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



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Authors

Institutions

R. J. C. Steele¹, J.-F. Rey², R. Lambert³

¹ Ninewells Hospital and Medical School, Dundee, United Kingdom

² Institut Arnault Tzanck, Saint Laurent du Var, France

³ Screening Group, Early Detection and Prevention Section, International Agency for Research on Cancer, Lyon, France

Keywords

- mass screening
- colorectal neoplasms
- professional requirements
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- multidisciplinary evidencebased guidelines
- 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 populationbased 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 professional requirements and training includes 23 graded 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 surveillance and other elements in the screening process, including multi-disciplinary diagnosis and management of the disease.

Background

According to the most recent estimates by the International Agency for Research on Cancer [6] 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 212000 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 [5]. The EU policy takes into account the principles of cancer screening developed by the World Health Organization [31] and the extensive experience in the EU in piloting and implementing population-based cancer screening programmes [28]. Screening is an important tool in cancer control in countries with a significant burden of CRC, provided the screening services are high quality [29]. 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 [22].

Methods

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The methods used are described in detail elsewhere in this supplement [14]. 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

Bibliography

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Corresponding author *R J C Steele*,

Professor of surgery Ninewells Hospital and Medical School Dundee DD1 9SY United Kingdom r.j.c.steele@dundee.ac.uk qas@iarc.fr 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 [13].

In the full guidelines document prepared by the authors and editors [22] 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, crosssectional 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

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Twenty-three graded recommendations are provided in Chapter 6.

Recommendations¹

General requirements

- 6.1 Colorectal cancer screening programmes should be operated by an adequately trained multidisciplinary team (see Ch. 8 [25], Rec. 8.1) (VI–A).^{Sect 6.2; 8.2}
- 6.2 Key performance indicators should be developed for the monitoring of a national or regional screening programme (VI-B).^{Sect 6.2}

Administrative and Clerical Staff

- 6.3 National or regional colorectal cancer programmes should be run in conjunction with other screening programmes by an experienced administrative team (VI–B).^{Sect 6.3}
- 6.4 All administrative and clerical staff in a colorectal screening programme should acquire a basic understanding of colorectal screening and specific courses should be developed for this purpose (VI–A).^{Sect 6.3}
- 6.5 Management, communication and project management skills for the administrative staff of a colorectal screening programme should be acquired by means of formal courses (VI-A). Sect 6.3

Epidemiologist

- 6.6 A specifically trained epidemiologist should be seconded to a national or regional colorectal cancer screening programme (VI-B).^{Sect 6.4}
- 6.7 Training of epidemiologists inexperienced in evaluation and monitoring in colorectal cancer screening should be organised as secondments to established screening centres running population-based screening programmes. Additional didactic courses on relevant aspects of the work should be attended depending on individual knowledge and experience (VI-B).^{Sect 6.4}

Laboratory staff

- 6.8 A fully trained laboratory staff with appropriate management should be in place for a national or regional colorectal cancer screening programme and internal quality control and external quality assurance mechanisms should be put in place for the laboratory (see Ch. 4 [9], Rec. 4.10 and 4.12) (VI–A). Sect 6.5; 4.3.3.4; 4.3.4
- 6.9 Training in the form of courses or secondments to existing laboratories should be available for all laboratory personnel (VI-B).^{Sect 6.5}
- 6.10 A European laboratory network should be established in order to provide appropriate external quality assurance (VI-C).^{Sect 6.5}

Primary care physicians

6.11 All general practitioners should be informed about national or regional colorectal cancer screening programmes and provided with appropriate infrastructure and training, in-

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 Chapter 1 to 5 see: [10,12, 16,9,27]; for Chapters 7 to 10 see: [19,25,3,4] respectively.

cluding adequate training to be able to help people make informed decisions about CRC screening (see Ch. 2 [12], Rec. 2.12; and Ch. 10 [4] Rec. 10.21) (II-C).^{Sect 6.6; 2.4.3.4.2;} 10.4.2.3.2

Endoscopists

- 6.12 Endoscopists who participate in a colorectal cancer screening programme should be fully trained in colonos-copy or flexible sigmoidoscopy, depending on the procedure they perform in the programme (V A).^{Sect 6.7}
- 6.13 Endoscopists who participate in a colorectal cancer screening programme should be fully trained in biopsy and polypectomy (V–A).^{Sect 6.7}
- 6.14 Endoscopists who intend to participate in a colorectal cancer screening programme should undergo assessment to ensure an adequate level of expertise before commencing practice within the programme (VI–B).^{Sect 6.7}
- 6.15 Endoscopists who participate in a colorectal cancer screening programme should be able to demonstrate high completion rates, low morbidity and appropriate adenoma detection rates (VI-B).^{Sect 6.7}

