

Metodologia dell'aggiornamento del Codice Europeo contro il Cancro – ECAC

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EUROPEAN CODE AGAINST CANCER

Update

- ❑ 3rd revision published in 2003.
- ❑ Mandate by European Commission to update the Code to:
 - (1) include most recent scientific findings into
 - the existing recommendations (update of guidelines)
 - potential additional recommendations (update by expansion)
 - (2) clear communication of the Code
- ❑ Update of the Code by the International Agency for Research on Cancer (IARC):
 - (1) Update of the Code evidenced by recent scientific data (update and expansion);
 - (2) Focus on target audience (European citizens)
 - (3) Inclusion of interventions proven to be successful, assessed by scientific evidence

WORKING GROUP



Participants in Screening WG meeting, held at IARC, 24-25 June 2013.
From left to right: L von Karsa, S Törnberg, E Paci, L Dillner, P Villain,
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International Agency for Research on Cancer

EVIDENCE

- **METHODOLOGY**
- **LITTERATURE SEARCH RESULTS**



ECAC

	Evidence	
	Causality	Effectiveness of interventions
		Individual level
Tobacco	IARC	CPO
Physical activity, obesity, nutrition, alcohol	WCRF,IARC	WCRF,IARC
Uv & radiation	IARC	CPO
Chemicals & environment	IARC	IARC
Screening	CPO	CPO
Vaccination, infection	IARC	IARC, CPO

EUROPEAN CODE AGAINST CANCER

Target audience

Revision of the 3rd European Code against Cancer

I CODE	II Public Health Messages (FAQ style)	III Scientific justification and evidence base
Recommendations # 1 # 2 	Specifications - definitions - synergies between risk factors, etc. Target groups - young & elderly - men & women - parents, etc. Interventions targeted at the individual and their effectiveness	Evidence base - ECAC (2003) - IARC Monographs - WCRF reports and databases - Additional systematic reviews - Summary of evidence

ECAC 3rd edition 2003

Recommendation#8

“Women from 25 years of age should participate in cervical screening. This should be within programmes with quality control procedures in compliance with “European Guidelines for Quality Assurance in Cervical Screening”.

