International Meeting on Breast Cancer Screening Rio de Janeiro, 16 – 17 April 2009

Implementation of breast cancer screening in the EU

The role of international cooperation and collaboration in developing and implementing quality assurance guidelines

Lawrence von Karsa

European Network for Cancer Screening and Prevention

Quality Assurance Group, Early Detection and Prevention Section

International Agency for Research on Cancer

Lyon, France

Implementation of breast cancer screening in the EU

- 1. Introduction
- 2. Council Recommendation on cancer screening
 - Rationale
 - Quality primate and guidelines
 - First status report
- 3. Focus of future efforts and opportunities for international cooperation and collaboration
 - Updating and expanding evidence-based guidelines
 - Accreditation and certification
 - Network of competence and reference centers
 - Collaborative research

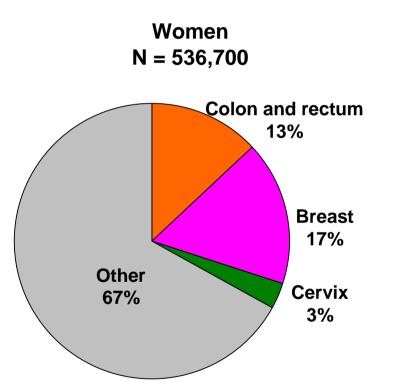


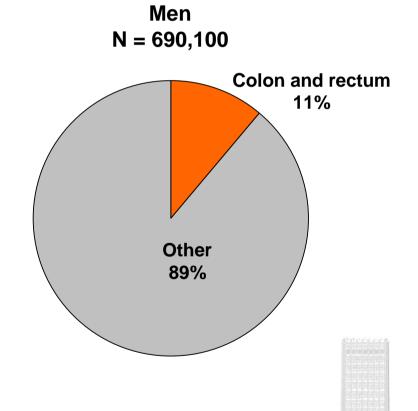


The European Union today

- 600 million population
 - 136 million men and women 50-74 yrs.
 - 109 million women 30-60 yrs.
 - 59 million women 50-69 yrs.
- > 27 Member States
 - 15 acceded before 2004
 Austria, Belgium, Denmark, Finland, France, Germany, Greece,
 Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden,
 United Kingdom
 - 12 recently acceded in 2004 and 2007
 Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia,
 Lithuania, Malta, Poland, Romania, Slovak Republic, Slovenia,

Burden of Breast, Cervical and Colorectal Cancer in the EU in 2006 – Deaths (except non-melanotic skin cancer)









THE COUNCIL OF THE EUROPEAN UNION





Over 30 specific recommendations

- How to implement cancer screening programmes
- How to maintain appropriate quality of screening programmes
- How to reach appropriate decisions on new or modified programmes
- 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;



THE COUNCIL OF THE EUROPEAN UNION

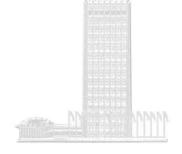




ANNEX:

- 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.







THE COUNCIL OF THE EUROPEAN UNION





- 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. HEREBY INVITES THE COMMISSION:

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.

Quality Primate of Cancer Screening - 1

- Screening is applied to predominantly healthy populations.
- The needs and concerns of healthy clients differ significantly from those of patients.
- Because the vast majority of clients are healthy, only a few will have a health benefit from screening.
- All of clients are exposed to the risks of screening
- The risks, even if only slight, may collectively shift the balance between harm and benefit into an inappropriate range.

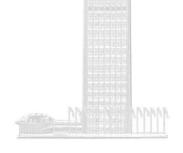




Quality Primate of Cancer Screening - 2

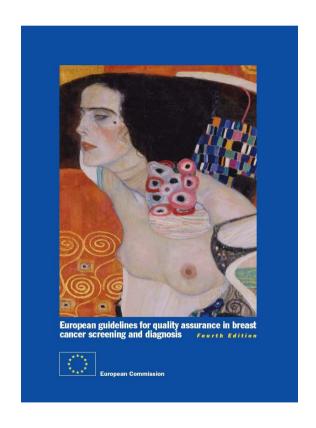
- To achieve and maintain an appropriate balance between benefit and harm...
- Quality must be optimal at every step in the screening process:
 - information and invitation of the target population
 - performance of the screening test
 - diagnostic work-up of persons with suspicious test results
 - treatment of screen-detected lesions

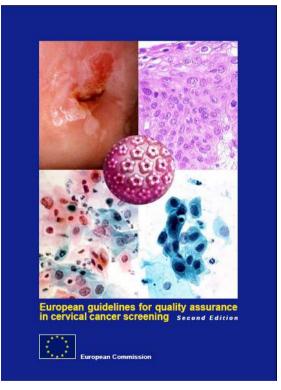




EU Guidelines for *BREAST* and *CERVICAL* cancer screening

COLORECTAL is coming soon





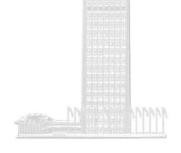




EU Screening Guidelines Underlying Concepts

- Screening as a public health endeavour
- Overriding aim of minimising harm and maximising benefit
- Comprehensive, multidisciplinary process of screening
- Standards of performance and procedures of best practice
- Continuous quality improvement
- Need for population-based organisation, monitoring and evaluation





1993

First edition:

67 pages



Main issues

- Screening process
- Organisational aspects
- Medical aspects
- European protocol for physico-technical quality control

1996

Second edition:

176 pages



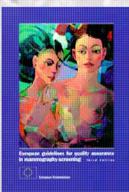
New chapters:

- Epidemiology quality assurance
- Cytopathology quality assurance
- Pathology quality assurance
- Revised physico-technical protocol

2001

Third edition:

366 pages



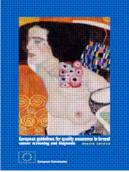
New chapters:

- Data collection
- Radiographical quality issues
- Radiological quality assurance
- Surgical management guidelines
- Training recommendations

2005

Fourth edition:

416 pages



New chapters:

