according to the level of the evidence and the strength of the recommendation using the following grading scales.

Level of evidence:

- I multiple randomised controlled trials (RCTs) of reasonable sample size, or systematic reviews (SRs) of RCTs
- II one RCT of reasonable sample size, or 3 or less RCTs with small sample size
- III prospective or retrospective cohort studies or SRs of cohort studies; diagnostic cross sectional accuracy studies
- IV retrospective case-control studies or SRs of case-control studies, time-series analyses
- V case series; before/after studies without control group, cross sectional surveys
- VI expert opinion

Strength of recommendation:

- A intervention strongly recommended for all patients or targeted individuals
- B intervention recommended
- C intervention to be considered but with uncertainty about its impact
- D intervention not recommended
- E intervention strongly not recommended

Some statements of advisory character considered to be good practice but not sufficiently important to warrant formal grading were included in the text.

Results

A number of guiding principles and 50 graded recommendations are provided in Chapter 5.

Guiding principles for a colorectal screening endoscopy service

1. People undergoing endoscopy, whether for primary screening, for assessment of abnormalities detected in screening, for assessment of symptoms, or for surveillance, should have as good an experience as possible, permitting them to encourage screening, assessment and surveillance of appropriate quality to their friends, family and colleagues.
2. The provision of the service must take into account the perspectives of endoscopists and public health to ensure that the experience is high-quality, safe, efficient as well as person-oriented.
3. Provision of screening should take account of historic development within different local and cultural contexts.
4. The provision of primary screening endoscopy is less complex than follow-up endoscopy (of screen-positives) primarily because of the lower frequency of high-risk lesions in primary screening endoscopy.
5. The introduction of screening must not compromise endoscopy services for symptomatic patients.
6. Screening and symptomatic (diagnostic) services should achieve the same minimum levels of quality and safety.
7. Wherever possible the quality assurance required for screening should have an enhancing effect on the quality of endoscopy performed for symptomatic patients and for other reasons.
8. Screening and diagnosis of appropriate quality requires a multidisciplinary approach to diagnosis and management of lesions detected during endoscopy.

Recommendations¹

Planning and location of endoscopy services

- 5.1 When implementing high-volume primary screening endoscopy consideration should be given to locating services in convenient locations for participants **(VI-B)**.^{Sect 5.1.4}
- 5.2 Screening services should be provided in proximity to clinical services **(VI-C)**.^{Sect 5.1.2}
- 5.3 The planning of screening services should take account of the frequency of high-risk lesions in the screening population and the competencies and equipment required to remove these lesions safely and completely **(III-B)**.^{Sect 5.1.2}
- 5.4 The referral rate for excision of high-risk lesions should be audited **(VI-B)**.^{Sect 5.1.2}
- 5.5 The clinical lead of the screening service should be satisfied that staff have the necessary competencies, that the equipment is sufficient to perform the necessary procedures and that adverse events can be dealt with effectively **(VI-A)**.^{Sect 5.1.2}
- 5.6 Equipment and training needs should be assessed before screening begins **(VI-A)**.^{Sect 5.1.2}
- 5.7 The impact of demand from screening on waiting times for symptomatic patients should be assessed to ensure that there is sufficient planned new capacity to avoid inap-

¹ **Sect** (superscript) after each recommendation in the list refers the reader to the section/s of the Guidelines dealing with the respective recommendation.*

Rec (superscript) throughout the chapter refers to the number of the recommendation dealt with in the preceding text.*

* The first digit of the section numbers and recommendation numbers refers to the respective chapter in the guidelines. For Chapters 1 to 4 see: [48,52,61,34], and for Chapters 6 to 10 see: [91,67,90,3,5], respectively.

appropriately long waiting times for symptomatic patients **(VI–A)**.^{Sect 5.1.5}

- 5.8 Any screening service, regardless of setting, should make an assessment of the risk of adverse events and develop the capability to respond to emergencies **(VI–A)**.^{Sect 5.1.8}

Infrastructure and equipment

- 5.9 The infrastructure of an endoscopy unit must include facilities for pre-procedure assessment and recovery, and be designed to allow good patient flow in order to maximise efficiency **(VI–B)**.^{Sect 5.1.6}
- 5.10 The environment must have sufficient privacy to maintain the dignity of patients **(VI–B)**.^{Sect 5.1.6; 5.3.6}
- 5.11 The volume of equipment should match the demand put upon it to maximise efficiency and avoid patient delays **(VI–B)**.^{Sect 5.4.3}
- 5.12 Video endoscopes with the facility for focal application of dye are required for the detection and assessment of high-risk colorectal lesions **(III–B)**.^{Sect 5.4.3}
- 5.13 There should be an adequate supply of accessories suited to the endoscopic interventions undertaken within the unit **(VI–B)**.^{Sect 5.4.3}
- 5.14 National policies on the use of re-usable accessories should be adopted **(VI–B)**.^{Sect 5.4.3}
- 5.15 There should be properly maintained resuscitation equipment in the endoscopy room and recovery area **(VI–B)**.^{Sect 5.4.3; 5.5.2}
- 5.16 Maintenance of equipment should be undertaken by competent staff **(V–A)**.^{Sect 5.4.3}
- 5.17 There should be regular review of the functioning and cleansing of all endoscopes, according to national or pan-European guidelines containing accepted, published recommendations and standards **(VI–B)**.^{Sect 5.4.3}
- 5.18 The results of the review should be available at all times in the endoscopic unit **(VI–A)**.^{Sect 5.4.3}

Preparation of the patient and aftercare

- 5.19 Follow-up colonoscopy after positive screening (any modality) should be scheduled within 31 days of referral (acceptable >90%, desirable >95%). (See also Ch. 3 [61], Rec. 3.16) **(VI–B)**.^{Sect 5.3.5; 3.3.4}
- 5.20 Each endoscopy service must have a policy for pre-assessment that includes a minimum data set relevant to the procedure. There should be documentation and processes in place to support and monitor the policy (see also Ch. 10 [5], Rec. 10.28) **(III–B)**.^{Sect 5.3.2; 10.4.3}
- 5.21 Bowel preparation for screening flexible sigmoidoscopy should involve a single procedure, either enema or oral preparation **(II)**. A single self-administered enema seems to be the preferred option, but cultural factors should be taken into account, and patient preferences should be assessed (see also Ch. 2 [52], Rec. 2.20) **(II–B)**.^{Sect. 5.3.3}
- 5.22 To date no single bowel preparation for colonoscopy has emerged as consistently superior over another **(I)** although sodium phosphate may be better tolerated and it has been shown that better results are obtained when the bowel preparation is administered in two steps (the evening before and on the morning of the procedure) **(II)**. It is therefore recommended that there should be colonic cleansing protocols in place and the effectiveness of these should be monitored continuously **(VI–A)**.^{Sect 5.3.3}

- 5.23 Several providers of bowel preparation close to the target population should be available when a patient is required to reach health or community facilities to obtain the preparation. Clear and simple instruction sheets should be provided with the preparation. For flexible sigmoidoscopy screening, organisational options should include the possibility of having the enema administered at the endoscopy unit. (See Ch. 2 [52], Rec. 2.21) **(VI–B)**.^{Sect 5.3.3}
- 5.24 Cleansing solution containing mannitol or other malabsorbed carbohydrates (e.g. sorbitol) must be avoided in the preparation of the colon because of the risk of explosion with electrocautery **(III–A)**.^{Sect 5.4.4}
- 5.25 The endoscopy service must have policies that guide the consent process, including a policy on withdrawal of consent before or during the endoscopic procedure (see also Ch. 10 [5], Rec. 10.29) **(VI–B)**.^{Sect 5.3.1; 10.4.3}
- 5.26 Before leaving the endoscopy unit, patients should be given a verbal explanation of the results of their procedure; they should also be given written information to support the verbal explanation (see also Ch. 10 [5], Rec. 10.30) **(VI–A)**.^{Sect 5.5.3; 10.4.3}
- 5.27 The outcome of screening examinations should be communicated to the primary care doctor (or equivalent) so that it becomes part of the core patient record (see also Ch. 10 [5], Rec. 10.31) **(VI–B)**.^{Sect 5.5.5; 10.4.3}
- 5.28 There should be pre-defined clinical pathways for individuals found to require further intervention for cancer, including pT1 cancers, incompletely-removed lesions and difficult-to-remove lesions; as well as for incomplete examinations; and for individuals requiring further surveillance. (See Sect. 5.4.4 and Ch. 8 [90], Sect. 8.3.6 and Ch. 9 [3]). In addition, failsafe mechanisms must be in place to ensure that these interventions occur **(I–B)**.^{Sect 5.5.5}