Radiologists

- 6.16 Radiologists participating in a colorectal cancer screening programme should have specialist training in colorectal imaging (VI-A).^{Sect 6.8}
- 6.17 Radiologists working within a screening programme should participate in quality assurance where at least a proportion of radiological examinations are double-read (VI-B). Sect 6.8

Pathologists

- 6.18 Pathologists participating in a colorectal cancer screening programme should have specific training in colorectal pathology (VI–B). Sect 6.9
- 6.19 Pathologists participating in a colorectal cancer screening programme should develop a network with other pathologists in order to share experience (see also Ch. 7 [19], Rec. 7.16) (VI–B). Sect 6.9; 7.6; 7.7

Surgeons

6.20 Surgeons treating patients with screen-detected disease should specialise (although not necessarily exclusively) in colorectal cancer surgery and should be able to demonstrate a high-volume practice (III – B).^{Sect 6.10}

Nurses

6.21 Nurses participating in colorectal cancer screening programmes should have a specific training to equip them with the necessary skills, including adequate training to be able to help people make informed decisions about CRC screening (see Ch.10 [4], Rec. 10.21) (VI–C).^{Sect 6.11;} 10.4.2.3.2

Public Health

- 6.22 Public health physicians should be involved in national or regional colorectal cancer screening programmes and should be provided with appropriate training (VI–C).^{sect} 6.12
- 6.23 Where necessary, public health specialists should have access to courses or the ability to visit screening centres to obtain this specific training (VI–C).^{Sect 6.12}

6.1 Introduction

The success of a colorectal cancer screening programme is dependant on specially trained individuals committed to implementation, provision and evaluation of a high quality, efficient service. The multidisciplinary team that is responsible for a colorectal screening programme includes:

- Administrative and clerical staff;
- Epidemiologists;
- Laboratory staff;
- Primary care physicians;
- Endoscopists;
- Radiologists;
- Pathologists;
- Surgeons;
- Nurses; and
- Public health specialists

All staff involved in the delivery of a colorectal cancer screening programme must have knowledge of the basic principles of colorectal cancer screening. To achieve this it would be appropriate for them to attend a course of instruction at an approved training centre prior to the commencement of the programme. The need for specialist training in screening differs between the different disciplines and is most important for those involved in the delivery of the service and diagnosis, e.g. laboratory staff, endoscopists, radiologists, pathologists and nurses. The surgical treatment of screen-detected cancer and post-operative treatment is not performed differently according to whether a cancer is screendetected or symptomatic, but there are certain considerations for the surgeon to take into account when treating a screen-detected cancer. Oncologists are not mentioned in this document, as, stage for stage, their role in the treatment of screen-detected disease is no different from that in symptomatic disease. High-quality screening performance is based on a multidisciplinary approach, and it is important that appropriate training packages are offered. Updating knowledge as part of continuing medical education should be encouraged.

Participation in training courses should be documented and certificates of attendance issued based on the levels of skill attained and evaluated. Specific training requirements in terms of quality and volume should determine eligibility for any certification or accreditation process which must be applied only to centres with sufficiently skilled personnel.

6.2 General requirements

The evidence that Multidisciplinary Teams (MDTs) improve outcomes for cancer patients is still scanty, but beginning to accumulate [8]. However, there is general agreement that multidisciplinary services provide better patient care for a variety of conditions and in colorectal cancer, multidisciplinary management is strongly recommended [17]. Effective communication between the various professionals of a colorectal multidisciplinary team is essential and training courses should therefore focus on good inter-professional communication. Joint courses given for the multidisciplinary team may facilitate this goal.

Continuing education including refresher courses at various intervals is essential to gaining information on new developments and to improve the quality of the screening and diagnostic therapeutic processes. It is important to keep records of training activities as they are useful indices of the quality of a service. These would be part of a certification or accreditation review process. Staff – all staff involved in the screening programme require basic knowledge of the foundation of the programme. Relevant topics are:

- Colorectal cancer epidemiology (incidence, prognosis, mortality);
- Introduction to screening theory;
- Screening terminology (sensitivity, specificity, predictive value, etc);
- Current screening practices (screening modalities used, methods of identifying target population, methods of invitation)
- Evaluation of screening effectiveness (key performance indicators)

Key performance indicators are essential for the effective monitoring of a national or regional colorectal cancer screening programme [24]. As a bare minimum, the key performance indicators of a colorectal screening programme include:

- Uptake of screening test;
- Time between screening test and definitive diagnosis (where screening test is not colonoscopy);
- Proportion of those with a positive test undergoing colonoscopy (where colonoscopy is not the screening test);
- Colonoscopy completion rate;
- Colonoscopy complication rate;
- Positivity rate (for a non-endoscopic screening test);
- Cancer detection rate;
- Stage of cancer at diagnosis;
- Adenoma detection rate;
- > Positive predictive value for cancer and adenomas; and
- Interval cancer rate.