- Certification protocol
- Communication
- Digital mammography
- Multidisciplinary diagnosis
- Specialist breast units



European Guidelines for Quality Assurance in Mammography Screening and Diagnosis

Maximise benefit and minimise harm of population-based screening through

continuous quality improvement of the entire screening process (from invitation to treatment)

4th edition:

- Communication*
- Radiography
- Radiology
- Diagnosis of breast disease*
- Pathology
- Surgery
- Specialist breast units*

- Epidemiology
- Data collection and monitoring
- Key performance indicators
- Physico technical control
- Digital mammography*
- Training
- Certification Protocol*



*new chapters



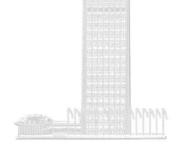
EU Breast Screening Guidelines Key general elements of QA and best practice - 1

- Population-based invitation to screening
- Training of all staff, particularly: radiographers, radiologists, pathologists and surgeons
- Dedicated equipment and specialisation of personnel
- Observance of volume levels
- Multidisciplinary team working, including above staff as well as breast care nurses and medical oncologist/radiotherapist

EU Breast Screening Guidelines Key general elements of QA and best practice – 2

- Targets, performance indicators and regular audit
- Organization of preoperative and post-operative multidisciplinary conferences
- Avoidance of mixing of screening and symptomatic women
- Complete and accurate recording of all relevant data for evaluation
- Accreditation of units meeting quality standards





More specific requirements for quality assurance of breast cancer screening

- Adequate, unbiased information to allow informed choice as to whether to attend
- Extensive QA protocols for equipment and technical performance in conventional and digital mammography
- Interpretation of screening mammograms by two independent readers
- Standardization of pathology procedures and reporting
- Standardization of data collection and monitoring
- Comprehensive protocols for professional QA
- Nomination of a given professional responsible for overall unit performance and with the authority to maintain standards and outcomes by suspending inadequate elements if necessary

Some key quality requirements for specialist breast units

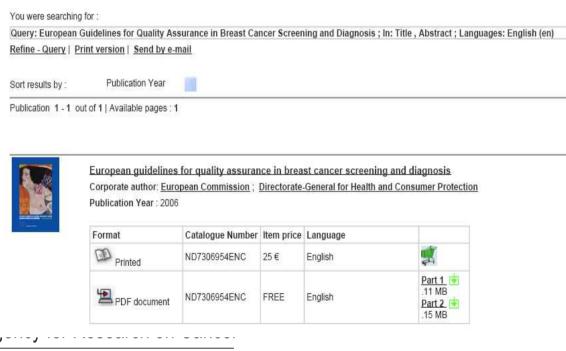
- Breast surgery by *specially trained surgeons* in *specialist units* providing a minimum of 150 primary breast cancer operations annually.
- Each breast surgeon should perform a minimum of 50 primary breast cancer operations per year.
- Clinical, imaging and pathology findings of all women requiring breast surgery should be discussed and documented in regular pre-operative and post-operative meetings of the full multidisciplinary team (radiologist, radiographer, pathologist, surgeon, nurse counsellor and medical oncologist/radiotherapist).
- Patient support by specialist breast care nurses or psychologically professionally trained staff with expertise in breast cancer.
- Continuous monitoring of outcomes and regular audit





To Order Breast Guideline Book and obtain Free electronic copies

- go to: http://bookshop.europa.eu
- 2. select language, then search by words function
- 3. enter title: European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis





EU Breast Screening Guidelines New Chapters and Updates in Next Edition

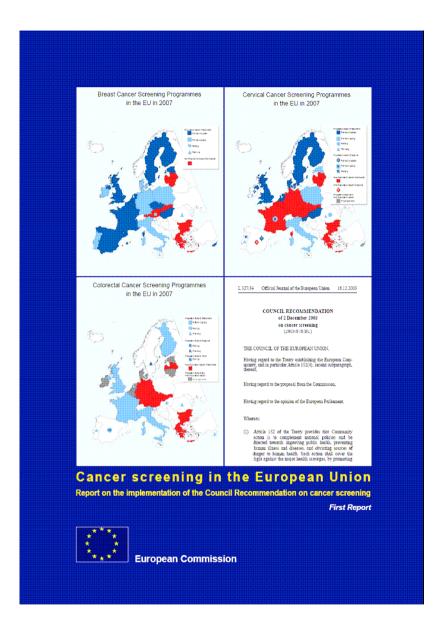
- Breast Care Nursing
- Certification of Specialist Breast Centers
- Cost-effectiveness of Screening
- Implementation of Screening Programmes
- Regional and National Status Reporting
- Updates on:
 - Pathology
 - Physico-technical aspects of digital mammography





Nationwide implementation of population-based screening improves the entire range of cancer care

- The population-based approach is essential to monitoring and maintaining high quality at every step in the screening process.
- Nationwide implementation of population-based programmes makes services performing to the high multidisciplinary standards accessible to the entire eligible target population.
- Large numbers of professionals undertake further specialisation in order to meet the screening standards.
- Consequently, these nationwide efforts also lead to widespread improvement in multidisciplinary diagnosis and management of cancers which are detected outside of screening programmes.