Endoscopic technique

- 5.29 There should be local policies and processes in place to optimise sedation and patient support in order to maximise tolerance and minimise risk of complications **(I–B)**.^{Sect 5.4.4}
- 5.30 Because there is no clear benefit from a particular approach **(I)**, and for practical reasons it is recommended that policies on the use of sedation should be adopted according to protocols based on national or pan-European guidelines, and must take into account historical context, the impact on the patient experience and costs **(I–B)**.^{Sect 5.1.3}
- 5.31 Carbon dioxide insufflation is recommended for colonic endoscopic procedures **(I–A)**.^{Sect 5.4.4}
- 5.32 Carbon dioxide insufflation should be avoided in patients with COPD, known CO₂ retention or reduced pulmonary function **(VI–A)**.^{Sect 5.4.4}
- 5.33 The utilisation of magnetic endoscope imaging (MEI) technology may be considered for patients requiring colonoscopy, particularly when little or no sedation is used **(II–B)**.^{Sect 5.4.2}
- 5.34 The use of variable stiffness colonoscopes is recommended for screening colonoscopy **(I–B)**.^{Sect 5.4.2}
- 5.35 To achieve a high-quality colonoscopic examination it is necessary to perform a complete intubation of the colon and to carefully inspect the mucosa during withdrawal **(I–A)**.^{Sect 5.4.5.1}
- 5.36 If the endoscopist doubts whether he/she is able to remove a high-risk lesion, the lesion must be appropriately docu-

mented and, if necessary, its position marked with a tattoo. The patient should then be referred elsewhere to have the lesion removed endoscopically or surgically **(VI – A)**.^{Sect 5.1.2}

Performance of endoscopists and quality improvement

- 5.37 It is recommended that the annual number of procedures performed by an endoscopist is recorded to ensure that the sample size for key performance indicators is sufficient **(III – A)**.^{Sect 5.4.5.1}
- 5.38 Each endoscopist participating in a colorectal cancer screening programme should undertake to perform at least 300 procedures per year to ensure there is a sufficient sample size to assess competence. A higher volume of procedures is desirable **(III – B)**.^{Sect 5.4.5.1}
- 5.39 Services should be planned such that individual endoscopists achieve a desirable volume of procedures (>300/year) **(III – B)**.^{Sect 5.1.2; 5.4.5.1}
- 5.40 There should be auditable photo documentation of completion, preferably a panoramic image of the ileo-caecal valve and caecum, or a video clip with a respective snapshot **(VI – A)**.^{Sect 5.4.5.1}
- 5.41 The unadjusted caecal intubation rate should be a prime indicator of quality of colonoscopy. The acceptable standard is >90%; >95% is desirable (see also Ch.3 [61], rec. 3.11) **(III – A)**.^{Sect 5.4.5.1; 3.3.2; 3.3.3}
- 5.42 There should be documentation and review of reasons for failed completion **(III – B)**.^{Sect 5.4.5.1}
- 5.43 Screening programmes should adopt a minimum set of outcomes to determine the quality of inspection of the colonic mucosa **(VI – A)**.^{Sect 5.4.5.1}
- 5.44 It is recommended that unplanned hospital admission on the same day as the endoscopic procedure be a key adverse outcome. Reasons for admission should be documented **(III – A)**.^{Sect 5.4.5.2}
- 5.45 Endoscopic services must have processes in place to identify and record adverse outcomes occurring after the patient leaves the endoscopy unit **(VI – B)**.^{Sect 5.4.5.2}
- 5.46 All screening programmes should have processes in place for monitoring, auditing, reviewing and acting upon key auditable outcomes and quality indicators **(III – A)**.^{Sect 5.2}
- 5.47 All endoscopists and centres performing endoscopy should participate in a continuous quality improvement programme, including tracking of quality and safety indicators for individual endoscopists. This should include action plans, for both endoscopists and staff, for addressing suboptimal performance **(VI – A)**.^{Sect 5.1.7}

Policies and processes

- 5.48 Decontamination policies and procedures should be compliant with national or pan-European guidelines containing accepted, published recommendations and standards. The policies should be available in the endoscopy department and updated regularly **(VI – A)**.^{Sect 5.4.1}
- 5.49 Decontamination processes should be audited against defined indicators **(VI – A)**.^{Sect 5.4.1}
- 5.50 The endoscopy unit should create and regularly review clinical guidelines, policies and processes, taking into account relevant national or pan-European guidelines **(VI – B)**.^{Sect 5.6}

5.1 Effect of screening modality on the provision of endoscopic services for screening



5.1.1 Clinical setting

Colonoscopy is the recommended test for follow-up investigation for individuals who have tested positive with other CRC screening tools (FOBT, Flexible sigmoidoscopy (FS), and also in experimental studies assessing potential screening tools, e.g. DNA faecal markers and CT colonography). High-quality endoscopy (colonoscopy and flexible sigmoidoscopy (FS)) is also used in some Member States as a screening tool for colorectal cancer. The frequency of endoscopy when used as a primary screening tool will be much higher than endoscopy used as a follow-up investigation of another screening test. Thus the phrase 'high-volume screening endoscopy' will be used to refer to endoscopy used as a primary screening tool and 'low-volume screening endoscopy' will be used to refer to follow-up endoscopy. However, it is recognised that if the test positivity rate in a FOBT screening programme is high a large volume of colonoscopies will be generated. The key practical difference of these high- and low-volume populations requiring endoscopy in a screening context is the probability of identifying and nature of high-risk lesions (see below).

The setting in which the endoscopic procedure will be performed will be determined by:

- ▶ quality and safety determinants;
- ▶ the need for sedation;
- ▶ patient-oriented factors;
- ▶ possible impact on symptomatic services;
- ▶ infrastructure and efficiency;
- ▶ staff competencies and equipment; and
- ▶ availability of support services.

5.1.2 Quality and safety

Diagnostic procedures, both flexible sigmoidoscopy and colonoscopy, can be performed safely in diverse clinical settings. When providing services for a colorectal cancer screening programme, the key consideration is what facilities and level of competence are required to remove high-risk lesions. Removing large high-risk lesions safely requires a considerable level of competence and appropriate support close at hand when a complication occurs. For example, it would be inappropriate to remove large or difficult high-risk lesions if the colonoscopist is only rarely faced with such a lesion (as in high-volume, low-risk population screening) or if the procedure is being done in a remote setting. The setting in which screening (or follow-up colonoscopy) is established will be determined by the ability to perform high-quality endoscopy (defined later) and by the probability of finding a high-risk lesion that is difficult to remove completely and safely. If there is concern about removing the lesion it is entirely appropriate for the colonoscopist to leave it (and perhaps tattoo it) and refer the patient on for either endoscopic, or in some instances, surgical excision.

The colonoscopist needs to judge whether he/she is competent to remove a lesion and whether it is safe to remove the lesion in this setting. On the basis of good practice it is recommended that if there is doubt, the lesion must be appropriately documented and the patient referred elsewhere to have the lesion removed **(VI – A)**.^{Rec 5.36}

Thus, when considering where endoscopic screening services are to be located, the commissioner should be aware of how often a patient may need to be referred elsewhere. If it is expected that referral somewhere else will be a frequent occurrence (perhaps

> 1% of patients) then it is better to consider locating the service elsewhere, i.e. where the competence of the available endoscopists would permit less referral.

To help in the planning of location of endoscopic services for screening, the following five levels of competency are proposed.

- ▶ **Level 0:** The operator does not remove any lesions, referring on all patients with any detected lesions. The operator will be able to biopsy lesions, and pathological material may inform the decision to refer. Basic level of competency for diagnostic FS but not recommended for screening FS.
- ▶ **Level 1:** Removing lesions < 10 mm in diameter at FS. Rationale: larger lesions will indicate a need for colonoscopy and can be removed when the colonoscopy is performed. Tissue is required from smaller lesions to decide whether colonoscopy is necessary. Thus any person performing FS screening should have this level of competency.
- ▶ **Level 2:** Removing polypoid and sessile lesions < 25 mm providing there is good access. All colonoscopists should have this level of competency.
- ▶ **Level 3:** Removing smaller flat lesions (< 20 mm) that are suitable for endoscopic therapy, larger sessile and polypoid lesions, and smaller lesions with more difficult access. Some flat lesions < 20 mm with poor access might be unsuitable for this level. Any person doing colonoscopy for positive FOBT in a screening programme should have this level of competency.
- ▶ **Level 4:** Removing large flat lesions or other challenging polypoid lesions that might also be treated with surgery. This is the type of lesion that would not be removed at the first colonoscopy because of time constraints, if applicable, or because the surgical option needs to be discussed with the patient. If the patient chooses to have endoscopic therapy, then he/she should be referred to a level 4 competent endoscopist. This level of competency would be expected of only a small number of regionally based colonoscopists.

In the context of colorectal screening and diagnosis in Europe, units only providing Level 0 competencies are not recommended, because unnecessary endoscopic procedures would be required to remove small lesions which could have been removed during the initial FS. Furthermore, unnecessary colonoscopies may be encouraged in the absence of histopathological evaluation of small lesions left in place during the initial FS.

The level of competency to perform high-quality endoscopy and to remove high-risk lesions is also dependent on the competency of the support team and the available equipment: a highly competent endoscopist requires equally competent support staff and the right equipment and supplies to perform the procedure and deal with any problems that might arise (such as clips for uncontrolled bleeding).