Summary of evidence

- > Optimal care is best provided by multidisciplinary teams (VI).
- Key performance indicators are essential for effective monitoring of a national or regional screening programme (VI).

Recommendations

Colorectal cancer screening programmes should be operated by an adequately trained multidisciplinary team (see Ch. 8 [25], Rec. 8.1) (VI-A).^{Rec 6.1}

Key performance indicators should be developed for the monitoring of a national or regional screening programme (VI-B).^{Rec 6.2}

6.3 Administrative and clerical staff

A colorectal screening programme can be run under the umbrella of a screening programmes division associated with the national or regional health department where this exists. This allows the colorectal screening programme staff to benefit from the experience gained from other screening programmes. In the UK, the organisation of the colorectal screening programmes is overseen by a programme manager who reports to a national or regional screening coordinator responsible for all screening programmes. In addition to a programme manager each centre that is responsible for sending out invitations and/or organising screening tests for those who accept the invitations is overseen by a screening manager who is responsible for the efficient operation of the screening programme and managing the staff of the screening centre [18, 21]. The staffing of the screening centre depends on the structure of the programme itself; e.g. if it is a centralised programme, staff are required for identifying individuals to be invited, sending out invitations, replying to those who have undergone testing and, where appropriate, organising further investigations for those with positive tests. The basic training requirements for all screening administrative and clerical staff should include the following:

- Basic understanding of colorectal cancer, the potential benefits and harms of screening, and the prime importance of quality assurance
- Basic understanding of the colorectal cancer screening programme; and
- Basic information technology skills.
- In addition, the centre manager requires:
- Advanced managerial skills; and
- Advanced communication skills (for dealing with queries, complaints etc).

In addition, the programme manager requires

Advanced project management skills.

Management communication and project management skills can be acquired by means of formal courses. However the administrative structure required for a colorectal cancer screening programme will depend very much on local and national conditions and must be modified accordingly.

Summary of evidence

No literature evidence was retrieved for this topic. National and regional screening programmes require an efficient administrative structure (VI).

Recommendations

National or regional colorectal cancer programmes should be run in conjunction with other screening programmes by an experienced administrative team (VI-B).^{Rec 6.3}

All administrative and clerical staff in a colorectal screening programme should acquire a basic understanding of colorectal screening and specific courses should be developed for this purpose (VI-A). Rec 6.4

Management, communication and project management skills for the administrative staff of a colorectal screening programme should be acquired by means of formal courses (VI–A).^{Rec 6.5}

6.4 Epidemiologist

As many disciplines contribute to providing data required for monitoring and evaluating a colorectal screening programme it is essential that a designated individual with relevant epidemiological expertise be assigned the task of overseeing the collection and analysis of the data required for evaluation. Assessing a programme's impact on colorectal cancer mortality is only possible if adequate provision has been made in the planning process for adequate collection and analysis of data (see Chapter 3 [16]). Basic Training: The individual overseeing data collection and analysis requires training in clinical epidemiology and statistics. Specific training: Training for epidemiologists involved in a colorectal cancer screening programme focuses on:

- Colorectal cancer epidemiology (incidence, prevalence, mortality, trends);
- Screening theory (pre-clinical disease, lead time, selection, length bias);
- Colorectal cancer screening terminology (sensitivity, specificity, positive predictive value etc);
- The colorectal screening programme (organisation, current screening modalities);
- Ethical and confidentiality issues;
- Setting up a colorectal cancer screening programme (identification and an invitation of target population, call-recall system, follow-up system);

- Strategies for data collection and management (use of appropriate databases, individual files, computerised archives, linkage to appropriate registries, classification of screening outcomes, quality control procedures and data collection);
- Statistical analysis and interpretation of results (performance indicators for evaluation, predictors of the impact of screening, assessing screening impact and effectiveness, cost-effectiveness calculations); and
- Presentation of data and report writing.

Acquisition of these skills may require specific courses for the individuals involved.

Summary of evidence

 No literature evidence was retrieved for this topic. Careful data collection and analysis is essential for the effective monitoring of a national and regional colorectal screening programme (VI).

Recommendations

A specifically trained epidemiologist should be seconded to a national or regional colorectal cancer screening programme (VI-B). Rec 6.6

Training of epidemiologists inexperienced in evaluation and monitoring in colorectal cancer screening should be organised as secondments to established screening centres running population-based screening programmes. Additional didactic courses on relevant aspects of the work should be attended depending on individual knowledge and experience (VI–B).^{Rec 6.7}

6.5 Laboratory staff

Where a screening programme is based on a laboratory test (in the case of colorectal cancer screening the only currently available laboratory test is faecal occult blood testing), it is self-evident that an adequately staffed laboratory is necessary. It is similarly self-evident that the training and skills required by the laboratory staff are dependent on the type of test (guaiac or immunochemical, qualitative or quantitative). The laboratory staff requires supervision by an appropriately qualified individual with expertise in clinical biochemistry (see Ch. 4 [9], Rec. 4.11), and the day-to-day running of the laboratory must be managed by an appropriately skilled scientific officer. When faecal occult blood testing is being used as the primary test for a colorectal screening programme it is essential that this be done with appropriate internal quality control (IQC) and external quality assurance (EQAS) (see Ch. 4 [9], Rec. 4.10 and 4.12, Sect. 4.3.3.4 and 4.3.4); and this requires centralisation, either on a national or regional basis, of the testing process [18, 21]. Delegation to individual practitioners is not appropriate.