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 Autier

http://bookshop.eu.int/eGetRecords?Template=Test_EUB /en_publication_details&CATNBR=ND7306954ENC

Financial support of EU Health Programme (ECN/EUNICE/ECCG)

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

- All 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. Ca. 1.000 million feasible in coming years
- Need for professional, technical and scientific support for quality assurance, monitoring, evaluation and accreditation
- Adequate resources, including expanded international collaboration, are essential

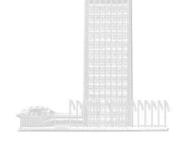
Report on the implementation of the Council Recommendation on cancer screening - *First Report*METHODOLOGY

- 1. Questionnaire in official languages of Member States sent by DG SANCO to EU representations of MS in Brussels in May 2007
 - Quantitative information on volume of screening (invitations and examinations) by type of screening
 - Qualitative information on implementation of the specific recommendations in the Council Recommendation
 - Other qualitative information (cancer control programmes)
- 2. Returned questionnaires translated into English and forwarded to ECN coordination office at IARC for data entry and analysis
- 3. Plausibility checks, for internal consistency and using data from EUNICE (Turin and Helsinki) and ECN (Lyon) projects. Missing data obtained from these projects, literature, official sources

Report on the implementation of the Council Recommendation on cancer screening - *First Report* METHODOLOGY, cnt'd

- 4. Definitions for uniform data presentation and descriptive analysis based on data received at IARC
- 5. Preliminary results (25 Member States, 20 Questionnaires) presented at Slovenian EU Presidency Conference in BRDO 2/2008 and at informal EU Health Council Meeting 4/2008
- 6. Data subsequently received 4-6/2008
 - Revised data from 10 Member States
 - Questionnaires from 2 additional Member States
- 7. Final data base (from official sources in all 27 Member States)
 - Quantitative data: 22 MS Questionnaires, 5 MS other sources (Ministries of Health, Screening Programmes, National Coordination/Management units)
 - Qualitative data from 22 MS Questionnaires





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

- **1. Programme screening** requires public responsibility, coordination, supervision. The screening policy should at least
 - Be defined by law or *official* regulation, decision, directive or recommendation
 - Specify screening test, examination interval, eligible group of persons
 - Provide for public financing of participation in screening (apart from own contribution)

Note: In many countries, in addition to programme screening, significant volumes of "wild" screening may be performed, outside of any programme

Report on the implementation of the Council Recommendation on cancer screening - *First Report* Screening Programme Type, cnt'd

2. Organised Screening (not used to classify programmes because the degree of organisation varies widely):

In addition to the targeted population group(s), the screening test, and the examination interval(s) programme policy generally

- Provides for national or regional team responsible for implementation (coordinating service delivery, quality assurance, and reporting of performance and results)
- Requires comprehensive guidelines, rules and standard operating procedures
- Defines a quality assurance structure and mandates supervision and monitoring of most steps in the screening process
- Requires ascertainment of the population disease burden

Report on the implementation of the Council Recommendation on cancer screening - *First Report* Screening Programme Type, cont'd

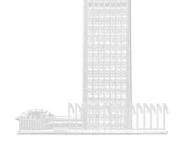
- **3. Population-based screening** generally requires a high degree of organisation in order to
 - Identify and invite each person in the eligible target population
 - Assure that the invitational activities are performed reliably and effectively and are adequately coordinated with the subsequent steps in the screening process

Note: It can take 10 or more years to implement populationbased screening nationwide due, among other things, to the translational phase of planning, feasibility testing and piloting, which is followed by geographically phased rollout.

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

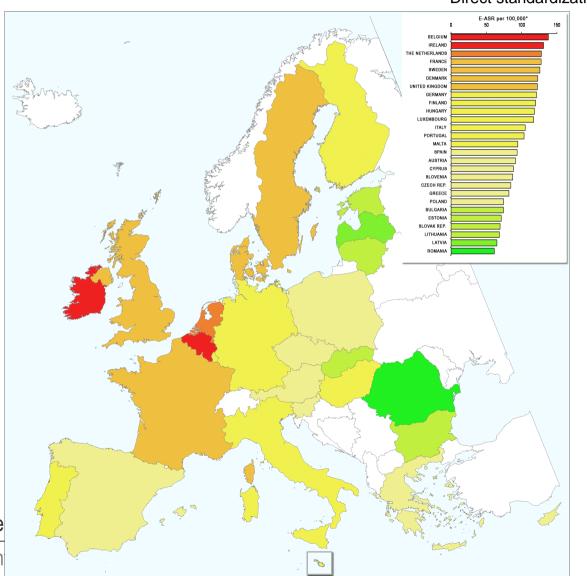
- Programme or No Programme
- 2. Nationwide or Regional (aim of public screening policy)
- 3. If Programmes are Population-Based
 - Pilot phase
 - Planning phase
 - Rollout ongoing: at least some invitations have been sent
 - Rollout complete (fully established)
 - At least ca. 90% of eligible target population in respective country or region personally invited at least once
 - All elements of screening process are fully functional
 - Mixed: different phases in various regions of the country





BREAST Cancer **Incidence** in the EU Estimates by Member State for 2006

Age-standardised rates (cases per 100,000 woman-years) Direct standardization, European reference population



138 / 100,000

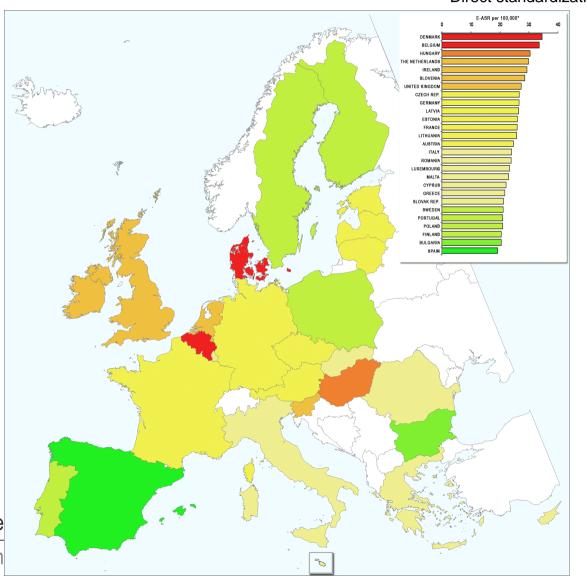
61 / 100,000



Karsa, Anttila, Ronco et al. 2008 IARC, ECN and EUNICE projects, Ferlay et al. Ann Oncol 18: 581-592

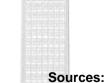
BREAST Cancer Mortality in the EU Estimates by Member State for 2006

Age-standardised rates (deaths per 100,000 woman-years) Direct standardization, European reference population