It is recognised that the methodology does not currently exist to reliably recognise who has achieved the proposed levels of competence. Thus, until a competency-based assessment process is available the clinical lead of the service should be satisfied that:

- ▶ the professionals have the necessary competence;
- ▶ the unit has the necessary equipment; and
- ▶ in the event of a serious adverse event, it will be possible to manage the patient locally or transfer the patient safely to another institution with the expertise and facilities to care for the patient.

A review of capabilities may identify shortcomings that can be addressed with further training or investment (see Chapter 6 [91]). This training and investment should occur before screening begins.

It is recommended that:

- ▶ Screening services be provided in proximity to clinical services **(VI-C)**.^{Rec 5.2}
- ▶ The planning of screening services should take account of the frequency of high risk lesions in the screening population and the competencies and equipment required to remove these lesions safely and expertly **(III-B)**.^{Rec 5.3}
- ▶ Services should be planned such that individual endoscopists achieve a desirable volume of procedures to maintain high competence (> 300/year, see section 5.4.5.1) **(III-B)**.^{Rec 5.39}
- ▶ The clinical lead of the screening service should be satisfied that staff have the necessary competencies, that the equipment is sufficient to perform the screening procedures, and that serious adverse events can be dealt with effectively **(VI-A)**.^{Rec 5.5}
- ▶ A review of equipment and training needs should be performed before screening begins **(VI-A)**.^{Rec 5.6}
- ▶ Referral rate for excision of high-risk lesions is an auditable outcome **(VI-B)**.^{Rec 5.4}

5.1.3 The need for sedation

The use of sedation for lower gastrointestinal endoscopic procedures varies between European countries. Three main patterns are readily discernible:

- ▶ infrequent use of sedation;
- ▶ frequent use of conscious sedation with opiates and benzodiazepines; and
- ▶ almost exclusive use of deep sedation with propofol or general anaesthesia.

This variation suggests there is no perfect approach, and emphasises the need to take into account historic cultural differences when implementing screening endoscopy. A review of the benefits and risks of sedation showed no clear advantage for a particular approach: conscious sedation provides a high level of physician and patient satisfaction and a low risk of serious adverse events with all currently available agents [57].

The risk of an adverse cardio-respiratory event is lower if the patient does not have sedation [29,51,73,77]. Thus, there is less need for monitoring equipment and recovery facilities if sedation is not used. Therefore sedationless endoscopy can occur in more remote settings, and it requires lower set-up costs. However, if no sedation is offered, the patient must accept a higher chance of unacceptable discomfort and the endoscopist a lower chance of completing the procedure because of patient discomfort. These downsides might affect the uptake and impact of screening: potential screenees are worried about comfort, and incomplete procedures may miss important pathology.

In most circumstances it is possible for the endoscopist to administer conscious sedation, but in some European countries propofol administration requires an attending anaesthetist. Thus the costs of providing sedation, particularly if an anaesthetist is required to administer propofol, will vary between countries. The relative quality and safety of different approaches are reviewed later in this chapter.

Because there is no clear benefit from a particular approach **(I)**, and for practical reasons it is recommended that policies on the use of sedation must be adopted according to protocols based on national or pan-European guidelines, and take into account historical context, the impact on the patient experience and costs **(I-B)**.^{Rec 5.30}

5.1.4 Patient considerations

Patients generally prefer services that are close to home and easily accessible. Thus high-volume screening endoscopy is probably best situated closer to the population to be screened. In contrast, level 3 and 4 expertise for removing high-risk lesions is likely to be provided at district and regional levels respectively. The priority here is the facility and expertise, not proximity.

When implementing high-volume screening endoscopy consideration should be given to locating services in convenient locations for patients to maximise engagement in screening **(VI–B)**.
Rec 5.1

5.1.5 Possible destabilising effect on symptomatic services

Unplanned introduction of screening endoscopy (at whatever level) creates additional demand and may lead to destabilisation of the symptomatic service. Thus, if endoscopy for screening is introduced alongside symptomatic services, care must be taken to ensure there is sufficient new capacity.

An assessment of the impact of demand from screening on waiting times for symptomatic patients should be made to ensure that there is sufficient planned new capacity such that screening does not lengthen waits for symptomatic patients **(VI–A)**.
Rec 5.7

5.1.6 Infrastructure and efficiency

The infrastructure requirements for high-volume screening endoscopy need to cater to large numbers of presumptively healthy people. High-volume screening endoscopy requires efficient booking, assessment and recovery processes to function effectively without compromising the patient experience. Thus, it may be advantageous for high-volume screening activities to be separated from routine clinical endoscopy and follow-up endoscopy of screen-positives.

It is self-evident that the infrastructure must be adequate. It must include facilities for pre-procedure assessment and recovery, and must also be designed to allow good patient flow in order to maximise efficiency **(VI–B)**.
Rec 5.9 In addition, a suitable environment will maintain the privacy and dignity of patients **(VI–B)**.
Rec 5.10

5.1.7 Endoscopist and support staff competencies

Endoscopists and supporting staff providing endoscopy screening must be competent to deliver high quality FS or colonoscopy in order to achieve high patient satisfaction and all the required performance standards relating to quality and safety (see Sect. 5.4.5 and Ch. 6 [91]).

It is a fundamental requirement of quality assurance that all endoscopists and centres performing endoscopy should participate in a continuous quality improvement programme, including individual tracking of quality and safety indicators. This should include management plans, for both endoscopists and staff, for addressing suboptimal quality **(VI–A)**.
Rec 5.47

5.1.8 Support services

Only rarely will a person undergoing a primary screening procedure require admission to hospital for further care. Thus it is not necessary to have medical support facilities close at hand. However, services performing endoscopy in more remote settings must have robust guidelines and processes in place to enable patients to be resuscitated effectively and be transferred rapidly and safely to a hospital where surgical services are available. On

this basis it is recommended that any screening service, regardless of setting, should make an assessment of risks and develop the ability to respond to emergencies **(VI–A)**.
Rec 5.8

5.1.9 Conclusion

While there are no absolutes, a case can be made for delivering high-volume screening endoscopy outside traditional hospital settings to improve the patient experience and to reduce health-care and societal costs. In contrast, risk assessments will indicate that colonoscopy following a positive FOBT or a positive FS is a more complex procedure that is associated with higher risks and should, therefore, be performed in acute hospital settings.

5.2 Audit and quality improvement



This section proposes that endoscopy services monitor key outcomes to ensure that a high-quality and safe service is being provided and to identify areas in need of improvement. Two terms are used for such outcomes: auditable outcomes and quality indicators. An auditable outcome refers to an outcome that should be measured, but for which there is not an evidence base to recommend a standard, such as the comfort of the procedure. A quality indicator is an outcome for which there is a sufficient evidence base to recommend a standard, such as caecal intubation rate.

It is expected that some auditable outcomes will become quality indicators as the evidence base improves, and that the standards of quality indicators will rise as standards improve.

On the basis of this, it is recommended that all screening programmes should have processes in place for monitoring, auditing, reviewing and acting upon key auditable outcomes and quality indicators in the following areas (see also Annex 5.1 and 5.2 and Chapter 3 [61]) **(III–A)**.
Rec 5.46

- ▶ Quality;
- ▶ Safety; and
- ▶ Patient feedback.

5.3 Before the procedure



Beginning the patient journey

Section 5.3 and subsequent sections follow the patient journey from invitation to discharge from the endoscopy service.

5.3.1 Patient information and consent

Information in this context includes information related to the endoscopic procedure and should include why the procedure is being done, what it involves, preparation for the procedure, and the risks. The patient should be told what he/she might expect to happen after the procedure (including contact details in case of emergency) and the plan of aftercare. The patient should be informed about the options for sedation and how this might affect their perception of the procedure and the associated restrictions on travelling home. There are subtle differences in the approach to consent between a primary screening test and one done following a positive screening test such as FS and FOBT, explained in more detail in Chapter 10 [5].

The consent process involves an explanation of the procedure, the potential benefits, the risks and possible consequences. Consent for endoscopic procedures begins with a recommendation

to have the examination, and ends when the procedure is complete. The individual must have the opportunity to withdraw consent at any stage during this process.

It is good clinical practice for an endoscopy service to have policies that guide the consent process, including a policy on withdrawal of consent immediately before or during the endoscopic procedure. **(VI–B)**.^{Rec 5.25}

The key elements of patient information for endoscopy include:

- ▶ considerations related to current medications including anticoagulants and antiplatelet agents;
- ▶ considerations related to previous medical illnesses;
- ▶ the benefits of the test;
- ▶ how to prepare for the procedure (including bowel cleansing);
- ▶ the nature of the procedure and what it involves;
- ▶ possible adverse events including discomfort and complications;
- ▶ what support the patient may need after the procedure, particularly if they are sedated; and
- ▶ the importance of not driving or making important decisions after sedation.