The training required for the laboratory staff should include the following:

- A basic understanding of colorectal cancer and the benefits of early diagnosis (a basic understanding of the colorectal cancer screening process);
- Training in good laboratory practice;
- Training in the performance of the faecal occult blood test (the specific training will depend on whether a guaiac or immunochemical test is used and whether it is a qualitative or quantitative test); and

Training in the use of the IT system used to record results. In addition, the training required by the Laboratory Manager includes:

Managerial skills;

- An appreciation of internal quality control and external quality assurance; and
- A thorough understanding of the interactions between the laboratory process and the whole screening programme.

An individual with expertise in clinical biochemistry is ultimately responsible for the operation of the laboratory and requires training in the following:

- An in-depth understanding of colorectal cancer (diagnosis, treatment, prognosis, staging and the importance of stage at diagnosis);
- An in-depth understanding of the colorectal cancer screening process (including screening theory and especially the potential benefits and harms of screening and the prime importance or quality assurance);
- Extensive knowledge of performance characteristics of different types of faecal occult blood test; and
- An in-depth understanding of the technology required to perform the faecal occult blood test.

In some parts of Europe the screening programme may not be based on faecal occult blood testing. Where it is, however, it is essential to ensure a uniformly high standard of testing, and a European laboratory network would facilitate this.

Summary of evidence

- No literature evidence was retrieved for this topic. Appropriately trained laboratory staff are essential for a FOBT-based colorectal cancer screening programme (VI).
- No literature evidence was retrieved for this topic. Internal quality control and external quality assurance are essential to ensure consistency of FOBT reporting (VI).

Recommendations

A fully trained laboratory staff with appropriate management should be in place for a national or regional colorectal cancer screening programme and internal quality control and external quality assurance mechanisms should be put in place for the laboratory (see Ch. 4 [9], Rec. 4.10 and 4.12, Sect. 4.3.3.4 and 4.3.4) (VI-A).^{Rec 6.8}

Training in the form of courses or secondments to existing laboratories should be available for all laboratory personnel **(VI–B)**.^{Rec 6.9} A European laboratory network should be established in order to provide appropriate external quality assurance **(VI–C)**.^{Rec 6.10}

6.6 Primary care physicians

There is ample evidence for the importance of involving primary care physicians in the implementation of colorectal cancer screening programmes (see Ch. 2 [12], Rec. 2.8, 2.12 and 2.13; and Sect. 2.3.1 and 2.4.3). The role of primary care physicians in colorectal cancer screening will vary widely from one European country to another. In some instances the general practitioner (GP) is required to invite the target population, in some instances they are required to encourage their patients to participate in a centrally organised screening programme and in some instances they may not play a direct role in the screening programme but will clearly be required to answer questions on screening posed by their patients. It must be emphasised however, that general practitioners should not be encouraged to perform faecal occult blood tests on an individual basis as it is impossible to ensure adequate quality assurance for the performance of the test.

The training required of general practitioners working in an area where there is an active screening programme should include the following:

- A thorough knowledge of colorectal cancer (diagnosis, treatment, prognosis, staging and importance of stage at diagnosis;
- An in-depth understanding of the colorectal screening process (including screening theory and particularly the potential benefits and harms of screening, and the prime importance of quality assurance); and
- A thorough knowledge of the organisation of the local screening programme and the role of GPs within the programme.

Whenever a colorectal screening programme is introduced into a region it is essential that all GPs serving the region are informed, and that specific training events for GPs are made available, including adequate training to be able to help people make informed decisions about CRC screening (see Ch. 10 [4], Rec. 10.21, and Sect. 10.4.2.3.2).

Summary of evidence

The involvement of primary care physicians (general practitioners) in a screening programme can enhance uptake **(I)** (see Chapter 2 [12]).

From evidence derived from two good-quality RCTs, it appears that educational programmes on CRC screening rationale, recommendation, CRC risk etc., towards primary care physicians are effective in improving CRC screening rates [7, 11]. However, a third RCT did not confirm such results [30] **(II)**.