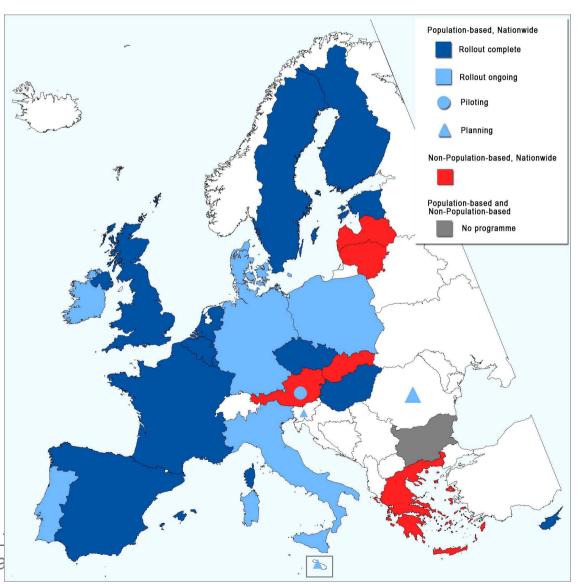
34 / 100,000

19 / 100,000



Karsa, Anttila, Ronco et al. 2008 IARC, ECN and EUNICE projects, Ferlay et al. Ann Oncol 18: 581-592

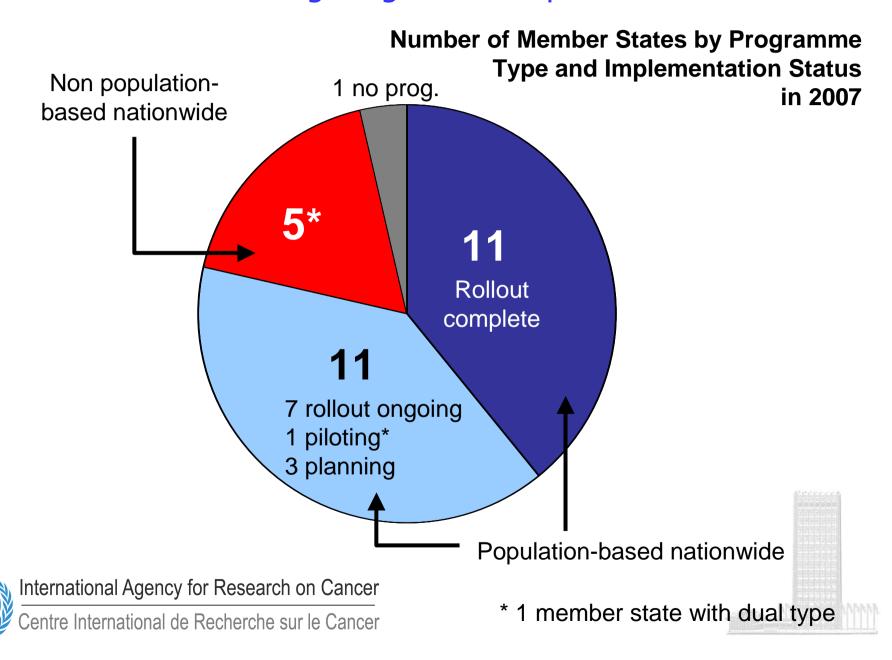
BREAST Cancer Screening Programmes in the EU in 2007



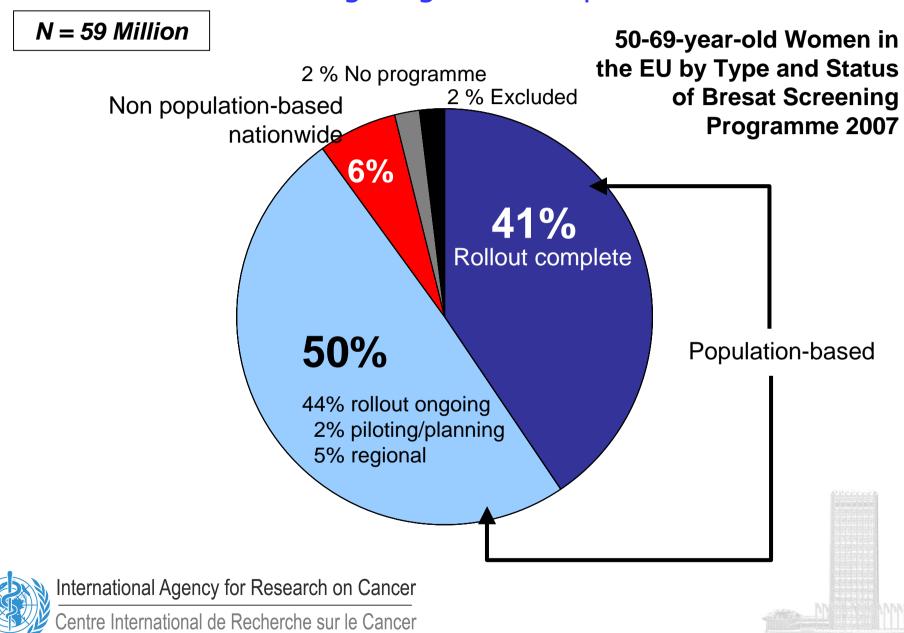


Sources:
Karsa, Anttila, Ronco
et al. 2008, European
Commission, IARC,
ECN and EUNICE
Financial support
of EU Public Health
Programme

