



EUROPEAN COLORECTAL CANCER DAYS
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Quality Assurance in Colorectal Cancer Screening in the EU

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European Guidelines for Quality Assurance in Colorectal Cancer Screening



1. Underlying principles and concepts
2. Scope of the EU Guidelines
3. Examples of recommendations
4. Conclusions

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Why screen for colorectal cancer?

- Colorectal cancer is one of the most common newly-diagnosed cancers and is the second most common cause of cancer death in the EU
- If detected early enough, many colorectal cancers can be cured - Mandel et al. 1993, Hardcastle et al. 1996, Kronborg et al. 1996
- In many cases, colorectal cancer can even be prevented by detecting and removing abnormalities before they progress to cancer - Mandel et al. 2000, Atkin et al. 2010

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THE COUNCIL OF THE EUROPEAN UNION Recommendation on Cancer Screening of 2 December 2003



- Covering how to:
 - implement cancer screening programmes
 - maintain appropriate quality of screening programmes
 - reach appropriate decisions on new or modified programmes
- Based on:
 - WHO principles of cancer screening (Wilson and Jungner)
 - Experience in implementing cancer screening programmes in EU Member States

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THE COUNCIL OF THE EUROPEAN UNION
 Recommendation on Cancer Screening of
 2 December 2003



1. Implementation of cancer screening *programmes*

- (a) Offer **evidence-based** cancer screening through a systematic **population-based approach** with **quality assurance at all appropriate levels**. The tests which should be considered in this context are listed in the Annex;

ANNEX:

- **pap smear screening for cervical cancer** precursors starting not before the age of 20 and not later than the age of 30*
- **mammography screening for breast cancer** in women aged 50 to 69 in accordance with European guidelines on quality assurance in mammography*
- **faecal occult blood screening for colorectal cancer** in men and women aged 50 to 74*



* Maximum age ranges subject to national epidemiological evidence and prioritizations, smaller age ranges may be appropriate.



THE COUNCIL OF THE EUROPEAN UNION
 Recommendation on Cancer Screening of
 2 December 2003



1. Implementation of cancer screening *programmes*

- (b) Implement screening programmes in accordance with **European guidelines** on best practice where they exist and **facilitate the further development of best practice for high quality cancer screening programmes** on a national and, where appropriate, regional level...

7. To **report on the implementation** of cancer screening programmes, on the basis of the information provided by Member States, not later than the end of the fourth year after the date of adoption of this Recommendation, to consider the extent to which the proposed measures are working effectively, and to **consider the need for further action**.



Need for Quality Assurance in Cancer Screening

- Screening is for predominantly asymptomatic populations
- At any given time, only a few people will have a health benefit from screening
- The risks are slight, but all participants are exposed
- Due to the very large number of people involved - the risks add up
- Quality assurance keeps the balance between benefit and harm in an appropriate range.

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To achieve an appropriate balance between benefit and harm - quality must be optimal at every step in the screening process:

- Information and invitation of the target population
- Performance of the screening test
- Diagnosis for people with suspicious test results
- Treatment of screen-detected lesions
- Surveillance and aftercare

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Organised Screening Programmes

- **Responsible** national or regional **team** for implementation (coordinating service delivery, quality assurance, and reporting of performance and results)
- **Comprehensive** guidelines, **rules** and standard operating procedures
- **Quality assurance structure** with supervision and monitoring of the screening process
- **Ascertainment** of the population disease burden

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IARC Handbook of Cancer Prevention, vol. 7

Population-based programmes promote equity and quality assurance

- Personal invitation
 - Equal chance of each eligible person to benefit
- Data bases for
 - Monitoring and auditing performance
 - Linkage with cancer registries for evaluating screening impact on the burden of disease

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Organized, Population-based Screening Preferred

- Infrastructure of organized, population-based programmes **facilitates QA**
- Implementation of population-based programmes **makes services** performing to the high multidisciplinary standards **accessible** to the entire eligible population
- **Large numbers of professionals** undertake further specialisation in order to **meet the screening standards**
- These nationwide efforts also lead to widespread **improvement in diagnosis and management** of cancers detected **outside of screening programmes**

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EU Guidelines for Quality Assurance in Breast, Cervical and Colorectal Cancer Screening





4th Edition
2006^{a)}



2nd Edition
2008^{a)}



1st Edition
2010^{a), b)}

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^{a)}EU Health Programme,
^{b)}UEGF, ACS, CDC



Web links to relevant documents



Segnan N, Patnick J & von Karsa L (eds.) (2010), **European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis - First Edition**. European Commission, Publications Office of the European Union, Luxembourg

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European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis



➤ Print version

- 10 chapters, 400 pages
- >250 recommendations
- >750 references

➤ Web version

- print version
- 1000 page evidence base

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European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis



- 102 authors, editors, reviewers, contributors
- 23 European countries (21 EU)
Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, United Kingdom
- Other countries
Argentina, Australia, Canada, China, Israel, Japan, and the United States of America.