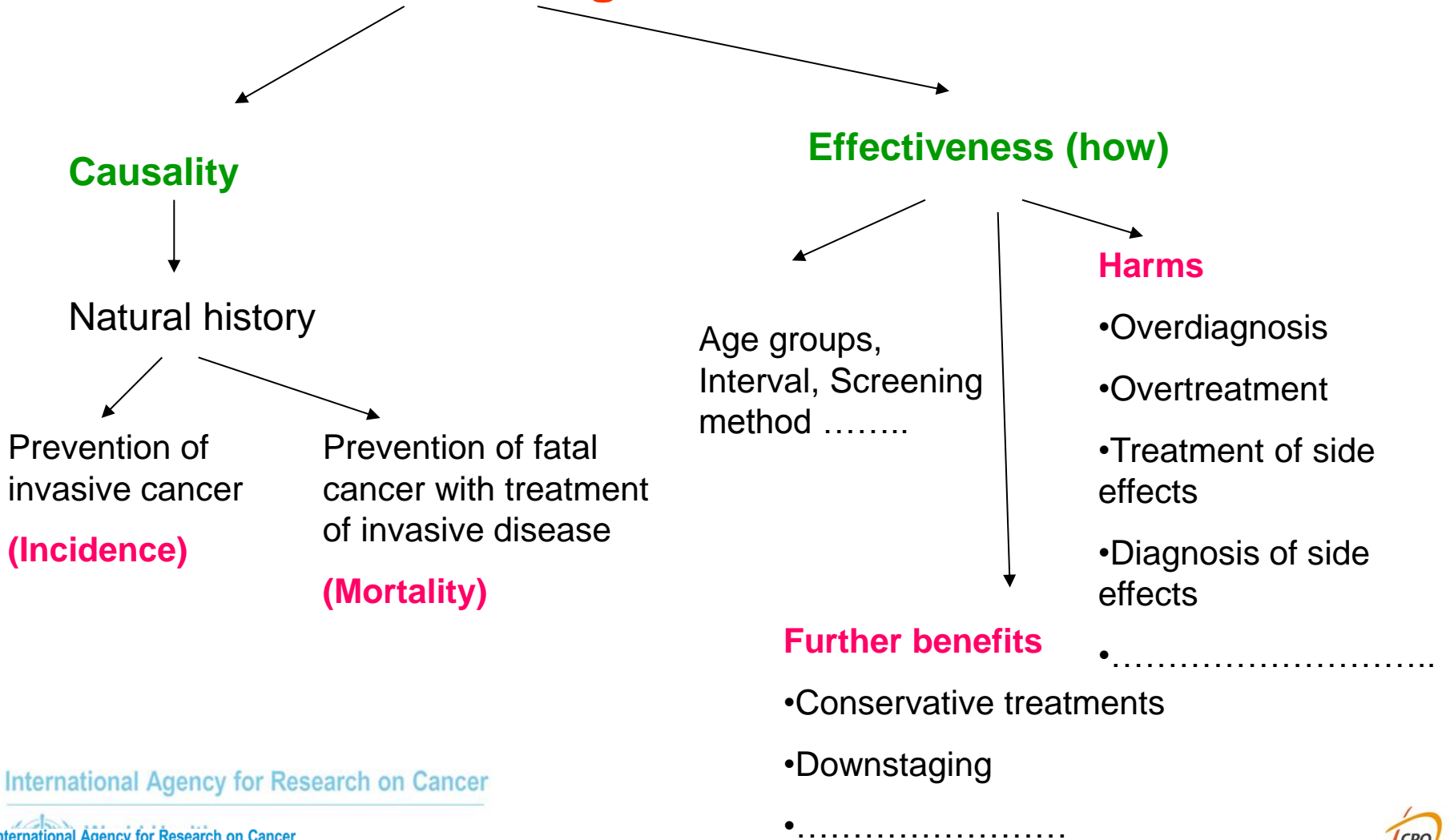
Recommendation#9

“Women from 50 years of age should participate in breast screening. This should be within programmes with quality control procedures in compliance with “European Guidelines for Quality Assurance in Mammography Screening”.

Recommendation#10

“Men and women from 50 years of age should participate in colorectal screening. This should be within programmes with built-in quality assurance procedures.”

Screening



Scientific questions

Causality

Which screening method is able to reduce **incidence** and/or **mortality** of cancer?

- CRC
- Breast
- Cervix
- Prostate
- Lung
- Others

Scientific questions for population based screening programmes

Effectiveness

- What **harms** for each screening method?
- What further **benefits** from each screening method?
- What **age** group(s), what screening **interval(s)** for what **screening method**?

JUSTIFICATION OF NEW RECOMMENDATION

- Scientifically justified prevention recommendation
- Relevant cancer burden in Europe related to recommendation
- Modifiable by the individual
- Communication possible in a way that it does not confuse the layman

EVIDENCE

- PICOS
- LITTERATURE SEARCH RESULTS



Methodology

1. PICOS FOR INTERVENTIONS

Clinical questions have been formulated following the PICOS methodology:

- **P**: patients/ population characteristics
- **I**: experimental intervention on which the question is focused
- **C**: comparison intervention / control /reference group
- **O**: outcome measure relevant for the clinical question
- **S**: study design on which to base the evidence search

SUMMARY DOCUMENT ON Mammography. Breast cancer Mortality

Cristina Bellisario, Elena Biagioli, Silvia Minozzi

Clinical question N 1

- **Is mammography screening effective in reducing breast cancer mortality and overall mortality in the general asymptomatic female population, at average risk of breast cancer by age range (50-69, 69 and above, 40-49, any other) ?**

PICOS

- **P:** General asymptomatic female population, at average risk¹ of breast cancer by age range (50-69, 69 and above, 40-49, any other)
- **I1:** opportunistic mammography screening
- **I2:** organised mammography screening programme
- **C:** no screening
- **O:** breast cancer mortality, overall mortality
- **S:** Systematic Reviews, RCTs, cohort studies with follow-up according to initial screen test results, including studies with registry linkages (screening, follow-up, cancer), case-control studies and population-based (temporal or geographical) trend studies
- ITT vs. PP analysis