BREAST Cancer Screening Programme Implementation in the EU

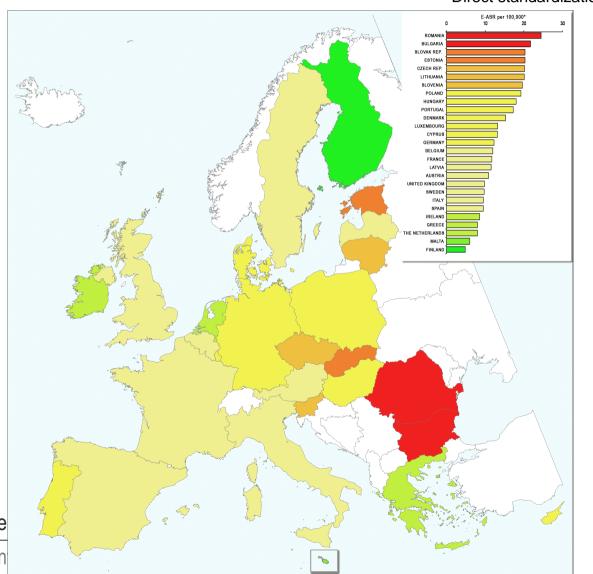


BREAST Cancer Screening Programme Implementation in the EU



CERVICAL Cancer Incidence in the EU Estimates by Member State for 2006

Age-standardised rates (cases per 100,000 woman-years)
Direct standardization, European reference population



25 / 100,000

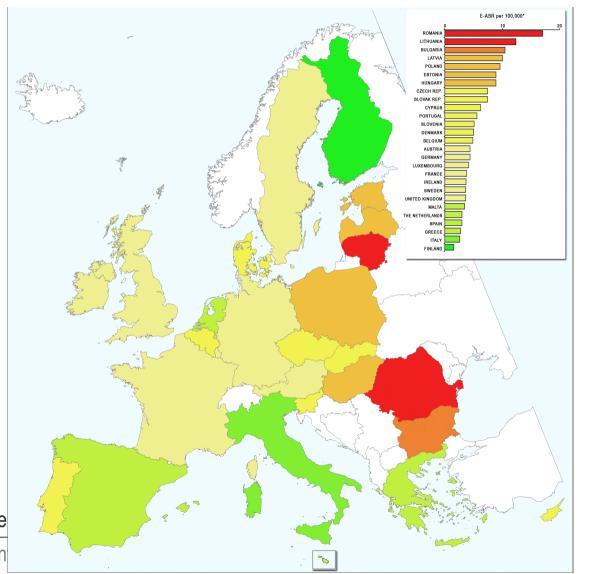
5 / 100,000

Sources:

Karsa, Anttila, Ronco et al. 2008 IARC, ECN and EUNICE projects, adapted from: Arbyn, et al. Ann Oncol 18: 1423-1425 and Arbyn, et al. Ann Oncol 18 1708-1715

CERVICAL Cancer Mortality in the EU Estimates by Member State for 2006

Age-standardised rates (deaths per 100,000 woman-years)
Direct standardization, European reference population



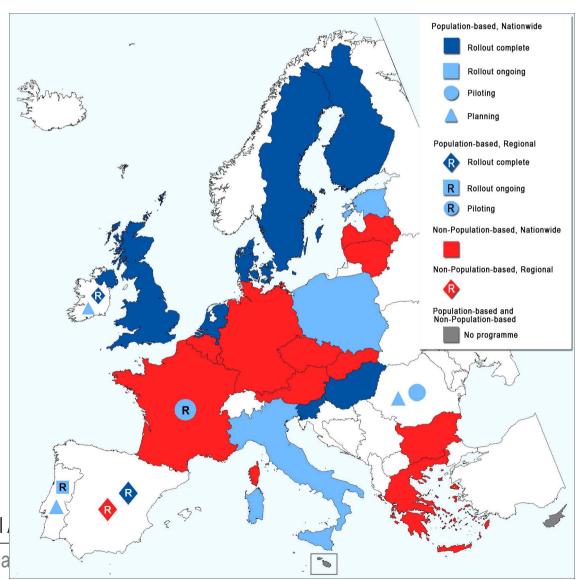
17 / 100,000

<2 / 100,000

Sources:

Karsa, Anttila, Ronco et al. 2008 IARC, ECN and EUNICE projects, adapted from: Arbyn, et al. Ann Oncol 18: 1423-1425 and Arbyn, et al. Ann Oncol 18 1708-1715