Recommendations

All general practitioners should be informed about national or regional colorectal cancer screening programmes and provided with appropriate infrastructure and training, including adequate training to be able to help people make informed decisions about CRC screening (see Ch. 2 [12], Rec. 2.12, Sect. 2.4.3.4.2; Ch. 10 [4], Rec. 10.21 and Sect. 10.4.2.3.2) (II–C).^{Rec 6.11}

6.7 Endoscopists

Endoscopists carrying out either flexible sigmoidoscopy or colonoscopy as the primary screening test, or colonoscopy as the investigation following a positive primary screening test, are central to the delivery of a successful screening programme. It is essential that they be skilled in complete examination of the colonic mucosa and in recognising both cancers and pre-cancerous lesions (i.e. adenomas). It is also essential that they be skilled in biopsy and polypectomy technique such that they can carry out lower gastrointestinal endoscopy safely and effectively. If the endoscopy associated with a colorectal cancer screening programme has an appreciable morbidity or mortality, this has the potential to negate any benefit derived from the programme. Likewise if a high proportion of neoplastic lesions are missed on endoscopy, this will undermine the confidence of the population in the screening programme and has the potential to create a damaging "certificate of health" effect.

In order to ensure that only the highest quality of colonoscopy is delivered by the national screening programme in the United Kingdom, a specific assessment process has been introduced, and all colonoscopists wishing to participate in the programme must complete this successfully. The assessment consists of a test of knowledge and direct observation of procedural skills [23] (for level of competency for endoscopists see Ch. 5 [27], Sect. 5.1.2).

Different countries will employ different types of health professionals to undertake endoscopy, including medically qualified gastroenterologists, medically qualified surgeons, nurse endoscopists and, in some instances, endoscopists who have neither a formal medical nor a nursing qualification.

In all cases, however, endoscopists working within a colorectal screening programme should meet national professional requirements for performing endoscopy (FS and/or colonoscopy depending on the type of programme and the role of the respective endoscopist) and should fulfil the following training requirements:

- Good knowledge of the normal large bowel, its anatomy and its physiology;
- Good knowledge of the disease processes that can affect the large bowel and its endoscopic appearance;
- An understanding of digital endoscopy technology including maintenance and cleaning;
- Full training in the performance of either flexible sigmoidoscopy or colonoscopy as required including appropriate accreditation where this is available;
- Full training in safe biopsy and polypectomy technique (note: in some instances where endoscopic mucosal resection or endoscopic sub-mucosal resection of extensive lesions is required, tertiary referral may be necessary); and
- Full training in managing complications of endoscopic procedures performed in screening and diagnosis, including local protocols for management of severe complications.

To ensure the requisite high quality of endoscopy within a screening programme, all participating endoscopists must engage in quality assurance, and they must provide the data and reports required to routinely generate returns on numbers of endoscopies performed, completion rates, morbidity rates (including perforation, bleeding and death) and both adenoma and cancer detection rates.

It is difficult to conclude which professional and training requirements for endoscopists can affect the efficacy, safety, tolerability, and accuracy of endoscopic procedures, but evidence suggests that the following patient variables should be identified and taken into account prior to FS or colonoscopy because they can be associated with more adverse events, more time duration, and incomplete examination:

- Use of anticoagulants e.g. warfarin;
- ► Female anatomy;
- ► Age of patient;
- ASA (American Society of Anaesthesiologists) physical status;
- Prior abdominal surgery;
- BMI; and
- Diverticular disease.

Furthermore, the conditions under which endoscopy is conducted also have an impact on performance (see Ch. 5 [27], Rec. 5.21, 5.30, 5.37–39, Sect. 5.1.3. 5.3.3 and 5.4.5.1):

- Poor bowel preparation is associated with lower rate of complete colonoscopy;
- Deep sedation is associated with a greater rate of complete colonoscopy but also with a higher risk of cardiovascular events;
- The volume of colonoscopy is associated with completeness of examination and lower complication rates.

Recommendations

Endoscopists who participate in a colorectal cancer screening programme should be fully trained in colonoscopy and/or flexible sigmoidoscopy, depending on the procedure they perform in the programme [2, 26] (V-A).^{Rec 6.12} Endoscopists who participate in a colorectal cancer screening programme should be fully trained in biopsy and polypectomy [2, 26] (V-A).^{Rec 6.13}

Endoscopists who intend to participate in a colorectal cancer screening programme should undergo assessment to ensure an adequate level of expertise before commencing practice within the programme [2]. However another study did not confirm these results [1] (VI–B).^{Rec 6.14}

Endoscopists who participate in a colorectal cancer screening programme should be able to demonstrate high completion rates, low morbidity and appropriate adenoma detection rates (VI-B).^{Rec 6.15}

6.8 Radiologists

While the majority of European countries will employ colonoscopy as either the main investigative technique for a positive test or as the primary screening test, radiology expertise is required to investigate the colon in those individuals in whom a complete follow-up or surveillance colonoscopy is not achievable. It is essential that the radiological examination be carried out by an experienced gastrointestinal radiologist. There is evidence that the "miss rate" is highest in situations where a colonoscopy has been incomplete and a subsequent radiological examination has not detected pathology.