Methodology

2. Bibliographic search

- Databases searched: Medline, Embase, PsychInfo, Cochrane Library
- Years covered by the search: 2000 - 31/1/2013
- Included studies published or accepted for publication and available as a reference in the databases
- No language restriction
- SRs are considered in first instance
- The search of primary studies is not done, unless retrieved SRs are out of date or very relevant studies not included in the SRs were known and suggested by the experts of each working group

Methodology

3. study selection:

- two reviewers independently screen titles and abstracts to retrieve potentially relevant studies
- Potentially relevant articles are acquired in full text and assessed for relevance against the PICOS inclusion criteria by two reviewers independently

Methodology

4. Quality assessment

- all the systematic reviews which meet the inclusion criteria based on PICOS are assessed.
- We use the AMSTAR instrument (Shea 2007). AMSTAR assesses the risk of bias (quality of conduct) against 11 distinct criteria
- Each AMSTAR item is rated as yes (clearly done), no (clearly not done), can't answer, or not applicable
- Quality rating was as follows:
 - 8 to 11 rated as yes: **high score for quality**
 - 4 to 7 rated as yes: **medium score for quality**
 - 3 or lower rated as yes: **low score for quality**

Included reviews

Breast cancer screening mortality

Methodological quality

- 4 SRs (Fitzpatrick-Lewis 2011, Gotzsche 2013, Nelson 2009, Magnus 2011) were classified as **high quality**, 5 (Ringash 2001, Ontario Health Technology Assessment Series 2007, Broeders 2012, Gabe 2005, UK Independent Panel 2012) **as medium**, 5 **as low** (Galit 2007, Green 2003, Njor 2012, Elmore 2005, Bastardis-Zakas 2010).
- See Table 1 in the appendix (results of quality assessment)

APPENDIX

Table 1. Results of quality assessment of reviews included.

Systematic Reviews assessing the impact of mammographic screening on BREAST CANCER MORTALITY

High quality 8 to 11 criteria met (yes answer)

Medium quality 4 to 7 criteria met (yes answer)

Low quality 3 or lower criteria met (yes answer)

	Gotzsche 2013	Elmore 2005	Ringash 2001	Njor 2012	Nelson 2009	Green 2003	Galit 2007	Gabe 2005	Ontario HTA 2007	Broeders 2012	Maguins 2011	Bastardis-Zakas 2010	UK panel 2012	Fitzpatrick Lewis, 2011
'a priori' design provided in a protocol:	YES	NO	NO	NO	YES	NO	NO	NO	NO	NO	YES	NO	NO	YES
duplicate study selection	YES	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	YES	UNCLEAR	UNCLEAR	YES	UNCLEAR	UNCLEAR	YES
duplicate data extraction	YES	UNCLEAR	UNCLEAR	UNCLEAR	YES	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	YES
comprehensive literature search	YES Up to November 2012	YES Date of the search not reported	YES Up to December 2000	NO Date of the search not reported	YES Up to December 2008	UNCLEAR	NO Up to August 2006	NO Up to April 2004	YES Up to December 2005	NO up to February 2011	YES up to December 2009	UNCLEAR	UNCLEAR	YES up to October 2010

Systematic Reviews Mortality

High quality 8 to 11 criteria met (yes answer)

Medium quality 4 to 7 criteria met (yes answer)

Low quality 3 or lower criteria met (yes answer)