CERVICAL Cancer Screening Programmes in the EU in 2007

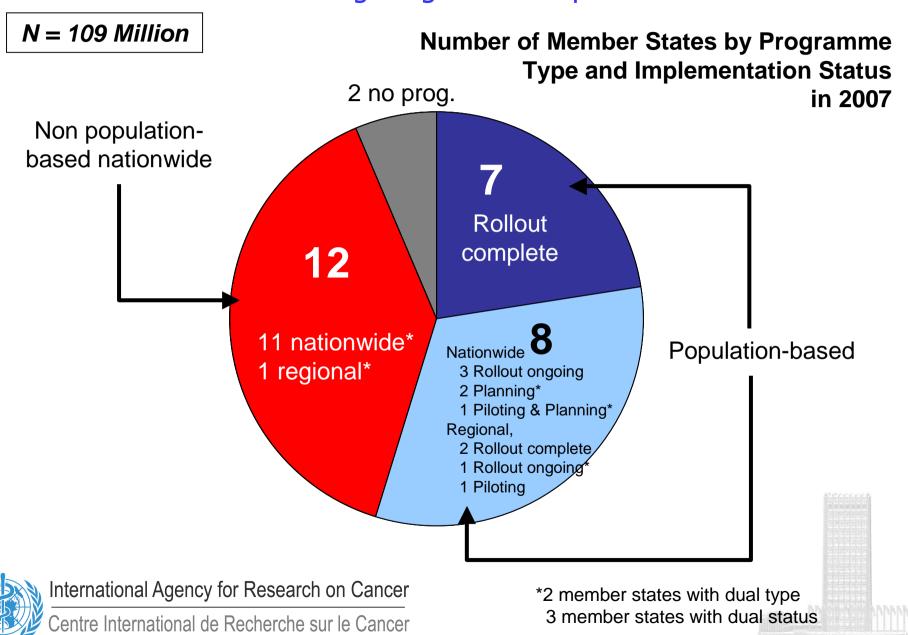




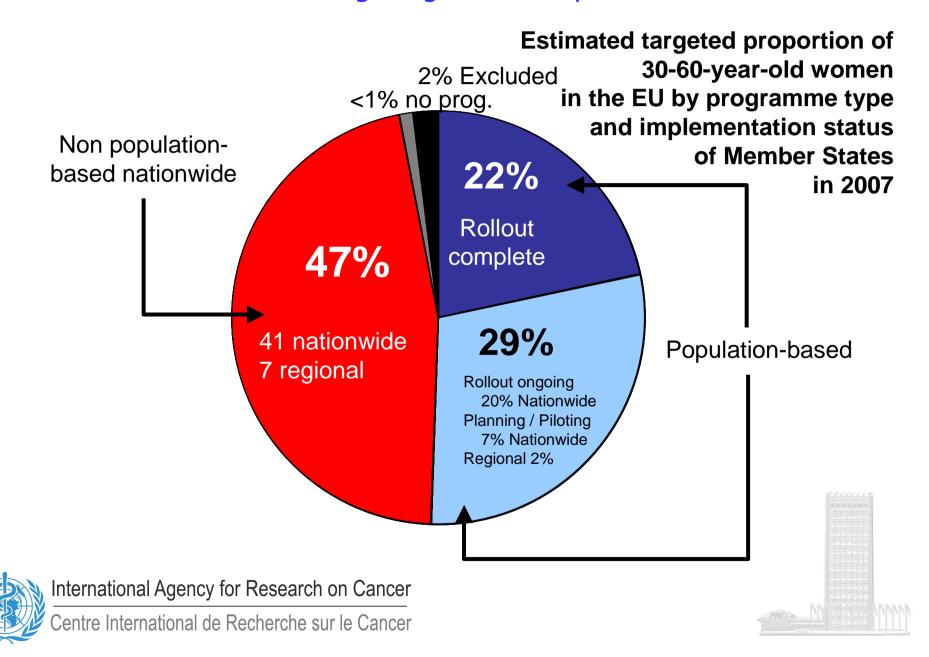
Karsa, Anttila, Ronco et al. 2008, European Commission, IARC, ECN and EUNICE Financial support of EU Public Health Programme



CERVICAL Cancer Screening Programme Implementation in the EU

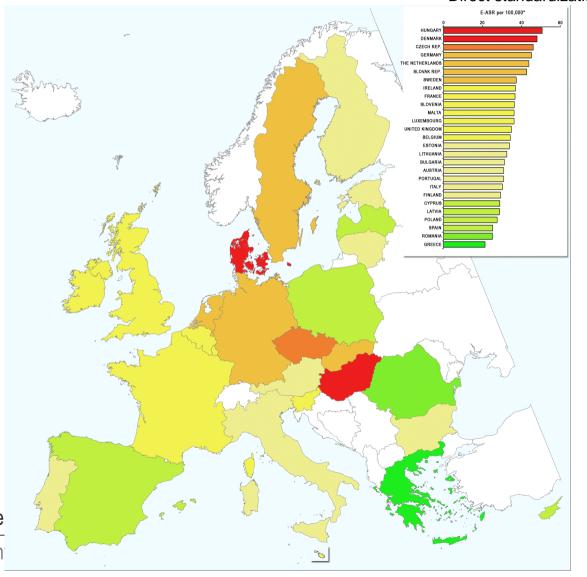


CERVICAL Cancer Screening Programme Implementation in the EU



COLORECTAL Cancer Incidence in Women in the EU Estimates by Member State for 2006

Age-standardised rates (cases per 100,000 woman-years)
Direct standardization, European reference population



51 / 100,000

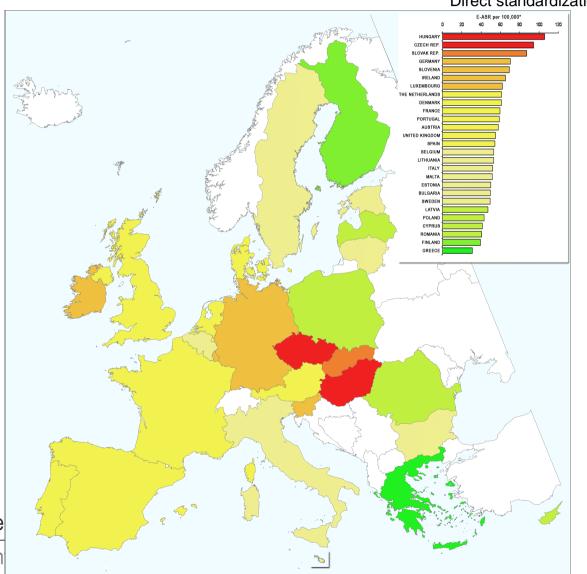
30 / 100,000

21 / 100,000

Sources:

COLORECTAL Cancer Incidence in Men in the EU Estimates by Member State for 2006

Age-standardised rates (cases per 100,000 man-years) Direct standardization, European reference population



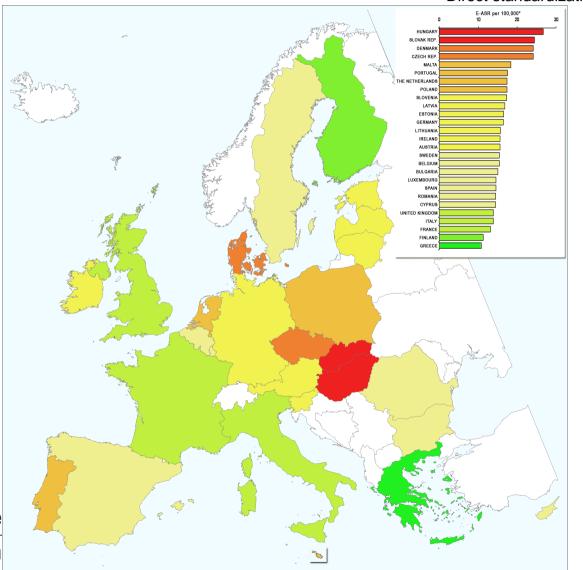
106 / 100,000

31 / 100,000



COLORECTAL Cancer Mortality in Women in the EU Estimates by Member State for 2006