Auditable outcomes: patient feedback on information and consent processes. These assessments should ideally be both qualitative and quantitative and make an assessment of the patient experience judged by the gap between the expectation and actual experience (see Chapter 3 [61]). Withdrawal of consent should be registered as an adverse clinical incident.

5.3.2 Pre-assessment

The purpose of pre-assessment is to identify factors that might influence the outcome of the procedure, such as anticoagulation and general health status. Pre-assessment also provides an excellent opportunity to ensure the patient understands the bowel cleansing process and to answer any questions the patient may have.

The nature of the pre-assessment will depend on whether there has been prior contact with an endoscopy service health professional. If there has been no prior contact with the service, it is advised to pre-assess the patient several days before the procedure, at least before starting bowel cleansing. This will enable the procedure to be rescheduled if there are concerns about safety, or for medication such as warfarin to be withdrawn in sufficient time to allow its anticoagulant effect to wear off.

Available evidence [11, 13, 35, 38, 49, 96] suggests that the following patient-related variables should be identified and taken into account prior to FS or colonoscopy because they can be associated with more adverse events, longer duration, and incomplete examination: **(III)**

- ▶ Use of anticoagulants e.g. warfarin;
- ▶ Anatomy (female sex);
- ▶ Age of patient;
- ▶ Prior abdominal surgery;
- ▶ BMI;
- ▶ Diverticular disease;
- ▶ ASA PS (American Society of Anesthesiology classification of Patient Status)² and information that may influence type and

level of sedation (for those procedures where sedation may be used); and

- ▶ Presence of risk factors for endocarditis.

On the day of the procedure there should be a brief review of the previously collected information and measurement of basic cardio-respiratory function.

It is recommended that each endoscopy service have a policy for pre-assessment that includes a minimum data set relevant to the procedure. There should be paperwork and processes in place to support the policy **(III–B)**.^{Rec 5.20}

Auditable outcomes: Recording and review of adverse clinical events related to inadequate pre-assessment (e.g. anticoagulants not stopped or risk factors for endocarditis not identified).

5.3.3 Colonic cleansing

Inspection of the colon requires careful preparation removing colonic contents to optimise the safety and quality of the procedure. Ideally there should be no residual stool or liquid in the lumen that could mask any suspicious area.

Flexible sigmoidoscopy

The ongoing European sigmoidoscopy trials adopted a bowel preparation based on a single enema, self-administered at home within two hours from the appointment, or, in one case, at the screening centre.

No studies were found assessing the effect of having the enema performed directly at the screening centre, although this represents an option that might enhance participation by reducing patient's concerns and enhancing engagement. Available evidence from one controlled trial did not indicate that using two enemas (the first the night before the test and the second two hours before the scheduled time for the exam) affects participation compared to using a single enema [84]. Oral preparation was associated with a reduced participation in a large screening trial, compared to enema [4]. Adding oral preparation to the enema resulted in reduced participation [14].

No difference in the proportion of inadequate exams was observed when comparing a single enema regimen to a preparation using two enemas or to oral preparation.

Bowel preparation for screening sigmoidoscopy should involve a single procedure, either enema or oral preparation **(II)**. A single self-administered enema seems to be the preferred option, but cultural factors should be taken into account, and patient preferences should be assessed (see also Ch. 2 [52], Rec. 2.20) **(II–B)**.^{Rec. 5.21}

Colonoscopy

Data on the impact of different preparation regimens in the context of population screening with colonoscopy are lacking. A recent systematic review concluded that no single bowel preparation emerged as consistently superior. Sodium phosphate was better tolerated [10], but safety alerts on its use have recently been issued by the US FDA and Health Canada. The authors identified a general need for rigorous study design to enable unequivocal conclusions to be drawn on the safety and efficacy of bowel preparations.

Timing of administration of the recommended dose appears important, as it has been established that split dosing (the administration of at least a portion of the laxative on the morning of the examination) is superior to dosing all the preparation the day be-

² The American Society of Anesthesiology classification of Patient Status (ASA PS) groups patients into 6 categories based on an assessment of their physical condition prior to an invasive procedure: (<http://www.asahq.org/For-Members/Clinical-Information/ASA-Physical-Status-Classification-System.aspx>)

fore the test, both for sodium-phosphate and polyethylene glycol [2, 23, 63, 79] **(II)**.

A systematic review [10] of different bowel cleansing regimens identified no significant differences other than improved patient tolerance of sodium picosulphate preparations. Furthermore, there are no preferred methods of assessing the effectiveness of bowel cleansing. Care must be taken however with some agents (i.e. phospho prep) in certain patient groups, especially the elderly and those with renal failure, due to potential renal side effects [102] **(I)**.

See also Chapter 2 [52] (Sect. 2.5.2.2, 2.5.2.3) for literature review about bowel preparation for FS and colonoscopy, and for organisational aspects.

To date no single bowel preparation for colonoscopy has emerged as consistently superior over another **(I)** although sodium phosphate may be better tolerated and it has been shown that better results are obtained when the bowel preparation is administered in two steps (the evening before and on the morning of the procedure) **(II)**. It is therefore recommended that there should be colonic cleansing protocols in place and the effectiveness of these should be monitored continuously (see also Ch. 2 [52], Rec. 2.22) **(VI–A)**.^{Rec 5.22}

Auditable outcome: Quality of preparation, patient satisfaction with the bowel cleansing regimen.

Accessibility

Several providers of bowel preparation close to the target population should be available when a patient is required to reach health or community facilities to obtain the preparation. Clear and simple instruction sheets should be provided with the preparation. For sigmoidoscopy screening, organisational options include the possibility of having the enema administered at the endoscopy unit. (See Ch. 2 [52], Rec. 2.21) **(VI–B)**.^{Rec 5.23}

5.3.4 Scheduling and choice

Booking processes must be robust to minimise late cancellations and failures to attend. To increase the chance of attendance an invitation for a primary screening test should be sent 2–3 weeks before the procedure is due, with an option for the patient to change the appointment if it is not convenient (see section 2.4.3.1).

Auditable outcome: Patient feedback on booking processes.

5.3.4 Timelines

A timely procedure is not critical in the context of primary screening but it is very important when endoscopy is performed following a previous positive screening test. A delayed procedure may not be critical biologically, but it can cause unnecessary anxiety for the screenee.

To ensure that patient anxiety is not unnecessarily increased, it is recommended that follow-up colonoscopy after positive screening be performed as soon as reasonably possible, but no later than within 31 days of referral (acceptable >90%, desirable >95%) (see also Ch. 3 [61], Rec. 3.16, Sect 3.3.4) **(VI–B)**.^{Rec 5.19}

Auditable outcome: Time taken from positive screening test to secondary endoscopic examination. If further pathological information is required before the decision to perform a colonoscopy, then the maximum and the desirable targets of four and two weeks, respectively, should be timed from the receipt of the pathology report. The pathology report should be delivered to the screening programme within two weeks.

5.3.6 Environment

The environment should be conducive to a good experience and efficient processing. It should be physically comfortable, offer privacy and there should be facility to hold private conversations with screenees and their relatives. The reception and assessment areas should be separate from recovery facilities **(VI–B)**.^{Rec 5.10}

Auditable outcomes: patient feedback on environment and patient turn around times.

5.4 During the procedure



There is an increasing body of evidence demonstrating unacceptable miss rates of cancer following colonoscopy. Miss rates vary between endoscopists suggesting that care with the examination and technique play a key role in ensuring cancer is not missed.

Endoscopists must have a mix of technical, knowledge and judgement competencies to identify and successfully remove high-risk lesions. Ideally they will perform a complete examination quickly, safely and with minimal discomfort, leaving time to properly inspect the colon, and safely remove and retrieve lesions. They will identify all abnormal areas, characterise them and make a judgement of what to do. They will then, if it is appropriate to do so, safely remove and retrieve all neoplastic lesions

Providing such high-quality and safe endoscopy requires a team approach with appropriate equipment immediately to hand. The nursing support team must ensure the patient is comfortable and has stable observations to allow the endoscopist to devote his attention to the procedure. The nurses also provide important technical support ensuring endoscopy equipment is serviceable and that all the necessary accessories are readily available. Finally they play an important role supporting the endoscopist during therapeutic procedures. Both endoscopist and nurse should regularly reflect on their practice together with pathology and surgical teams in order to optimise patient outcomes.

High-quality and safe endoscopy also depends on adequate maintenance of equipment, and on an adequate supply of accessories for the range of procedures undertaken in the department. This should include equipment to manage complications of excision of high-risk lesions such as bleeding and in some instances, perforation. Endoscopy equipment is expensive and is subject to frequent and occasionally heavy use. It is essential that equipment be maintained by competent staff. Maintaining and repairing old endoscopic equipment is often more expensive than replacing it.

It is not appropriate for this chapter to provide a manual of how to perform colonoscopy and detect and remove high-risk lesions. However, there have been significant advances in decontamination processes, technique and technology in recent years. Because these advances might affect service provision and patient outcomes, it is considered important to review the evidence for their effectiveness.