Radiologists working within the colorectal cancer screening programme have the following training requirements:

- Good knowledge of the normal colon, its anatomy and physiology;
- Good knowledge of the disease processes that can affect the colon and their radiological appearances;
- An understanding of the technology underlying barium enema and computer tomographic (CT) colography²; and
- Full training in the performance of either barium enema or CT colography or both, depending on local availability.

For quality assurance, a proportion of radiological examinations should be double-read. The use of virtual colonoscopy² following an incomplete colonoscopy assessment is increasing for patients with poor health. The same requirements, specific for training to barium enema, should apply to virtual colonoscopy.

Summary of evidence

 Currently the role of radiologists in the colorectal cancer screening programme is limited to the investigation of individuals who have undergone incomplete follow-up or surveillance colonoscopies (V).

Recommendations

- Radiologists participating in a colorectal cancer screening programme should have specialist training in colorectal imaging (VI-A).^{Rec 6.16}
- Radiologists working within a screening programme should participate in quality assurance where at least a proportion of radiological examinations are double-read (VI-B).^{Rec 6.17}

6.9 Pathologists

Pathologists working within a colorectal cancer screening programme require full training in the histopathology of gastrointestinal disease with specific emphasis on colorectal cancer. These pathologists should be skilled in the following areas:

- The interpretation of biopsies taken from benign and malignant tumours of the colon and rectum;
- The preparation and histological interpretation of endoscopic polypectomy specimens; and
- The preparation and histological interpretation of surgical resection specimens.

The histological examination of a polypectomy specimen is a particularly demanding area within a screening programme, as large, complex endoscopically removed lesions are common and often exhibit equivocal features of possible invasive malignancy. It is also particularly important for a pathologist to be able to comment on the degree of differentiation, the presence or absence of lymphovascular invasion, and distance of invasive cancer from the resection margin in endoscopically excised pT1 i.e. "polyp" cancers.

In addition, quality control of surgery is particularly important within a screening programme, as it is essential that individuals with lesions detected at screening are afforded the highest possible standards of care (see Ch. 8 [25]). The pathologist has an essential role in the quality assurance of surgery by assessing the completeness of tumour excision in surgical resection specimens. Pathologists working within a colorectal screening programme have the following training requirements:

- Good knowledge of the disease processes that can affect the colon and their histological appearances;
- An ability to distinguish between benign and malignant biopsy specimens;
- An ability to distinguish between benign and malignant polypectomy specimens;
- An ability to access the risk factors associated with recurrence after endoscopic excision of malignant polyps;
- An appreciation of immunohistochemistry where it relates to histological interpretation of colorectal tumours; and
- The ability to prepare a colorectal resection specimen, with particular emphasis on harvesting lymph nodes and assessing the circumferential resection margin.

Quality assurance in pathology is important and essential within a colorectal screening programme and image exchange is an important component of ensuring consistency of reporting, particularly with the interpretation of difficult endoscopically removed lesions (see Ch. 7 [19], Sect. 7.7).

Summary of evidence

Colorectal cancer screening results in increased workload for pathology departments, and creates significant demands in terms of the interpretation of complex histology of endoscopically removed lesions (see Ch. 7 [19], Rec. 7.17 and 7.22, Sect. 7.6.5.2) (V).

Recommendations

Pathologists participating in a colorectal cancer screening programme should have specific training in colorectal pathology (VI-B).^{Rec 6.18}

Pathologists participating in a colorectal cancer screening programme should develop a network with other pathologists in order to share experience (see also Ch. 7 [19], Rec. 7.16, Sect. 7.6 and 7.7) (VI-B).^{Rec 6.19}

6.10 Surgeons

Most cancers and a small proportion of large adenomas detected within a colorectal screening programme will require surgical excision, and it is important that this be carried out as effectively

² CT colography is also known as virtual colonoscopy.

and safely as possible. The beneficial effect of early detection of colorectal cancer is dependant on low mortality and morbidity rates associated with the subsequent surgery.

It is now recognised that both short- and long-term results of surgery for both rectal and colon cancer are highly surgeon-dependant and there is now good evidence that specialisation associated with high volume is associated with improved results [15, 20]. It is therefore mandatory that all screen-detected cancers requiring surgery are treated by surgeons who specialise in colorectal surgery, preferably with a particular interest in cancer. It is also essential that these surgeons work in multidisciplinary teams with access to oncologists experienced in both adjuvant and palliative treatment of colorectal cancer (see Ch. 8 [25], Rec. 8.1). It follows that surgeons treating patients with screen-detected colorectal cancer should be fully trained and possess the appropriate qualifications for a colorectal surgeon. In addition to the specialist training that this entails, surgeons working within a colorectal screening programme have the following training re-

- quirements:An understanding of the basic principles of screening, with particular reference to colorectal cancer; and
- An understanding of the significance of pT1 cancers with reference to the need for completion surgery (see Ch. 8 [25], Rec. 8.17).