Age-standardised rates (deaths per 100,000 woman-years)
Direct standardization, European reference population



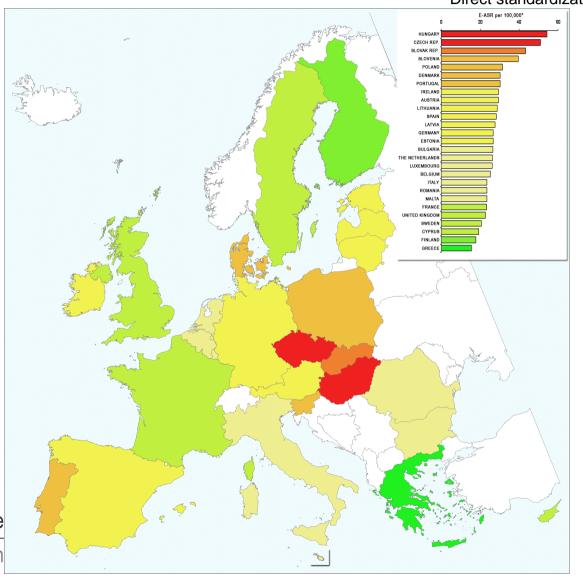
27 / 100,000

11 / 100,000



COLORECTAL Cancer Mortality in Men in the EU Estimates by Member State for 2006

Age-standardised rates (deaths per 100,000 man-years) Direct standardization, European reference population



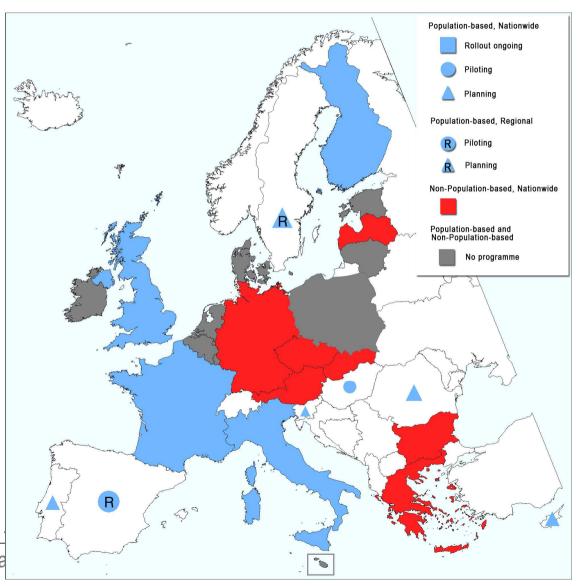
54 / 100,000

23.5 / 100,00

16 / 100,000



COLORECTAL Cancer Screening Programmes in the EU in 2007



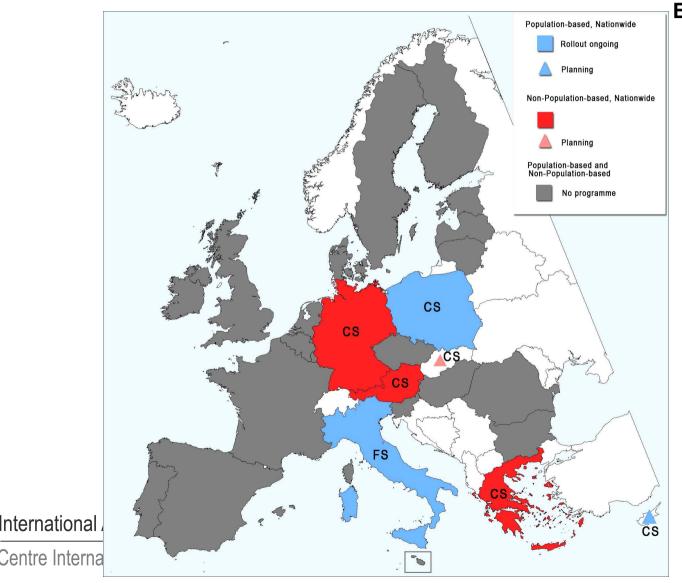
FOBT-based programmes

Sources:

Karsa, Anttila, Ronco et al. 2008, European Commission, IARC, ECN and EUNICE Financial support of EU Public Health Programme



COLORECTAL Cancer Screening Programmes in the EU in 2007



Endoscopy-based programmes

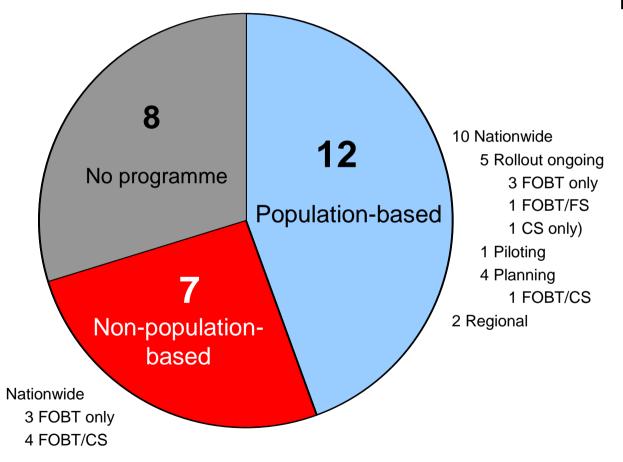
CS: Colonscopy FS: Flexible sigmoidoscopy

Sources:

Karsa, Anttila, Ronco et al. 2008, European Commission, IARC, ECN and EUNICE Financial support of EU Public Health Programme