Technological improvements have promised easier insertion of endoscopes and better visualisation of the mucosa. However, despite the potential of advances in endoscopic technology, they cannot be recommended for routine use until they have been demonstrated to be of benefit in clinical practice. The following sections provide an overview of the current state of these technologies and best practice for safe, high-quality endoscopy.

5.4.1 Cleansing and disinfection

Patients need to be reassured that decontamination processes are up to date and effective. Guidelines on cleaning and disinfection of endoscopes and endoscopic devices have been developed by the ESGE-ESGENA³ [8, 9].

It is recommended that decontamination policies and procedures be compliant with national or pan-European guidelines based on accepted, published recommendations and standards and should be audited against defined indicators. The policies should be available in the endoscopy department and updated regularly **(VI – A)**.^{Rec 5.48, 5.49}

Auditable outcomes: Defined by national or European guidance.

5.4.2 Kit – technologies for improving insertion of the colonoscope

A variety of endoscope technologies may facilitate caecal intubation and improve patient tolerance. These include variable stiffness instruments, magnetic tracking devices and wire-guided techniques.

A recent meta-analysis [62] of variable stiffness colonoscopes identified seven randomised trials involving 1923 patients: four trials comparing adult variable stiffness colonoscopes with standard adult colonoscopes in adults, and three evaluating the paediatric variable stiffness colonoscope. The caecal intubation rate was higher with the use of variable stiffness colonoscopes. The variable stiffness colonoscope was associated with lower abdominal pain scores and decreased need for sedation during colonoscopy. Intubation times were unaffected by the variable stiffness colonoscope **(I)**. The use of variable stiffness colonoscopes is recommended for screening colonoscopy **(I – B)**.^{Rec 5.34}

The present bibliographic search did not yield any relevant publications on improvement of completeness of colonoscopy through wire-guided techniques. This new technology has been investigated in endoscopic management of obstructive tumours [70].

Two RCTs of the magnetic endoscopic imaging (MEI) device showed improved performance of endoscopists, both with variable stiffness colonoscopy and with traditional colonoscopy, in terms of patient tolerance and caecal intubation rates, in particular when little or no sedation is used [86, 87] **(II)**. The utilisation of magnetic endoscope imaging (MEI) technology may be considered for patients requiring colonoscopy, particularly when little or no sedation is used **(II – B)**.^{Rec 5.33}

5.4.3 Kit – techniques and technologies to enhance detection, characterisation and removal of high-risk lesions

Image enhancing techniques and technology promise to improve management of high-risk lesions in three ways.

1. First, they might improve the detection of lesions. This will only add value if the lesions detected are important biologically: identifying more biologically unimportant lesions will add workload and risk.
2. Second, they might better define the margins of the lesion to help the endoscopist ensure that it is completely excised.
3. Third, they might help characterise the nature of the lesion, helping the endoscopist decide whether to remove it. This third aspect is of critical importance because it might be more appropriate not to remove the lesion because of an increased

risk of malignancy. Alternatively, if an endoscopist can safely leave lesions that do not need to be removed, such as small hyperplastic polyps, considerable time could be saved and small risks of polypectomy avoided.

Essentially there are two approaches to enhanced lesion recognition and characterisation: dye-spraying or chromoendoscopy, and image manipulation techniques or image-enhancing technology.

Chromoendoscopy

Widespread application of dye to the lumen of the colon (pan-chromoendoscopy) improves the detection of diminutive lesions [20] **(I)**. However, pan-chromoendoscopy is time consuming and the extra lesions detected may be unimportant clinically as a significant number of diminutive lesions may regress [80]. The authors of a recent Cochrane review concluded that *selective application* of dye to suspicious areas (selective chromoendoscopy) may be more appropriate during colonoscopy **(VI)**.

This approach is consistent with the conclusions of a recent international workshop which reviewed the role of non-polypoid lesions in the aetiology of colorectal cancer. The endoscopist should be skilled in recognising subtle changes in the appearance of the mucosal surface, particularly alterations in colour, vascularisation and morphology, to identify suspicious areas requiring dye spraying and to better detect polypoid lesions. Small patches of mucus may require rinsing to expose underlying suspicious areas worthy of staining, particularly in the right colon [46].

Selective chromoendoscopy with dye spraying on the lesion has been shown to be superior to conventional colonoscopy predicting polyp histology [66] **(III)**. Magnification chromo-endoscopy is more effective than conventional chromocolonoscopy for diagnosing neoplastic colorectal polyps [31] **(II)**.

Expert opinion **(VI)** suggests that selective chromoendoscopy facilitates:

- ▶ assessment of the lesion and its borders;
- ▶ excision of the lesion and of residual tissue;
- ▶ colonoscopy for patients with chronic inflammatory bowel disease; and
- ▶ colonoscopy for high-risk family syndromes such as HNPCC.

Thus for most polypoid and non-polypoid colorectal abnormalities, a flexible high-definition video endoscope and the facility for selective application of dye (chromoscopy) to the lesion is currently sufficient for detection and characterisation of high-risk lesions. It is recommended that all but the smallest flat or sessile lesions be 'lifted' with submucosal injection of saline or colloid to facilitate safe removal (endoscopic mucosal resection). Lesions that do not 'lift' should not be removed because they are more likely to be malignant, and removal is more likely to lead to perforation **(VI)**.

Image enhancing technology

There is conflicting evidence regarding the potential for narrow band imaging (NBI), Fuji Intelligent Chromo Endoscopy (FICE), and other techniques of image processing commonly referred to as "virtual chromoendoscopy" to improve detection and characterisation of high-risk lesions. One trial showed an increase in the detection rate of diminutive adenomas [39]. There was no difference in adenoma detection rates using NBI technique compared to white-light colonoscopy reported by other published trials [1, 41–43, 74] **(II)**.

The use of autofluorescence was associated with a higher polyp detection rate compared with conventional endoscopy in one

³ ESGE-ESGENA: European Society of Gastrointestinal Endoscopy – European Society of Gastroenterology and Endoscopy Nurses and Associates.

study, although the observed improvement was mainly attributable to an increased diagnostic yield of diminutive adenomas [53–55] **(II)**.

Studies comparing the performance of colonoscopy with high definition versus standard colonoscopes did not show an increase in the detection rate of adenomas or hyperplastic polyps when using high-definition instruments [21, 28, 64] **(II-III)**.

The results of diagnostic accuracy studies showed better accuracy of NBI colonoscopy compared to standard colonoscopy in differentiating between neoplastic and non-neoplastic lesions [45, 92] **(III)**. In the recent Cochrane review of chromoendoscopy, it was suggested that NBI may become the gold standard in enhanced techniques for detection of colorectal lesions, but with the advantage of reduced procedure time compared to chromoendoscopy. One trial comparing diagnostic accuracy of NBI with chromoendoscopy on 99 Patients has been retrieved [95]. The study did not find a significant difference in accuracy between the two technologies for the differentiation of neoplastic vs. non-neoplastic lesions. Further trials comparing NBI and chromoendoscopy are needed.

Further experience and evidence about efficacy, benefits and potential adverse effects, as well as cost-effectiveness, are required before additional technologies can be recommended for routine, pan-European use in colorectal cancer screening and diagnosis. Particularly in the screening context, improvements in detection and diagnosis may be accompanied by unacceptable decreases in specificity, and/or disproportionate, unacceptable increases in cost, measured both in human and financial resources.

After sufficient standardisation of procedures and protocols in feasibility studies, pilot studies conducted in the framework of population-based screening programmes, and based on a randomised public health policy, could provide appropriate evidence to justify future recommendations for widespread implementation of new technologies.

In view of the above it is recommended that:

- ▶ The provision and maintenance of equipment in the endoscopic unit should be carefully managed based on local guidelines that comply with relevant national and pan-European guidelines containing accepted, published recommendations and standards.
- ▶ Flexible video endoscopes and the facility for focal application of dye to the lesion should be used in colorectal cancer screening **(III–B)**.^{Rec 5.12}
- ▶ The volume of equipment should match the demand put upon it to maximise efficiency and avoid patient delays **(VI–B)**.^{Rec 5.11}
- ▶ There should be an adequate supply of accessories suited to the endoscopic interventions undertaken within the unit **(VI–B)**.^{Rec 5.13}
- ▶ Use of re-usable accessories should be based on national policy **(VI–B)**.^{Rec 5.14}
- ▶ There should be properly maintained resuscitation equipment in the endoscopy room and recovery area **(VI–B)**.^{Rec 5.15}
- ▶ Maintenance of equipment should be undertaken by competent staff **(V–A)**.^{Rec 5.16}
- ▶ There should be regular review of the functioning of all endoscopes, in accordance with manufacturer specifications and instructions and relevant national or pan-European guidelines **(VI–B)**.^{Rec 5.17}
- ▶ The results of the review should be available at all times in the endoscopy unit **(VI–A)**.^{Rec 5.18}

5.4.4 Sedation and comfort

Flexible sigmoidoscopy

Although flexible sigmoidoscopy is not currently recommended by the EU for colorectal cancer screening, previous results of ongoing trials indicate that screening is feasible and the procedure is well accepted by screenees [37, 82, 83, 97, 101]. No sedation for FS was used in these studies **(I)**.