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European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis



Chapters in First Edition

- | | |
|-----------------|------------------------|
| 1. Introduction | 6. Training |
| 2. Organisation | 7. Pathology |
| 3. Evaluation | 8. Clinical management |
| 4. FOBT | 9. Surveillance |
| 5. Endoscopy | 10. Communication |

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Grading of Evidence

- I** Multiple randomised controlled trials (RCTs) of reasonable sample size, or systematic reviews 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 systematic reviews (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

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Strength of Recommendations

- 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

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Examples of Conclusions & Recommendations Guaiac Faecal Occult Blood Test (FOBT)

1.1 There is good evidence that invitation to screening with FOBT using the guaiac test reduces mortality from colorectal cancer (CRC) by approximately 15% in average risk populations of appropriate age **(I)**.

Sect 1.2.1.1

1.2 RCTs have only investigated annual and biennial screening with guaiac FOBT (gFOBT) **(II)**. To ensure effectiveness of gFOBT screening, the screening interval in a national screening programme should not exceed two years **(II - B)**. **Sect 1.2.1.2**

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Example of Conclusions – Immunological FOBT

1.4 One RCT has shown that immunological FOBT (iFOBT) can reduce rectal cancer mortality, but the study did not show an effect on overall CRC mortality **(II)**. Sect 1.2.2.1

Three case-control studies have shown a significant mortality reduction from iFOBT screening **(IV)**. Sect 1.2.2.1

Additional evidence indicates that iFOBT is superior to gFOBT with respect to detection rate and positive predictive value for adenomas and cancer (see also Ch. 4, Rec. 4.2) **(III)**. Sect 1.2.2.1; 4.2.5; 4.3; 4.4.2

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Example of Conclusions – Endoscopic Screening

1.7 There is reasonable evidence from one large RCT that flexible sigmoidoscopy (FS) screening reduces CRC incidence and mortality if performed in an organised screening programme with careful monitoring of the quality and systematic evaluation of the outcomes, adverse effects and costs **(II)**. Sect 1.3.1.1

1.10 Limited evidence exists on the efficacy of colonoscopy screening in reducing CRC incidence and mortality **(III)**.

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Example of Conclusions

New screening technologies under evaluation

- 1.14** There currently is no evidence on the effect of new screening tests under evaluation on CRC incidence and mortality **(VI)**.

New screening technologies such as CT colonography, stool DNA testing and capsule endoscopy should therefore not be used for screening the average-risk population **(VI - D)**.
Sect 1.5

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Examples of Recommendations – Organisation

- 2.1** In order to maximise the impact of the intervention and ensure high coverage and equity of access, **only organised screening programmes** should be implemented, as opposed to case finding or opportunistic screening as only organised programmes can be properly quality assured **(III - A)**. **Sect 2.2.1; 2.2.2; 2.2.3**
- 2.3** A **population registry should be implemented for screening** if not yet available, combining the most accurate and updated information about the target population **(VI - A)**. **Sect 2.3.1**

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Example of Guiding principles – Endoscopy

- 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.

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Examples of Recommendations – Endoscopy

- 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 inappropriately long waiting times for symptomatic patients **(VI - A)**. **Sect 5.1.5**
- 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**

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Example of Recommendations – Pathology

7.5 Due to the increased risk of colorectal cancer associated with flat and/or depressed lesions they should be reported as non-polypoid lesions **(III)**, and further classified by the Paris classification **(V - B)**. Sect 7.2; 7.2.3

7.10 Hyperplastic polyps are non-neoplastic and their complete removal is optional. All other lesions in the serrated pathway should be excised and serrated lesions with neoplasia should be followed up (surveillance) as if they were adenomas **(VI- C)**. Sect 7.1; 7.2.4.4-5

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Conclusions

- Cancer screening programmes are continuously expanding in the EU. At the same time, techniques are continuously evolving.
- Priority should now be given to:
 - Quality documentation, monitoring and evaluation of the experience in the Member States to provide evidence to continuously update the European standards
 - Facilitation of effective implementation of the Guidelines in the Member States
- The opportunity of the experience and the special capacity in the Czech Republic in organizing, documenting, monitoring and evaluating cancer screening programmes should be used for this purpose.

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Thank you for your attention

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