

Expert Consultation on Colorectal Cancer Screening in
Latin America and the Caribbean

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Programme requirements for an effective colorectal cancer screening programme

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Insights from Europe on cancer screening

For further references see:

- The dimensions of the CRC problem. von Karsa L, Lignini TA, Patnick J et al. (2010) *Best Pract Res Clin Gastroenterol*; 24: 381-396
- Stockholm statement on successful implementation of population-based cancer screening programmes. von Karsa L, Anttila A, Primic Žakelj M et al. (2013). Annex 1a. In: European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition, Supplements. Perry N, Broeders M, de Wolf C et al. (eds.). European Commission, Office for Official Publications of the European Union, Luxembourg, pp. 123–128.
- Determinants of successful implementation of population-based cancer screening programmes. Lynge E, Tornberg S, von Karsa L et al. *Eur J Cancer* 2012; 48: 743-748
- European guidelines for quality assurance in colorectal cancer screening and diagnosis: overview and introduction to the full supplement publication. von Karsa L, Patnick J, Segnan N et al. (2013) *Endoscopy* 45(1):51-59
- Cancer Screening in the European Union. Report on the implementation of the Council Recommendation on Cancer Screening—First Report, von Karsa L, Anttila A, Ronco G, et al., European Commission, Luxembourg, 2008.
- Development and implementation of guidelines for quality assurance in breast cancer screening: the European experience. von Karsa L, Arrossi S (2013) *Salud Publica Mex*, 55:318–328.



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;
 - (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...

Screening tests that fulfil EU criteria

➤ Breast cancer screening

- Biennial mammography

➤ Cervical cancer screening

- Papanicolaou (PAP) staining *
- Validated liquid-based cervical cytology (LBC) #
- Primary HPV testing #

➤ Colorectal cancer screening

- Fecal occult blood testing (FOBT) *
- Fecal immunochemical testing (FIT) &
- Flexible sigmoidoscopy §

* Council recommendation of 2003

Supplements to European Guidelines for QA in cervical cancer screening

& European Guidelines for QA in colorectal cancer screening and diagnosis

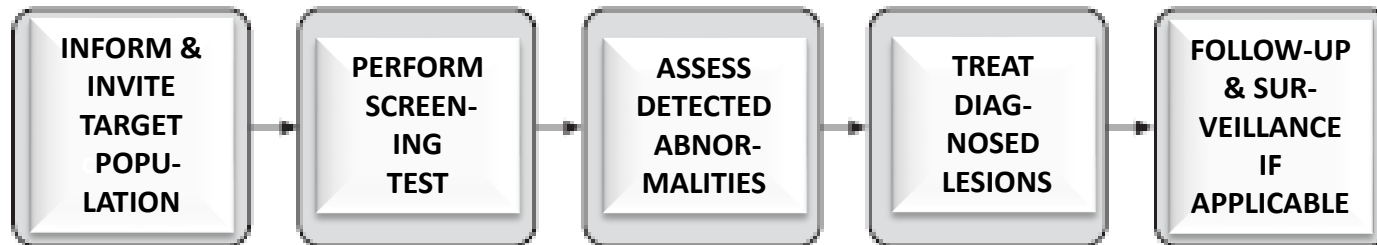
§ Armaroli P, Villain P, Suonio E, et al. (2015) Cancer Epidemiol. 2015 Dec; 39 Suppl 1:S139-52.

Need for quality assurance in cancer screening

- Screening is for mostly asymptomatic populations
- At any 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.

Importance of the screening process

To achieve and maintain an appropriate balance
between benefit and harm
quality must be optimal at every step



von Karsa L, Dean PB, Arrossi S, Sankaranarayanan R.
Screening - principles. In Stewart BW, Wild CP, eds. World
Cancer Report 2014. Lyon, International Agency for Research on
Cancer, 2014, 322-329.