Colonoscopy

Colonoscopy can be an uncomfortable and distressing experience. These adverse effects can be reduced by careful patient preparation and sedation. As mentioned previously in this chapter, there are widely differing practices of sedation for endoscopy in the EU that reflect historic practice and cultural differences.

Sedation improves patient tolerance of colonoscopy, particularly sedation using propofol combined with other sedative agents such as midazolam and analgesics such as pethidine and fentanyl [57] **(I)**. However, excessive sedation is considered to be an important contributor to cardio-respiratory related deaths following endoscopy in high-risk patients, particularly the elderly.

According to Rex [73], most of the risk of colonoscopy is related to sedation. Cardio-respiratory complications are infrequent for patients without known heart or lung disease, but monitoring of oxygenation and blood pressure should be performed for all sedated patients.

Although hypoventilation, cardio-pulmonary events and vasovagal reactions may be related to pain and distension caused by the endoscopic procedure, in most cases they are more closely associated with the use of sedatives and opioids. Reduction in risk for these reactions has been observed in a study aimed to determine the incidence of such events when sedation is given only as required. All procedures in this study were performed by senior gastroenterologists with optimal equipment and nursing staff. Patients undergoing colonoscopy without sedation had less decline in blood pressure and fewer hypoxic episodes than sedated patients [29] **(V)**.

Heavily sedated patients are more difficult to turn, and this may compromise caecal intubation and mucosal visualisation **(V)**.

The available evidence indicates that the quality and safety of colonoscopy in patients that receive propofol sedation is comparable to that in patients receiving light, conscious sedation (or no sedation), provided patients given sedation are assessed properly prior to their procedure [57, 89] **(I)**.

Propofol seems to be better than benzodiazepines or narcotics on recovery, discharge time and patient satisfaction and equivalent on procedure time, caecal intubation rate and adverse events **(I)**. However, in many countries an anaesthesiologist is required for propofol administration.

It is recommended that there be local policies and processes in place to optimise sedation and patient support in order to maximise tolerance and minimise risk of complications **(I–B)**.^{Rec 5.29}

The following categories and data relevant to sedation should be monitored:

1. No sedation;
2. Conscious sedation and substances used;
3. Propofol sedation or general anaesthesia, and substances used; and
4. Insufflation gas: air or CO₂ (see below).

Auditable outcomes: Sedation levels, patient feedback on comfort, dignity and privacy, and adverse incidents related to sedation, including use of reversal agents.

Carbon dioxide insufflation

Gas insufflation is mandatory to ensure good visualisation during colonoscopy. Currently, air is commonly used for this purpose [40]. However, significant amounts of air can be retained in the GI tract [17] causing pain and discomfort for the patient. Pain associated with colonoscopy has been identified as a major barrier to participation in CRC screening [24, 27, 56].

Randomised trials have shown that carbon dioxide insufflation significantly reduces abdominal pain and discomfort in patients undergoing colonoscopy and flexible sigmoidoscopy [16, 19, 22, 93, 105] (I).

Side effects of CO₂ insufflation were not detected in unsedated patients in two randomised studies identified in the present literature search and involving 350 patients [18, 19]. Slightly elevated end-tidal CO₂ levels were detected in sedated patients in the latter study, but only 52 sedated patients were included in the study and patients with chronic obstructive pulmonary disease, as well as patients with known CO₂ retention, were excluded.

Since carbon dioxide is an inert gas that cannot form a combustible mixture with hydrogen and methane, CO₂ insufflation will avoid the very rare risk of explosion during sigmoidoscopy or colonoscopy (see below).

Following incomplete colonoscopy, an alternative examination is frequently required. Provided adequate facilities are available, same-day CT or MRI colonography, or, in appropriate cases, double-contrast barium enema would be desirable. However, same-day radiologic examination following colonoscopy frequently yields suboptimal quality when air insufflation is used for colonoscopy, due to retained air in the colon. If CO₂ insufflation has been used, same-day radiologic imaging is generally feasible with appropriate quality. This avoids the necessity of scheduling the additional radiologic examinations on another day and further colon cleansing [65, 78] (III).

In light of the above evidence and considerations:

- ▶ Carbon dioxide insufflation is recommended for colonic endoscopic procedures (I–A).^{Rec 5.31}
- ▶ Carbon dioxide insufflation should be avoided in patients with COPD, known CO₂ retention or otherwise reduced pulmonary function (VI–A).^{Rec 5.32}

Risk of explosion from electrocautery during air insufflation of the colon

Oxygen in room air, insufflated during colonoscopy, has been shown to react with colonic hydrogen and methane gas to produce a combustible gas mixture [12]. A recent review found 20 cases of colonic explosion during electrocautery published since 1952 and confirmed that colonic gas explosion is a rare, but potentially lethal complication during colonoscopy with electrocautery [47].

Accumulation of colonic combustible gases at potentially explosive concentrations due to inadequate colon preparation and use of air, rather than a non-inert gas such as carbon dioxide for insufflation are the principal causes of gas explosion. Fifteen of the 20 reported cases were associated with bowel preparation using malabsorbable, fermentable carbohydrates (14 cases with mannitol, which is no longer commonly used in colonoscopy, and one with sorbitol). The five other cases involved argon plasma coagulation for post-radiation colitis. Cleansing solution containing mannitol or other malabsorbed carbohydrates (e.g. sorbitol) must be avoided in the preparation of the colon because of the risk of explosion with electrocautery (III–A).^{Rec 5.24}

5.4.5 Endoscopist techniques and performance

There is ample evidence of varying performance of endoscopists and, as a consequence, varying outcomes for patients in endoscopy [15, 26, 32, 68, 85, 88] (III).

High-quality and safe endoscopy is critical for the success of screening therefore it is vital to have continuous monitoring of performance. Performance can be assessed by measuring outcomes that directly affect the patient or surrogate outcomes that are linked with true patient outcomes. Examples of outcomes that directly affect the patient are discomfort, reduced probability of developing cancer, perforation and interval cancer. Examples of surrogate outcomes include caecal intubation rates, withdrawal times and adenoma detection rates.

Very often it is difficult to identify true patient outcomes and link them with individual performance such as missed cancer or reduced risk of cancer. Thus, surrogate outcomes are relied on for assessing individuals. Given limitations on the volume of procedures that a competent endoscopist can regularly perform, the frequency with which an event occurs will affect the ability of a measure to determine individual performance. If the event rate is high (such as adenoma detection), relatively small numbers suffice to assess performance. In contrast, if the event rate is low (such as perforation), very large numbers of procedures are required to assess professional performance.

If there are concerns about performance, or if there is a desire to assess competence prior to participation in a screening programme, it is possible to assess knowledge and skills-based competencies in addition to reviewing key performance indicators [7]. This approach may become particularly important for assessing skills, knowledge and judgments associated with excision of high-risk lesions once a competency framework has been created.

5.4.5.1 Quality outcomes

The quality of a colonoscopic examination is not only dependent on complete intubation of the colon. Careful and complete visualisation of the mucosa during withdrawal is equally important [20] (I–A).^{Rec 5.35} The following quality indicators should be monitored for each endoscopist to secure good quality of the examination:

Documentation of consent

Prior informed consent should be documented for every examination. Fail-safe mechanisms should be in place to assure that the endoscopist does not conduct a procedure for which prior consent is not documented. Any exceptional cases in which prior consent is not provided should be documented and reviewed.

Numbers of procedures

There is evidence that endoscopic proficiency increases with the number of procedures performed [32]. Furthermore, low numbers of procedures are associated with a greater risk of complications: the lowest complication rate in a population-based study of outpatient colonoscopy was associated with the highest number of procedures (more than 300 per endoscopist per year [68, 88]). However, performing a large number of procedures is not sufficient proof of competency; bad habits can persist even in very experienced endoscopists.

As already mentioned, large numbers are required to provide accurate estimates of performance, particularly if events are infrequent. The 95% confidence interval for a completion rate of 90%

for 150 procedures per year is 85–95%; the interval for 300 procedures per year is 87–93%.

It is recommended that the annual number of procedures performed by each endoscopist be recorded to ensure that the sample size for other performance indicators is sufficient **(III–A)**.^{Rec 5.37}

Although the number of procedures performed annually is not a reliable measure of quality, achieving an adequate volume is essential to maintaining skills and effectively monitoring performance. It is therefore recommended that each endoscopist participating in a colorectal cancer screening programme should undertake to perform at least 300 procedures per year. A higher volume of procedures is desirable to maintain high quality **(III–B)**.^{Rec 5.38} Services should be planned such that individual endoscopists achieve a desirable volume of procedures (>300/year) **(III–B)**.^{Rec 5.39}

Insertion to caecum and withdrawal time

Rapid insertion of the colonoscope is a proxy indicator of technical performance of colonoscopy, provided comfort levels are satisfactory and complication rates are not elevated. Rapid insertion leads to greater efficiency but particular caution should be observed in heavily sedated patients. Withdrawal time is a proxy for careful inspection of the mucosa (see below). If adenoma detection rates are low and withdrawal times short, endoscopists should be encouraged to withdraw more slowly.