Screen-detected cancers may be particularly suitable for laparoscopic resection, and it is essential that any surgeon utilising this technique is fully trained and, where appropriate, accredited. While some surgeons may be in a position to obtain appropriate training for laparoscopic surgery within their own institutions, this may not always be the case; and it is essential that surgeons wishing to carry out laparoscopic colorectal surgery should attend the appropriate courses and obtain the appropriate training wherever this is available.

Summary of evidence

High quality of surgery in a colorectal cancer screening programme is essential to avoid creating unnecessary morbidity in patients requiring surgery for asymptomatic disease. Surgeon specialisation and volume are associated with short- and long-term outcome in colorectal cancer (III).

Surgeons

All surgeons treating patients with screen-detected disease should specialise (although not necessarily exclusively) in colorectal cancer surgery and should be able to demonstrate a high-volume practice (III-B).^{Rec 6.20}

6.11 Nurses

Nurses have important roles throughout the colorectal screening pathway, from the initial contact with the screening invitees through diagnostic endoscopy both as an endoscopy nurse or as a nurse endoscopist, to the care of the patient requiring surgery [18, 21]. The importance of these roles will vary from country to country and indeed from region to region within countries. The nursing skills required to care for screening patients are essentially the same as those required to care for symptomatic colorectal patients in many situations. However, the specialist colorectal nurse may have a specific role to play, particularly in counselling individuals with positive screening tests. Such nurses are fully qualified and have experience in specialist colorectal nursing. The training requirements for nurses in a colorectal cancer screening programme include the following:

- An in-depth understanding of colorectal cancer (diagnosis, treatment, prognosis, staging and importance of stage at diagnosis);
- An in-depth understanding of the colorectal screening process (including screening theory and particularly the potential benefits and harms of screening, and the prime importance of quality assurance); and
- Advanced communication skills.

Appropriate courses should be available for nurses involved specifically in colorectal cancer screening programmes to address these issues, including adequate training to be able to help people make informed decisions about CRC screening.

Recommendations

Nurses participating in colorectal cancer screening programmes should have a specific training to equip them with the necessary skills, including adequate training to be able to help people make informed decisions about CRC screening (see Ch. 10 [4], Rec. 10.21) (VI–C). Rec 6.21

6.12 Public health

The role of the public health specialist in a colorectal cancer screening programme is to ensure coordination of the component parts of the screening programme in such a way as to optimise delivery of the programme to the target population [18, 21]. This will include endeavouring to maximise uptake by means of health promotion initiatives and addressing inequality issues. The role of the public health physician may vary from country to country and from region to region within countries, but public health specialists are well placed to act in a coordinating role. Public health specialists engaging in colorectal cancer have the following training requirements:

- An in-depth understanding of colorectal cancer (diagnosis, treatment, prognosis, staging and the importance of stage at diagnosis);
- An in-depth understanding of the colorectal cancer screening process (including screening theory and particularly the potential benefits and harms of screening, and the prime importance of quality assurance);
- A full understanding of the mechanisms whereby colorectal cancer screening is delivered in their population; and
- ► Training in effective health promotion.

Courses or the ability to visit screening centres can provide this specific training.

Summary of evidence

No literature evidence was retrieved for this topic. Public health Physicians have important roles within a Colorectal Cancer Screening Programme in terms of coordination and optimisation of delivery (VI).

Recommendations

Public health physicians should be involved in national or regional colorectal cancer screening programmes and should be provided with appropriate training (VI–C).^{Rec 6.22}

Where necessary, public health specialists should have access to courses or the ability to visit screening centres to obtain this specific training (VI–C).^{Rec 6.11}

Conclusions

In a multidisciplinary process, wide consensus has been achieved on a comprehensive package of evidence-based recommendations on professional requirements and training in colorectal cancer screening. 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.

Disclaimer

The views expressed in this document are those of the authors. Neither the European Commission nor any person acting on its behalf can be held responsible for any use that may be made of the information in this document.

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References

- 1 Aslinia F, Uradomo L, Steele A et al. Quality assessment of colonoscopic cecal intubation: an analysis of 6 years of continuous practice at a university hospital. Am J Gastroenterol 2006; 101: 721–731
- 2 Atkin W, Rogers P, Cardwell C et al. Wide variation in adenoma detection rates at screening flexible sigmoidoscopy. Gastroenterology 2004; 126: 1247-1256
- 3 Atkin W, Valori R, Kuipers EJ et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Colonoscopic surveillance following adenoma removal. Endoscopy 2012; 44: SE151 – SE163
- 4 Austoker J, Giordano L, Hewitson P et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Communication. Endoscopy 2012; 44: SE164–SE185
- 5 Council of the European Union. Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC). Off J Eur Union; 2003: 34–38