Population-based screening programmes

- Aim to make the entire screening process available to each individual in the eligible population
- Personally invite each eligible individual to attend each round
- Use individual records to ensure that assessment, treatment and follow-up or surveillance take place
- Build administrative and clinical data bases for effective management and evaluation of services and programmes

Population-based programmes promote equity and quality assurance - 1

- Identification and personal invitation of each individual in the eligible population
 - Equal chance to be invited
 - Equal chance of participating, provided communication is effective and socio-economic barriers are addressed
- Individual data on performance and outcomes
 - Failsafe mechanisms for ensuring access to assessment, diagnosis and treatment

Population-based programmes promote equity and quality assurance - 2

- Individual data on performance and outcomes, cnt'd
 - Data bases for quality-driven performance monitoring and outcome audit
 - Linkage with cancer registries for evaluating screening impact on the burden of disease
- Essential conditions for studies to continuously improve screening protocols and practice
 - Eg, randomized public health policies

Organised Screening Programmes

Minimum requirements

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

Organized, population-based screening

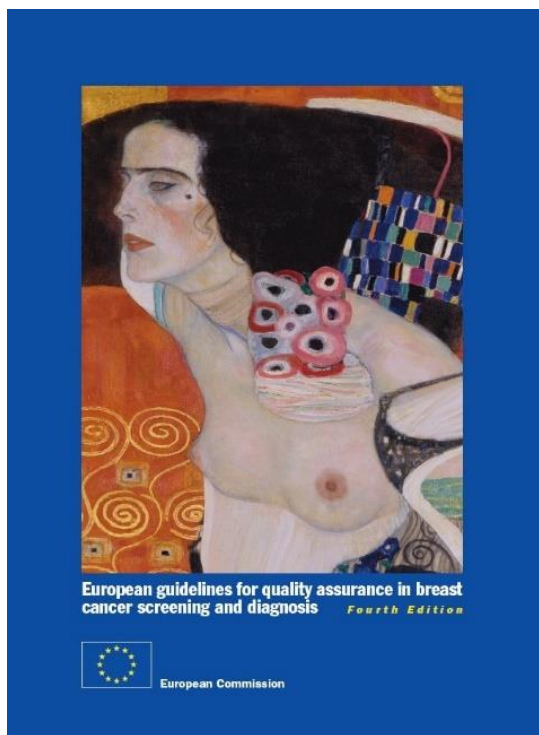
preferred in EU, recommended globally

- Infrastructure of organized, population-based programmes **facilitates quality assurance**
- Implementation of population-based programmes **makes services with 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**

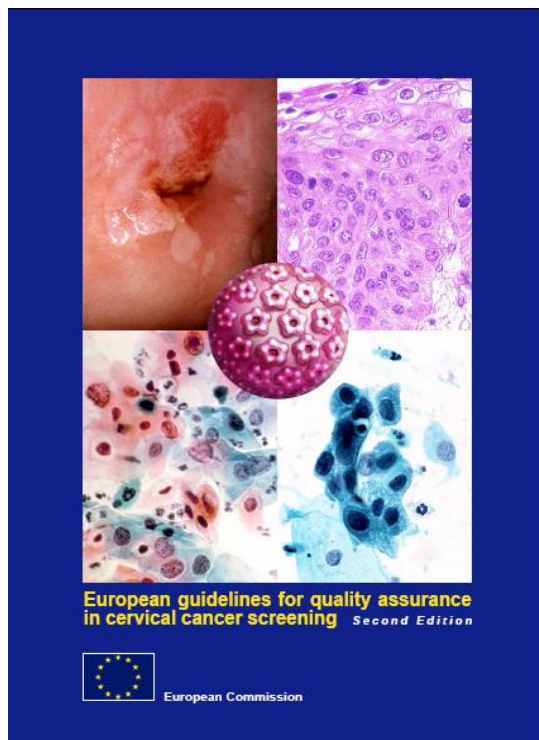
- von Karsa L, Anttila A, Ronco G, et al. (2008) *Cancer Screening in the European Union. First Report*, EC, Lux
- von Karsa L, Dean PB, Arrossi S, Sankaranarayanan R. (2014) Screening - principles. In: Stewart BW, Wild CP, eds. *World Cancer Report 2014*. Lyon, IARC, pp 322-329.
- WHO Position Paper on Mammography Screening (2013) WHO Press, Geneva



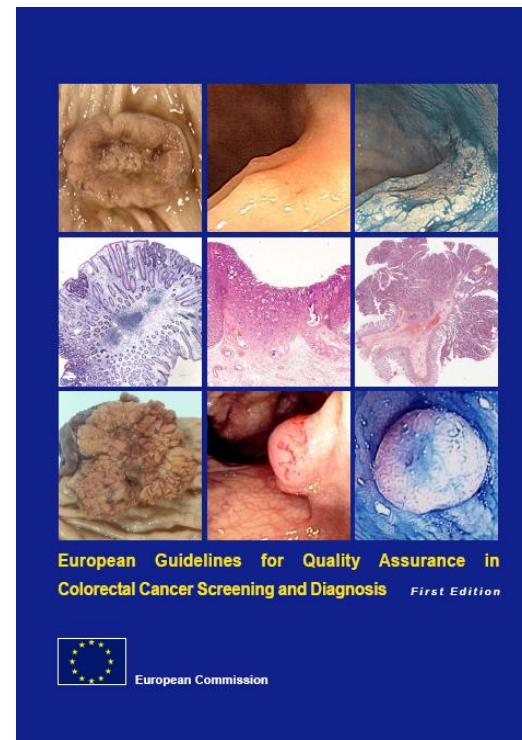
European Guidelines for Quality Assurance in Breast, Cervical and Colorectal Cancer Screening