Documentation of completion of colonoscopy

Only one study was retrieved assessing specificity and sensitivity of a pair of photographs to assess the completeness of colonoscopy, using a video-clip as the reference standard. The study found a sensitivity of 51.4% and a specificity of 89.2% which were considered too low to be used for reliably documenting colonoscopy completion [94]. A single panoramic shot showing both the ileo-caecal valve and the caecum may improve sensitivity **(VI)**.

While ileal intubation is not required in the context of colorectal screening, a picture of ileal mucosa provides strong evidence of completion. Taking ileal biopsies to document completion is discouraged, however, because of concern about transmission of variant Creutzfeldt-Jakob Disease (CJD). Also, intubation of the ileum takes extra time and effort.

It is therefore recommended that completion be documented by auditable photo documentation: preferably a panoramic image of the ileo-caecal valve and caecum, or a video clip with a respective snapshot **(VI–A)**.^{Rec 5.40}

Completion rates

Caecal intubation rate is one of the key quality indicators of colonoscopy. Caecal intubation rates are affected by a number of factors including age, sex, low BMI, bowel cleansing, sedation, diverticular disease and general health status [30, 36, 69, 71, 83, 98].

It can be expected from this evidence that it is possible to achieve a higher caecal intubation rate in patients attending for average risk screening than those attending for investigation of symptoms. US guidelines recommend a different intubation rate standard for screening and for symptomatic populations: 95% and 90%, respectively [75]. Adjusted completion rates (for factors such as bowel prep or obstruction) are open to diverse interpretation, and it is recommended to use unadjusted rates for the standard. The exception to this would be an obstruction leading to operative intervention. This is a clear-cut reason for adjusting the rate.

It is recommended that unadjusted caecal intubation rate (as defined above) be a prime indicator of quality of colonoscopy The

acceptable standard is >90%; >95% is desirable (see also Ch. 3 [61], Rec. 3.11, sect 3.3.2 and 3.3.3) **(III–A)**.^{Rec 5.41} There should be documentation and review of reasons for failed completion **(III–B)**.^{Rec 5.42}

Complete and correct identification of neoplastic lesions

The principal aim of screening FS and colonoscopy is to identify and, in appropriate cases, remove neoplastic lesions in order to lower the burden of colorectal cancer in the population.

Furthermore, a complete colonoscopy that has identified all the relevant pathology is a prerequisite for assessing future risk for inclusion in colonoscopy surveillance programmes (see Chapter 9 [3]). There is good evidence of varying rates of detection of high-risk lesions and of missed lesions in back-to-back colonoscopy studies [76]. Rapid withdrawal at colonoscopy is associated with lower adenoma detection rates [6, 58, 72]. Internationally accepted guidelines on performance indicators of colonoscopy recommend monitoring direct or proxy markers of detection of suspicious lesions: polyps, adenomas or withdrawal times [50, 75]. In a recently published retrospective study based on data from a colonoscopy screening programme with a high percentage of participants with a family history of colorectal cancer, adenoma detection rate has been shown to be an independent predictor of interval cancer [44].

Counting polyps is relatively easy but capturing adenoma detection rates can be problematic if endoscopy and pathology databases are not linked. Withdrawal times are a proxy measure and inferior to measuring detection of polyps or adenomas.

There are now well-defined criteria for high risk and the evidence base underpinning these criteria is discussed in Chapter 9 [3]. It is recommended that these criteria be used as a marker of careful inspection of the colonic mucosa. These criteria also indicate which persons should enter into surveillance programmes. Therefore it is proposed that the rate of referral into surveillance programmes (whether they are part of the screening programme or not) be an essential outcome for evaluating the quality of inspection of colonic mucosa in the context of screening.

It is recommended that screening programmes adopt, as a minimum, the following outcomes to determine the quality of inspection of the colonic mucosa **(VI–A)**:^{Rec 5.43}

1. Referral into surveillance programmes (see above and Chapter 9 [3]); and
2. Withdrawal times from caecum to anus (in patients who have not had biopsy or therapy).

NOTE 1: Monitoring more than one outcome will support quality improvement. For example monitoring withdrawal times might indicate that an individual with low adenoma detection rates may need to withdraw more slowly. However, if acceptable withdrawal times are associated with poor detection rates another solution may be required.

NOTE 2: Different patient populations will have different prevalence rates of neoplastic lesions, thus the standards for different populations will differ.

NOTE 3: To permit monitoring of professional performance, the above minimum outcomes should be generated from complete, individual data sets recorded according to standardised procedures specified by programme rules.

Excision and retrieval of pathological material

Incomplete excision of a high-risk lesion is associated with an increased risk of development of cancer [104]. Incomplete removal of tissue may lead to misclassification of pathology (see Chapter 8

[90]). There are currently no validated methods of determining completeness of excision but it is possible to measure retrieval rates for pathological material. Chromoendoscopy may facilitate assessment of completeness of excision (see section 5.4.3). At this stage it is recommended that there be raised awareness of the importance of complete excision (or at the very least careful documentation of whether a lesion has been completely excised) and retrieval rates of excised tissue should be recorded.

Information provided for the pathologist

The quality of histopathology is affected by the information provided by the endoscopist and the extent to which the endoscopist and pathologist communicate with each other (see Chapter 7 [67]).

Information on histology request forms for suspicious colonic lesions should include (see also Chapter 7 [67]):

- ▶ Site of lesion;
- ▶ Size of the lesion (as estimated by the endoscopist);
- ▶ Nature of lesion, including whether it is ulcerated; and
- ▶ Completeness of excision as judged by the endoscopist

NOTE: An optimal colonoscopy report will contain this information and it is recommended that a copy of the report should be sent with the pathology request form.

5.4.5.2 Safety outcomes

Adverse outcomes can occur immediately or several days after the procedure. In this context an immediate adverse outcome is defined by an adverse outcome occurring before the patient leaves the endoscopy department. An adverse outcome occurring after this is a late outcome. Endoscopic services must have processes in place to identify and record adverse outcomes occurring after the patient leaves the endoscopy department (VI–B).^{Rec 5.45}

Three methods are recommended:

- ▶ Contacting all patients within a defined time frame;
- ▶ 30-day mortality review of all screened patients; and
- ▶ 8-day unplanned admission review of all screened patients.

It is appreciated that for some health care systems capturing 30-day mortality and 8-day readmissions may be challenging. Furthermore, it is clear that a person may be admitted or die for reasons that have nothing to do with the procedure. The key point is that if there are factors related to the procedure contributing to death or admission, they should be reviewed and an action plan created if the review indicates there is a need for a change in practice.

To simplify the collection of immediate adverse outcomes, it is recommended that unplanned admission on the same day as the endoscopic procedure be a key adverse outcome. It is recommended that the reason for the admission be recorded in the following categories. Furthermore, the primary reason for admission should be indicated (III–A).^{Rec 5.44}

- ▶ Abdominal pain;
- ▶ Suspected or confirmed perforation;
- ▶ Bleeding;
- ▶ Cardio-respiratory event; or
- ▶ Other (specify).

5.5 After the procedure



5.5.1 Recovery facilities and procedures

A person having an endoscopy needs a period of recovery, particularly if they have received sedation. There should be a designated area for recovery and sufficient equipment for them to recover (such as chairs and trolleys).

Auditable outcomes: Patient feedback on recovery collected when the patient has recovered from sedation

5.5.2 Emergency equipment and protocols

The recovery area should be equipped with adequate resuscitation and monitoring equipment, and there should be policies and procedures in place for monitoring patients and dealing with emergencies (VI–B).^{Rec 5.15}

Auditable outcomes: Regular audit of resuscitation equipment check

5.5.3 Patient information – post procedure

Ideally patients should be informed about the outcome of their procedure before leaving the endoscopy unit and given written information that supports a verbal explanation, particularly if they have had sedation (VI–A).^{Rec 5.26} They need to be told (orally and with written information) whether any follow up will be arranged (written or outpatient), by whom and during what time-scales. Oral and written information must contain an explanation of what to do in the event there are problems, and patients should be given a contact telephone number (24 hours/day, 7 days/week) in case of a procedure-related complication.

Auditable outcomes: Patient feedback on adequacy and helpfulness of post-procedure information

5.5.4 Patient feedback

It is essential to obtain patient feedback on a regular basis in order to correct issues that concern patients that health professionals are unaware of. This feedback can be expected to contain considerable praise for the service provided, and such positive feedback will have a strong motivating effect on staff to provide an even better service.