- 6 Ferlay J, Shin HR, Bray F et al. GLOBOCAN 2008 v1.2, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10. Internet Lyon, France: International Agency for Research on Cancer; 2010: Available from: http://globocan.iarc.fr Accessed on 05/04/2012
- 7 *Ferreira MR*, *Dolan NC*, *Fitzgibbon ML* et al. Health care provider-directed intervention to increase colorectal cancer screening among veterans: results of a randomized controlled trial. J Clin Oncol 2005; 23: 1548–1554
- 8 Fleissig A, Jenkins V, Catt S et al. Multidisciplinary teams in cancer care: are they effective in the UK? Lancet Oncol 2006; 7: 935–943
- 9 Halloran S, Launoy G, Zappa M. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Faecal Occult Blood Testing. Endoscopy 2012; 44: SE65 – SE87
- 10 Landsorp-Vogelaar I, von Karsa L. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Introduction. Endoscopy 2012; 44: SE15–SE30
- 11 Lane DS, Messina CR, Cavanagh MF et al. A provider intervention to improve colorectal cancer screening in county health centers. Med Care 2008; 46: 109–116
- 12 Malila N, Senore C, Armaroli P. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Organisation. Endoscopy 2012; 44: SE31–SE48
- 13 *Minozzi S, Armaroli P, Banzi R* et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First edition. Appendix 1: Systematic evidence review. 2010: http://bookshop.europa. eu/en/european-guidelines-for-quality-assurance-in-colorectal-cancer-screening-and-diagnosis-pbND3210390/ Accessed 11/2/2012
- 14 Minozzi S, Armaroli P, Segnan N. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Principles of evidence assessment and methods for reaching recommendations. Endoscopy 2012; 44: SE9 – SE14
- 15 Morris M, Platell CF. Surgical volume influences survival in patients undergoing resections for stage II colon cancers. ANZ J Surg 2007; 77: 902–906
- 16 Moss S, Ancelle-Park R, Brenner H. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition – Evaluation and interpretation of screening outcomes. Endoscopy 2012
- 17 NHS Executive. The NHS Cancer Plan and the New NHS. Report no. 264924 London: 2004
- 18 Public Health Resource Unit. Bowel cancer Screening Programme Guidance for Public Health and Commissioners. BCSP Publication No 3 Sheffield: NHS Cancer Screening Programmes; 2008
- 19 *Quirke P, Risio M, Lambert R* et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Quality assurance in pathology in colorectal cancer screening and diagnosis. Endoscopy 2012; 44: SE116–SE130
- 20 Salz T, Sandler RS. The effect of hospital and surgeon volume on outcomes for rectal cancer surgery. Clin Gastroenterol Hepatol 2008; 6: 1185–1193
- 21 Scottish Bowel Screening Programme. 2010: http://www.bowelscreening.scot.nhs.co.uk/ Accessed 11/2/2012
- 22 Segnan N, Patnick J, von Karsa L (eds.) European guidelines for quality assurance in colorectal cancer screening and diagnosis. First edition. Luxembourg: European Commission, Publications Office of the European Union; 2010
- 23 Shorthouse A. Specialist Training a vision for the future. Association of Coloproctology of Great Britain and Ireland 2009; 8: 522–524
- 24 *Steele RJ, McClements PL, Libby G* et al. Results from the first three rounds of the Scottish demonstration pilot of FOBT screening for colorectal cancer. Gut 2009; 58: 530–535
- 25 *Steele RJC, Pox C, Kuipers EJ* et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Managment of lesions detected in colorectal cancer screening. Endoscopy 2012; 44: SE140–SE150
- 26 Thomas-Gibson S, Bassett P, Suzuki N et al. Intensive training over 5 days improves colonoscopy skills long-term. Endoscopy 2007; 39: 818-824
- 27 Valori R, Rey J-F, Atkin W et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: First edition. Quality assurance in endoscopy in colorectal screening and diagnosis. Endoscopy 2012; 44: SE88 – SE105
- 28 von Karsa L, Anttila A, Ronco G et al. Cancer Screening in the European Union. Report on the implementation of the Council Recommendation on Cancer Screening. First Report. Luxembourg: European Commis-

sion; 2008: http://ec.europa.eu/health/archive/ph_determinants/ge-

- netics/documents/cancer_screening.pdf Accessed 11/2/2012 29 von Karsa L, Lignini TA, Patnick J et al. The dimensions of the CRC problem. Best Pract Res Clin Gastroenterol 2010; 24: 381 – 396
- 30 Walsh JM, Salazar R, Terdiman JP et al. Promoting use of colorectal cancer screening tests. Can we change physician behavior? J Gen Intern Med 2005; 20: 1097-1101
- 31 Wilson JM, Jungner YG. Principles and practice of mass screening for disease. World Health Organization; 1968: http://whqlibdoc.who.int/ php/WHO_PHP_34.pdf Accessed 11/2/2012