**4th Edition 2006^{a)}
Supplements 2013^{a)}**



**2nd Edition 2008^{a)}
Supplements 2015^{a)}**



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

**Co-financing: ^{a)}EU Health Programme & project partners
^{b)}UEGF, ACS, CDC**

European Union quality assurance guidelines

Scope

- Best practice in the organization and management of cancer screening programmes and provision of screening services
 - General principles
 - Detailed recommendations
- Screening process up to and including diagnosis of screen-detected lesions
 - Including post-polypectomy surveillance in CRC Guidelines
- Cross-cutting themes

European Union quality assurance guidelines

Key aspects

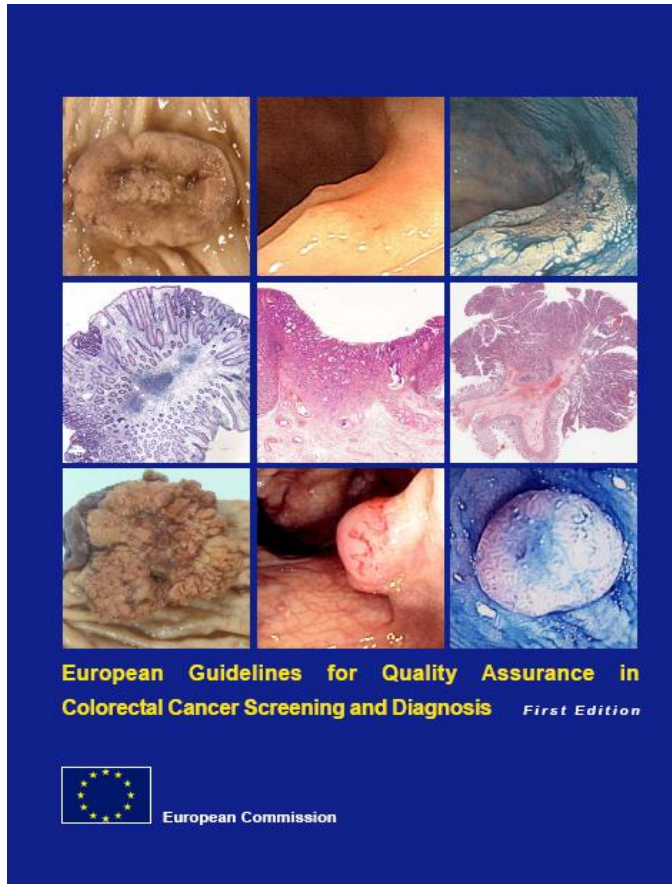
- Adequate, unbiased information (informed choice)
- Multidisciplinary services & teamwork, standards & procedures of best practice
- Specialized training
- Targets, performance indicators & databases, including population, cancer & screening registries
- Regular audit - continuous quality improvement
- Programmatic, population-based implementation
- Effective, sustainable coordination
- Oversight and evaluation of screening impact

Methods of experience- and evidence-based guideline development

- Editorial board experienced in screening implementation and quality assurance:
 - defines scope, manages process, reviews and revises if necessary all chapters
- Multidisciplinary teams of authors
 - define key (clinical) questions in collaboration with editors & experts in systematic review (literature group)
- Literature group performs systematic reviews
 - collects & grades evidence on key (clinical) questions
- Authors write chapters and grade key recommendations
- Independent experts review chapters & recommendations
- International discussion of interim & final results
 - in network meetings for consensus & dissemination



European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis

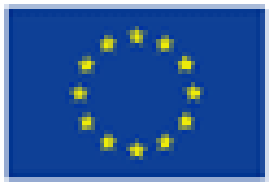


➤ Print version

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

➤ Web version

- print version
- 1000 page evidence base



European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis

Chapters in First Edition

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

Open access publication of all chapters (2012) and overview* (2013) in *Endoscopy*

European guidelines for quality assurance in colorectal cancer screening and diagnosis: Overview and introduction to the full Supplement publication