	Hewitson 2011 (Items:10)	Kerr 2007 (items:6)	Moayyedi 2006 (Items:3)	Heresbach 2006 (Items:4)	Paz- Valinas 2004 (Items:3)	Walsh 2003 (Items:3)	Pignone 2002 (Items:5)	McLeod 2001 (Items:3)	Mas 2009 (Items:3)	Whitlock 2008 AHRQ (Items:10)	Lee 2012 BMJ (Items:5)
'A priori' design provided in a protocol	YES	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	YES	YES
Duplicate study selection	YES	Unclear	NO	Unclear	Unclear	Unclear	YES	Unclear	Unclear	YES	Unclear
Duplicate data extraction	YES	Unclear	NO	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	YES	Unclear
Compreh ensive literature search	YES Up to May 2010	YES Up to December 2004	NO No info	NO No info	YES Up to December 2002	NO Up to August 2002	NO Up to September 2001	NO Up to January 2001	YES Up to February 2008	YES Up to January 2008	NO Up to 2009
Status of publicatio n not used as an inclusion criterion	YES (not limited years); YES for unpublish ed; YES for no restricted language	NO (years are limit of research); Unclear for language; NO dor unpublished	NO	Unclear (not reported years); Unclear for unpublished; Unclear for language	NO for unpublished; YES for language YES for year not limited	NO for unpublished; NO for language; YES for year not limited	NO for unpublished; Unclear for language; YES for year not limited	NO for unpublished; NO for language; YES for year not limited	NO for unpublished NO for language	NO for unpublished UNCLEAR for language	NO

Methodology

5. Overlapping of Primary Studies included in the reviews

- the overlapping of primary studies included in all the reviews which met the PICOS inclusion criteria was assessed (also for the reviews of low methodological quality) .
- The scope of this analysis was to ascertain if primary studies of good methodological quality and discordant results could have been included in the excluded review. If this was the case, the primary studies were acquired in full text, their quality appraised, and their results considered.

RCT on mammography screening	Studies	Systematic reviews									
		Gotzsche 2013	UK Independent Panel	Elmore 2005	Ringash 2001	Green 2003	Nelson 2009	Ontario Health Technology Assessment series 2007	Magnus 2011	Bastardis-Zakas 2010	Fitzpatrick-Lewis 2011
HIP (New York)	Chu 1988		*						X		
	Habbema 1986	X					X				X
	Shapiro 1966				X						X
	Fink 1972										X
	Fink 1968										X
	Shapiro 1982	X			X	X			X		X
	Shapiro 1977	X			X						
	Shapiro 1985					X			X		

Table 2. Overlapping of primary studies included in systematic reviews.

RCT FOBT (guaiac or immunochemical)	Studies	Systematic reviews									
		Hewitson 2011	Kerr 2007	Heresbach 2006	Moayyedi 2006	Paz-Valinas 2004	Walsh 2003	Pignone 2002	McLeod 2001	Mas 2009	Whitlock 2008
Funen RCT	Kronborg 1996	X	X	X	X	X	X	X	X	X	X
	Jorgensen 2002	X	X	X	X	X	X				X
	Kronborg 2004	X	X	X					X		X
	Rasmussen 1999							X			
Goteborg RCT	Kewenter 1994	X				X			X	X	
	Kewenter 1996	X									
	Lindholm 2008	X									
	Towler 1998										X
	Hewitson 2007										X
Minnesota RCT	Mandel 1993	X		X	X	X	X	X	X		X
	Mandel 1999	X	X	X			X	X	X		X
	Mandel 2000	X	X	X			X	X			X
Nottingham RCT	Hardcastle 1996	X	X	X	X	X	X	X	X		X
	Robinson 1999	X									

Level of evidence for effectiveness of interventions

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

Results

For each PICOS question/intervention are provided:

- **An evidence table for each included study:** with the main characteristics of the study (study design, objective of the study, comparisons, participants' characteristics, outcome measures, results, methodological quality, level of evidence)
- **A summary document reporting:**
 - the methodology (search strategy and selection criteria)
 - the number of SRs finally included
 - the results of the quality assessment
 - the results of the overlapping of primary studies
 - the number of SRs finally considered for data abstraction
 - the results, conclusions and the overall level of evidence.