5.5.5 Communication to other health professionals

The outcome of screening examinations should be communicated to the primary care doctor (or equivalent) so that it becomes part of their core patient record (see Ch. 2 [52], Sect. 2.4.3.4.2; Ch. 10 [5], Rec.10.31) (II–B).^{Rec 5.27} In some EU countries the consent of the patient is needed for transmitting the information to the primary care doctor. There should be pre-defined clinical pathways for patients found to require further intervention for cancer, incompletely removed lesions and difficult-to-remove lesions (and failsafe mechanisms to ensure that interventions do occur) (II–B).^{Rec 5.28}

Auditable outcomes: Time to definitive treatment for patients with cancer; turnaround times for communicating pathology results to patients

5.5.6 Immediate and late safety outcomes

There should be a process in place for systematically recording immediate and late outcomes following screening colonoscopy. See above for types of outcomes and methods of assessment.

Auditable outcomes: Outcomes identified by this process

5.6 Guidelines

The endoscopy service should create and regularly review guidelines for the following, taking into account previous experience and results as well as relevant national and pan-European guidelines containing accepted, published recommendations and standards (VI–B):^{Rec 5.50}

- ▶ Sedation;
- ▶ Monitoring after the use of conscious sedation;
- ▶ Antibiotic prophylaxis;
- ▶ Anticoagulants;
- ▶ Colonic cleansing;
- ▶ Endoscopic assessment of colorectal abnormalities;
- ▶ Endoscopic removal of lesions (both high- and low-risk);
- ▶ Marking of high-risk lesions;
- ▶ Further management of high-risk lesions; and
- ▶ Equipment.

5.7 Policies and processes

There should be policies, and processes to support them, for the following:

- ▶ Consent and patient information;
- ▶ Withdrawal of consent;
- ▶ Decontamination;
- ▶ Assessment of competence;
- ▶ Staff training;
- ▶ Transfer of care following complications;
- ▶ Completing the audit cycle; and
- ▶ Selection and assessment of equipment.

Annex 5.1 Suggested quality indicators and auditable outcomes.

	QI/AO	mandatory	desirable
1 Age and sex of patient	QI/AO	+	
2 Cancer detection rate (all cancers)	QI/AO	+	
3 Cancer detection rate (endoscopically removed cancers) ¹	QI/AO	+	
4 Referral rate into surveillance programmes (total and by risk category)	QI	+	
5 Adenoma excision and retrieval rate +/- withdrawal times	QI	+	
6.1 Numbers and detection rates of colorectal lesions, in total and broken down by: polypoid and non-polypoid (Paris classification: Ip Ls, IIb IIc sessile non-neoplastic)	QI/AO	+	
6.2 Numbers and rates in 6.1 broken down by sector of the colon (caecum; ascending, transverse, descending colon; sigmoid; rectum)	AO	+	
7.1 Numbers and detection rates of colorectal lesions, in total, and by predicted histology: 1) non-neoplastic (hyperplastic polyp, sessile serrated lesion, other), 2) neoplastic (low-grade adenoma, high-grade adenoma, submucosal carcinoma) and 3) uncommon lesions	QI/AO	+	
7.2 Numbers and rates in 7.1 broken down by sector of the colon (caecum; ascending, transverse, descending colon; sigmoid; rectum)	AO	+	
8.1 Numbers and detection rates of colorectal lesions, in total, and by confirmed histology: 1) non-neoplastic (hyperplastic polyp, sessile serrated lesion, other), 2) neoplastic (low-grade adenoma, high-grade adenoma, submucosal carcinoma) and 3) uncommon lesions	AO	+	
8.2 Numbers and rates in 8.1 broken down by sector of the colon (caecum; ascending, transverse, descending colon; sigmoid; rectum)	AO	+	
9.1 Numbers and rates of discrepant lesions broken down by categories in 7.1 and 8.1	AO	+	
9.2 Numbers and rates of discrepant lesions broken down by categories in 7.2 and 8.2	AO	+	
10 Withdrawal times from caecum to anus (in patients who have not had biopsy or therapy)	QI/AO	+	
11 Colonoscopy completion rate	QI	+	
12 Wait time: FOBT to colonoscopy	QI	+	
13 Wait time: FS to colonoscopy	QI	+	
14 Wait time: colonoscopy to pathology results	QI	+	
15 Wait time: FS to pathology results	QI	+	
16 Wait time: pathology results to definitive treatment	QI	+	
17 Unplanned admission on day of procedure: four options	AO	+	
18 Type of insufflation gas (air or CO ₂)	AO	+	
19 Type of sedation used: three options	AO	+	
20 Comfort: only if conscious or no sedation used	AO		+
21 Adequacy of preparation	AO	+	
22 Delayed adverse outcomes: two options	AO	+	
23 Key endoscopic characteristics of polyps written on pathology request form: five key characteristics: number, site, size, completeness of excision, separate pots used for different sites (see also 6–9)	QI	+	
24 Lesions referred elsewhere for excision	AO	+	
25 Patient feedback on information and consent, booking, environment, comfort and aftercare	AO		+
26 Adverse incidents related to incomplete pre-assessment	AO	+	
27 Decontamination indicators	AO	+	

¹ Removed by endoscopic polypectomy and mucosectomy.

Conclusions

In a multidisciplinary process, wide consensus has been achieved on a comprehensive package of evidence-based recommendations for quality assurance in endoscopy in colorectal cancer screening and diagnosis. Following these recommendations has the potential to enhance the control of colorectal cancer in Europe and elsewhere through improvement in the quality and effectiveness of the screening process that extends from systematic invitation to management of screen-detected cases.

Annex 5.2: Minimum requirements for endoscopic reporting

Performance of a unit and staff can be affected by a number of factors.

Therefore for each endoscopically removed lesion it is important to record:

1. Specification of the procedure in which the lesion has been obtained
 - 1.1. Patient/client information
 - 1.2. Type of endoscopy (FS or CS)
 - 1.3. Team performing procedure (endoscopist(s) and ancillary staff)
 - 1.4. Purpose of procedure
 - 1.4.1. Primary screening
 - 1.4.1.1. Initial screening or subsequent screening
 - 1.4.1.2. Interval to last primary screening procedure, if applicable
 - 1.4.1.3. Interval to last endoscopic examination if not the same as above
 - 1.4.2. Assessment of abnormal findings
 - 1.4.2.1. After positive screening test (indicate if FOBT or FS or other)
 - 1.4.2.2. After positive symptomatic test (indicate if FOBT or FS or other, e.g. symptoms)
 - 1.4.2.3. For repeat assessment of abnormal findings
 - 1.4.3. Surveillance
 - 1.5. Interval to last endoscopic procedure and type of procedure
2. Preparation, insufflation and sedation
 - 2.1. Bowel cleansing regimen
 - 2.2. Insufflation gas (air or CO₂)
 - 2.3. Type of anesthesia and substances used
 - 2.4. Kit
3. Caecal intubation
 - 3.1. End of caecum visualized
 - 3.1.1. Panoramic image of ileo-caecal valve and end of caecum? (Other imaging confirmation of caecal intubation?)
 - 3.1.2. Signs of inadequate preparation in caecum?
 - 3.1.3. Intubation time (time at beginning of procedure, time at visualization of end of caecum)
 - 3.2. End of caecum not visualized:
 - 3.2.1. Maximum extent of intubation/inspection of colonic mucosa
 - 3.2.2. Reasons for incomplete examination
4. End of procedure (withdrawal time from caecum)
5. Number of abnormalities detected:
6. For each abnormality detected:
 - 6.1. Location
 - 6.1.1. Distance in cm from ano-rectal junction

6.1.2. Sector: caecum; ascending, transverse, descending colon; sigmoid; rectum

6.2. Size and morphology:

6.2.1. Maximum diameter in millimeters

6.2.2. Depth in mm and layer (mucosal/submucosal)

6.2.3. Mucous patch

6.2.4. Polypoid

6.2.5. Non-polypoid (Paris classification): Ip Ls, IIb, IIc sessile

6.3. Prediction of histology (endoscopic diagnosis)

6.3.1. Non-neoplastic (hyperplastic polyp, sessile serrated lesion, other)

6.3.2. Neoplastic (low-grade adenoma, high-grade adenoma⁴, submucosal carcinoma)

6.3.3. Uncommon lesions

7. When endoscopic treatment is conducted

7.1. Complications (bleeding, use of coagulation, perforation, other adverse effects)

7.2. For each abnormality endoscopically treated:

7.2.1. Technique of resection (polypectomy, mucosectomy)

7.2.2. Information provided for the pathologist:

7.2.2.1. Location (see 5.1)

7.2.2.2. Size and morphology: (see 5.2)

7.2.2.3. Completeness of excision as judged by the endoscopist)

7.2.2.4. Prediction of histology (endoscopic diagnosis, see 5.3)

Disclaimer

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⁴ Very rare mucosal carcinomas, if diagnosed, are included in "mucosal high grade neoplasia and are treated endoscopic biopsy/excision".

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