Authors

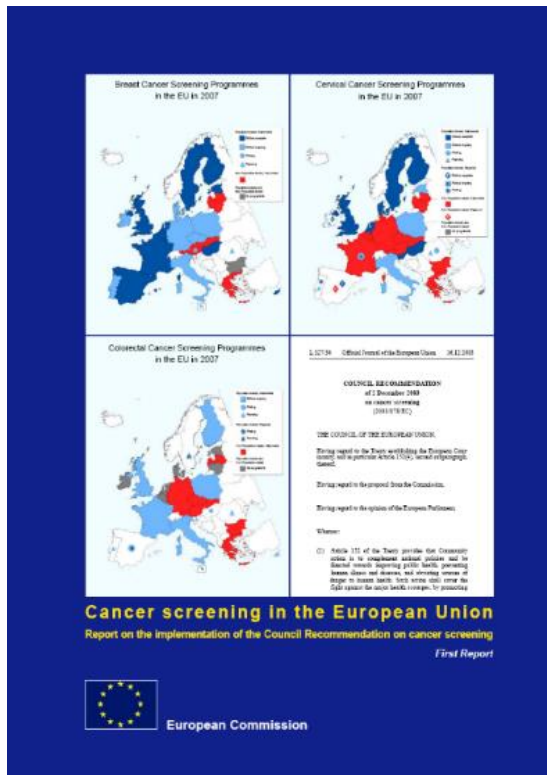
European Colorectal Cancer Screening Guidelines Working Group:

L. von Karsa¹, J. Patnick^{2,3}, N. Segnan^{1,4}, W. Atkin⁵, S. Halloran^{6,7}, I. Lansdorp-Vogelaar⁸, N. Malila⁹, S. Minozzi⁴, S. Moss¹⁰, P. Quirke¹¹, R. J. Steele¹², M. Vieth¹³, L. Aabakken¹⁴, L. Altenhofen¹⁵, R. Ancelle-Park¹⁶, N. Antoljak^{17,18}, A. Anttila⁹, P. Armaroli⁴, S. Arrossi¹⁹, J. Austoker^{20,†}, R. Banz²¹, C. Bellisario⁴, J. Blom²², H. Brenner²³, M. Bretthauer²⁴, M. Camargo Cancela^{25,26}, G. Costamagna²⁷, J. Cuzick²⁸, M. Dai²⁹, J. Daniel^{26,30}, E. Dekker³¹, N. Delicata³², S. Ducarroz¹, H. Erfkamp³³, J. A. Espinàs³⁴, J. Faivre³⁵, L. Faulds Wood³⁶, A. Flugelman³⁷, S. Frkovic-Grazio³⁸, B. Geller³⁹, L. Giordano⁴, G. Grazzini⁴⁰, J. Green²⁰, C. Hamashima⁴¹, C. Herrmann^{26,42}, P. Hewitson²⁰, G. Hoff^{43,44}, I. Holten⁴⁵, R. Jover⁴⁶, M. F. Kaminski⁴⁷, E. J. Kuipers⁸, J. Kurtinaitis^{48,†}, R. Lambert¹, G. Launoy⁴⁹, W. Lee⁵⁰, R. Leicester⁵¹, M. Leja⁵², D. Lieberman⁵³, T. Lignini¹, E. Lucas¹, E. Lynge⁵⁴, S. Mádai⁵⁵, J. Marinho⁵⁶, J. Maučec Zakotnik⁵⁷, G. Minoli⁵⁸, C. Monk⁵⁹, A. Morais⁶⁰, R. Muwonge¹, M. Nadel⁶¹, L. Neamtiu⁶², M. Peris Tuser⁶³, M. Pignone⁶⁴, C. Pox⁶⁵, M. Primit-Zakelj⁶⁶, J. Psaila³², L. Rabeneck⁶⁷, D. Ransohoff⁶⁴, M. Rasmussen⁶⁸, J. Regula⁴⁷, J. Ren²⁶, G. Rennert³⁷, J. Rey⁶⁹, R. H. Riddell⁷⁰, M. Risio⁷¹, V. Rodrigues⁷², H. Saito⁴¹, C. Sauvaget¹, A. Scharpantgen⁷³, W. Schmiegel⁶⁵, C. Senore⁴, M. Siddiqi⁷⁴, D. Sighoko^{26,75}, R. Smith³⁰, S. Smith⁷⁶, S. Suchanek⁷⁷, E. Suonio¹, W. Tong⁷⁸, S. Törnberg⁷⁹, E. Van Cutsem⁸⁰, L. Vignatelli⁸¹, P. Villain²⁰, L. Voti^{26,82}, H. Watanabe⁸³, J. Watson²⁰, S. Winawer⁸⁴, G. Young⁸⁵, V. Zaksas⁸⁶, M. Zappa⁴⁰, R. Valori⁸⁷