COLORECTAL Cancer Screening Programme Implementation in the EU

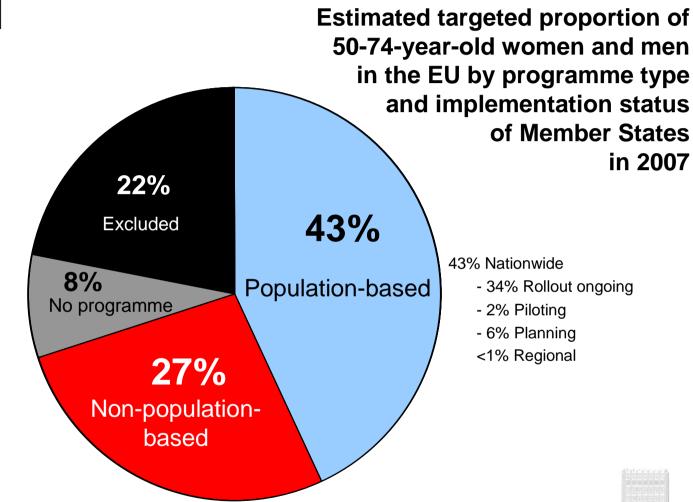
Number of Member States by Programme
Type and Implementation Status
in 2007





COLORECTAL Cancer Screening Programme Implementation in the EU

N = 136 *Million*



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

- Substantial consensus between EU Member States and Council on priority of establishing population based screening programmes
- 2. Screening volume (now >500 million/10 yrs, 1.000 million feasible) demonstrates potential of Council recommendations to improve health of the population model for other chronic disease
- 3. Nevertheless, still substantial room for improvement:
 - Several Member States still in planning, piloting stage or without programmes, particularly CRC cancer screening
 - Large volume of non-population-based programmes (particularly cervical and CRC screening)
 Population-based approach would
 - Save more lives and avoid more suffering
 - Release resources for quality improvement





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

Table 6	Number of Persons attending Breast, Cervical and Colorectal Cancer Screening Programmes in the European Union in 2007 by Target Cancer and Programme Type							
	Persons attending screening programmes for							
	Breast Cancer		Cervical Cancer		Colorectal cancer		Total	
	persons (X 1000)	% of column	persons (X 1000)	% of column	persons (X 1000)	% of column	persons (X 1000)	% of column
1	2	3	4	5	6	7	8	9
Population- based	11,262	97%	7,791	25%	3,519	30%	22,572	41%
Non-population- based	343	3%	23,744	75%	8,120	70%	32,207	59%
Total	11,606	100%	31,535	100%	11,639	100%	54,780	100%

Source: European Commission, 2007 (DG SANCO); IARC, 2007 (ECN and EUNICE projects); other sources see Tables 3 b - 5 b.

^{*} Estimates of volume of screening in 2007. Volumes in Tables 3 b - 5 b corrected for programmes with missing data and for programmes in rollout phase in 2007.



Centre International de Recherche sur le Cancer :er

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

• Current expenditure in human and financial resources is considerable and is likely to increase substantially in the future

The scale of these activities and the challenge of maintaining an appropriate balance between benefit and harm of screening call for an adequate strategy at the Community level to ensure that appropriate professional, technical and scientific support is available to Member States to

- Convert respective programmes to the population-based approach
- Implement population-based programmes where screening is lacking taking into account the translational phase of planning, feasibility testing and piloting prior to programme rollout
- Continuously improve the quality and effectiveness of existing population-based programmes

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

- Development and piloting of an EU-wide accreditation/certification scheme mandated by the Member States and based on EU quality assurance guidelines would encourage programmes throughout the EU to take the initiative to continuously improve performance and would help consumers to recognise which services achieve the EU standards.
- Given the current need for professional, organisational and scientific support for Member States seeking to implement or improve cancer screening programmes, adequate resources for appropriate Community actions are vital.

Sequence of Steps in Quality-controlled Implementation of Screening Programmes

- 1. Comprehensive planning of screening process (professional performance, organisation and financing, quality assurance)
- 2. Preparation of all components of screening process to perform at requisite high level
- 3. Expert verification of adequacy of preparations
- 4. Pilot testing and modification, if necessary, of all screening systems and components, including QA
- 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



THE COUNCIL OF THE EUROPEAN UNION



Council Conclusions on reducing the burden of cancer 2876th EPSCO Meeting, Luxembourg, 10 June 2008

- 4. WELCOMES the European Parliament Resolutions on combating cancer and on breast cancer, which underline the new challenges in this field for the enlarged EU...
- 20. INVITES the Commission to:

...

 explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate followup of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the European guidelines for quality assurance in breast cancer screening and diagnosis;





Support for Implementation of the Council Recommendation on Cancer Screening through Accreditation and Certification

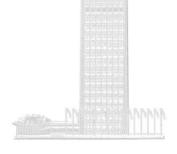
- 1. Development of standards for a voluntary EU accreditation/certification scheme for cancer screening (ECN and EA)
 - Mandated by the Member States
 - In conformity with the EU Regulation on Accreditation
 - To stimulate continuous quality improvement
 - To make services fulfilling the EU quality assurance guidelines recognizable to consumers and payers
- 2. Coordinated network of competence and reference centers
 - To train and assist the staff needed to implement and continuously improve screening programmes
 - To provide expert support needed for piloting an EU accreditation/cerification scheme
- 3. Piloting by EA in cooperation with ECN recommended by:
 - DG SANCO and DG Enterprise
 - European Parliamentary Group for Breast Cancer



Major challenges in development of an accreditation/certification scheme for breast units

- The major challenge in the project will be to specifically adapt the rules and procedures developed in the EU for accreditation and certification, and currently applied to a number of economical and social activities, to the special professional activities in multidisciplinary diagnosis and management of breast cancer
- These activities should not be performed in isolation. They should be integrated into overall efforts to improve the quality, effectiveness and cost effectiveness of cancer services in the EU





Key elements in piloting an EU-wide accreditation/certification scheme for breast units

- Piloting and training incentives for proactive quality improvement
- Voluntary EU-wide quality competition to stimulate innovation
- Robust monitoring of professional performance in certified units
- Professional evaluation of the accrediting and certifying bodies (expert review of certified units)
- Network of expert centres and programmes to develop resources for quality improvement and quality control





Thank you for your attention