Institutions

Institutions are listed at the end of the article.

von Karsa L. et al. *Endoscopy*. 2013; 45: 51-59



Cancer Screening in the European Union Report on the implementation of the Council Recommendation on cancer screening - First Report*

L v Karsa, A Anttila, G Ronco, A Ponti, N Malila, M Arbyn, N Segnan, M Castillo-Beltran, M Boniol, J Ferlay, C Hery, C Sauvaget, L Voti, P Autie

Scientific basis for:

Implementation of the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC) – December 2008*

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0882:FIN:EN:PDF>
*Financial support of EU Health Programme

REPORT FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

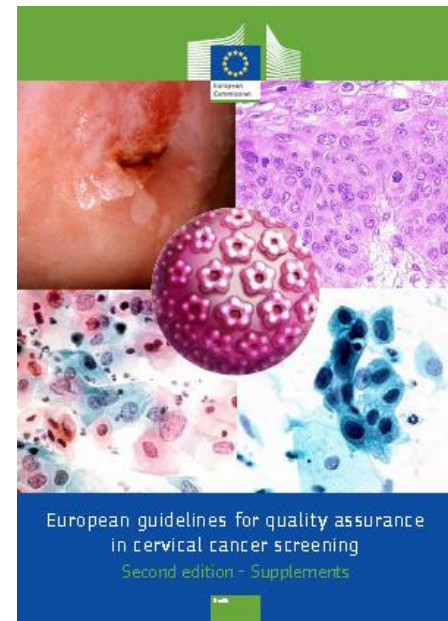
Report on the implementation of the Council Recommendation on cancer screening - First Report*

- All EU Member States aim to follow EU quality assurance guidelines
- Over 50 population-based programmes for breast, cervical, or colorectal cancer screening running or being established in 26 Member States
- Already over 500 million screening examinations in 10-year period (over 50 million screening tests per year)
- Despite substantial efforts
 - less than half of the recommended tests are actually being provided
 - less than half of these are in programmes with appropriate organisation for comprehensive quality assurance
- Professional, technical and scientific support for quality assurance, monitoring, evaluation and accreditation is needed
- Adequate resources, including expanded collaboration between Member States, are essential.

EU Quality Assurance Guidelines for Breast and Cervical Cancer Screening *Supplements**



- Breast Supplements: Digital Mammography and Pathology
- Cervical Supplements: HPV Primary Testing, Organization of Cytology- and HPV-based screening, and Implementation of HPV vaccination programmes



- Joint Annex 1 – Recommendations on successful implementation of population-based screening programmes, applicable to all currently recommended programmes in Europe (breast, cervical and colorectal)
 - Annex 1 a: von Karsa L, Anttila A, Primic Žakelj M et al. (2013) Stockholm statement on successful implementation of population-based cancer screening programmes
 - Lynge E, Tornberg S, von Karsa L et al. (2012) Determinants of successful implementation of population-based cancer screening programmes. *al. Eur J Cancer*, 48: 743-748

***Financial support:** EU Health Programme

Sustainable resources for quality assurance of population-based screening programmes - Excerpt from Stockholm Statement

...successful implementation of population-based cancer screening programmes requires **long-term political commitment, a comprehensive quality management programme and sustainable resources.**

In a fully established programme, the proportion of the **expenditure devoted to quality assurance should be no less than 10–20%, depending on the scale of the programme.** In the initial years, this proportion may be substantially higher due to the low volume of screening examinations compared with the situation after complete rollout of a nationwide programme. This investment is cost-effective and will save lives.

Implementation of pop.-based cancer screening programmes: Sequential phases, (Nos. of) projects/tasks, Key conditions

1. Before planning (15)
2. Comprehensive planning (19)
3. Feasibility testing (7)
4. Piloting or trial implementation (6)
5. Scaling up from pilot to service (14)
6. Running full scale programme (5)
7. Sustainability (4)

Key conditions for success in every implementation phase:

- Coordination and autonomous programme management
- Good governance, with adequate, sustainable resources
- Societal acceptance and local ownership
- The best evidence-based practice, including comprehensive QA
- Verification of adequate performance and continuous quality improvement

Implementation of cancer screening programmes: Before planning

1. Review of scientific literature.
2. Collection of information on disease incidence, stage distribution, and survival.
3. Collection of information on availability and quality of cure offered.
4. Understanding the potential role of screening in cancer control.
5. Assessment of evidence for adding screening to existing cancer control measures.
6. Collection of experience from other countries.
7. Building up professional and public understanding of the benefits and risks of screening.
8. Political will, commitment, at all relevant levels (EU, Member States and regional).
9. Decision on political responsibility for the process.
10. Review of existing guidelines.
11. Availability of treatments and facilities (both competence and resources).
12. Assessment of facilitating factors/barriers for implementation of organised screening.
13. Economic impact and cost-effectiveness of the programme.
14. Formal decision and allocation of budget.
15. Organisation of continuous societal debate and input.

Implementation of cancer screening programmes: Comprehensive planning

1. Creation of professional dedication (understanding)
2. Planning infrastructure
3. Establishing coordinating office with supervision mandate
4. Ensuring that screening is seen as a process
5. Designation of a process owner with mandate to run and manage the quality of the programme
6. Organisational development (self-learning, quality driven)
7. A separate coordination budget.
8. Multidisciplinary case management.
9. Collaboration between screening and treatment systems.
10. Appropriate diagnostic assessment of patients
11. An appropriate screening monitoring IT-system with access and possibility to link registers e.g. population-, patient- and cancer registers
12. Comprehensive information system, serving all purposes
13. Development of a quality assurance plan, including technical QA
14. Adoption of approved QA plan
15. Definition of performance parameters and acceptable levels, including standards for health professionals
16. Contracts with health care providers
17. System for auditing, training and retraining
18. Assessment tools to exclude bad performers
19. Consideration of accreditation system or other comprehensive systems for ensuring competent service delivery.

Implementation of cancer screening programmes: Piloting and Scaling up from pilot to service

PILOTING

1. Budgeting.
2. Ensuring financial commitment
3. Supervision and coaching of screening staff
4. Testing the legal framework
5. Ability to exclude bad performers
6. Scientific publication of outcome
4. Developing a plan for evaluation
5. Availability of staff (professional skills and numbers)
6. Multidisciplinary case management.
7. Special training, reference centre.
8. Comprehensive information system, covering all steps in the screening process
9. Collaboration between screening, treatment and IT systems

SCALING UP

1. Defining and contracting the local, regional and national programme teams, defining responsibilities
2. Setting-up infrastructure for coordination within health care settings
3. Identifying possible obstacles
10. Technical quality assurance
11. Reduction of barriers to participation.
12. Tools to encourage compliance
13. Advocacy and collaboration with local civil society organisations.
14. Population confidence.

Considerable time is needed to successfully implement population-based cancer screening programmes

- Careful planning and feasibility study phase
 - 1-3 years
- Pilot phase: randomised or non-randomised pilot settings
 - from 3-5 to 10 years
 - depending whether to include performance only or also outcome evaluations
- Nationwide rollout
 - 5-10 years until fully established

Potential bottlenecks in planning and implementing colorectal cancer screening programmes

- Selecting, testing the feasibility of, and piloting the screening test and protocol.
- Establishing colonoscopic capacity of appropriate quality to avoid inappropriate waiting times in symptomatic care and in screening
- Developing and testing materials and approaches to communication that permit appropriate information about benefit and harm while as well as achievement of appropriate uptake

Quality assurance of the process of screening programme implementation

1. Comprehensive **planning** of screening process: feasibility of screening models, professional performance, organisation and financing, quality assurance (QA)
2. Preparation of all components of screening process to perform at requisite high level (including **feasibility testing**)
3. Expert **verification** of adequacy **of preparations**
4. **Piloting** and modification, if necessary, of all screening systems and components, including QA, in routine settings
5. Expert **verification** of adequacy **of pilot performance**
6. Transition of pilot to service screening and geographically phased programme rollout in other regions of the country
7. Intensive monitoring of programme rollout for early detection and correction of quality problems
8. Regular internal and **external audit** of programme performance
9. **International collaboration** in scientific evaluation of programme impact

Conclusions

Considerable time and effort is required to establish quality-assured cancer screening programmes that are accessible to the entire population that can benefit.

An organized, population-based approach, and international cooperation in the development and implementation of comprehensive quality assurance guidelines has facilitated the successful implementation of cancer screening programmes in Europe.

A similar voluntary collaborative effort could facilitate implementation of effective CRC screening programmes in Latin America

Thank you for your attention.