Author, publication year	Objective Methods	Intervention and control	Inclusion criteria	Outcome	Results	Level of evidence Conclusions
Independent UK Panel on Breast Cancer Screening, 2012	To provide estimates of the level of benefits and harms, focusing on women aged 50–70 years invited to screening every 3 years. <u>Bibliographic search</u> Information taken from various publications, but mainly the Cochrane Review (Gotzsche 2011), Nyström 2002, and Tabar 2011	<u>Intervention</u> screening with mammography <u>Control</u> no screening with mammography	RCTs with Women without previously diagnosed breast cancer.	Deaths ascribed to breast cancer (RR)	Included trials: Canada I, Canada II, Malmö I, UK age trial, Göteborg, New York -HIP, Stockholm, Two-County (splitted in Kopparberg, Ostergotland) Deaths ascribed to breast cancer: <u>13 years follow up</u> RR=0.80 (95% CI 0.73 to 0.89)	LEVEL OF EVIDENCE I Information is taken from various publications, mainly the Cochrane Review (Gotzsche 2011), Nyström 2002, and Tabar 2011. These summaries are sometimes simplifications of characteristics that differ between subtrials or subgroups. Conclusions The Panel's review of the evidence on benefit suggests a 20% reduction in mortality in women invited to participate in a 20-year screening programme

Author, publication year	Objective Methods	Intervention and control	Inclusion criteria	Outcome	Results	Level of evidence Conclusions
Nelson H D., 2009	<p>To determine the effectiveness of mammography screening in decreasing breast cancer mortality among average-risk women aged 40 to 70 and older; the effectiveness of clinical breast examination (CBE) and breast self examination (BSE); and harms of screening.</p> <p><u>Bibliographic search</u></p> <p>Cochrane Controlled Trials Registry and Cochrane Database of Systematic Reviews</p>	<p><u>Intervention</u></p> <p>Mammography or mammography plus clinical breast examination</p> <p><u>Control</u></p> <p>Usual care</p>	<p>Randomized controlled trials</p> <p>Reviewed meta-analyses that included studies with mortality data</p> <p>Multiple study designs and data sources for harms of screening: systematic reviews and meta-analyses.</p> <p>Primary studies published more recently than the included systematic reviews and meta-analyses, data from the Breast Cancer Surveillance Consortium</p>	<p>RR for breast cancer mortality, Number needed to invite to screening to Prevent 1 Breast Cancer Death</p>	<p>Included studies: 8 trials</p> <p>RR for breast cancer mortality</p> <p><u>Age (years): 39-49</u> 8 trials: RR=0.85 (95% CI 0.75-0.96)</p> <p><u>Age (years): 50-59</u> 6 trials: RR=0.86 (95% CI 0.75-0.99)</p> <p><u>Age (years): 60-69</u> 2 trials: RR=0.68 (95% CI 0.54-0.87)</p> <p><u>Age (years): 70-74</u> 1 trial: RR=1.12 (95% CI 0.73-1.72)</p> <p>Number needed to invite to screening to Prevent 1 Breast Cancer Death</p> <p><u>Age (years): 39-49</u> 1904 (95% CI:929-6378)</p> <p><u>Age (years): 50-59</u> 1339 (95% CI: 322-7455)</p> <p><u>Age (years): 60-69</u> 377 (95% CI: 230-1050)</p> <p><u>Age (years): 70-74</u> Not available</p>	<p>LEVEL OF EVIDENCE I</p> <p>Meta-analysis of mammography screening trials indicates breast cancer mortality benefit for all age groups between age 39 to 69, with insufficient data for older women. False positive results are common in all age groups and lead to additional imaging and biopsies. Women age 40 to 49 experience the highest rate of additional imaging while their biopsy rate is lower than older women. Mammography screening at any age is a tradeoff of a continuum of benefits and harms. The ages at which this tradeoff becomes acceptable to individuals and to society are not clearly resolved by available evidence.</p>

Results

For each PICOS question/intervention are provided:

- **An evidence table for each included study:** with the main characteristics of the study (study design, objective of the study, comparisons, participants' characteristics, outcome measures, results, methodological quality, level of evidence)
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 - the methodology (search strategy and selection criteria)
 - the number of SRs finally included,
 - the results of the quality assessment ,
 - the results of the overlapping of primary studies
 - the number of SRs finally considered for data abstraction.
 - the results, conclusions and the overall level of evidence

BREAST CANCER SCREENING

Clinical question N 1

Is mammography screening effective in reducing breast cancer mortality and overall mortality in the general asymptomatic female population, at average risk of breast cancer by age range (50-69, 69 and above, 40-49, any other) ?

CONCLUSIONS

(LEVEL OF EVIDENCE I)

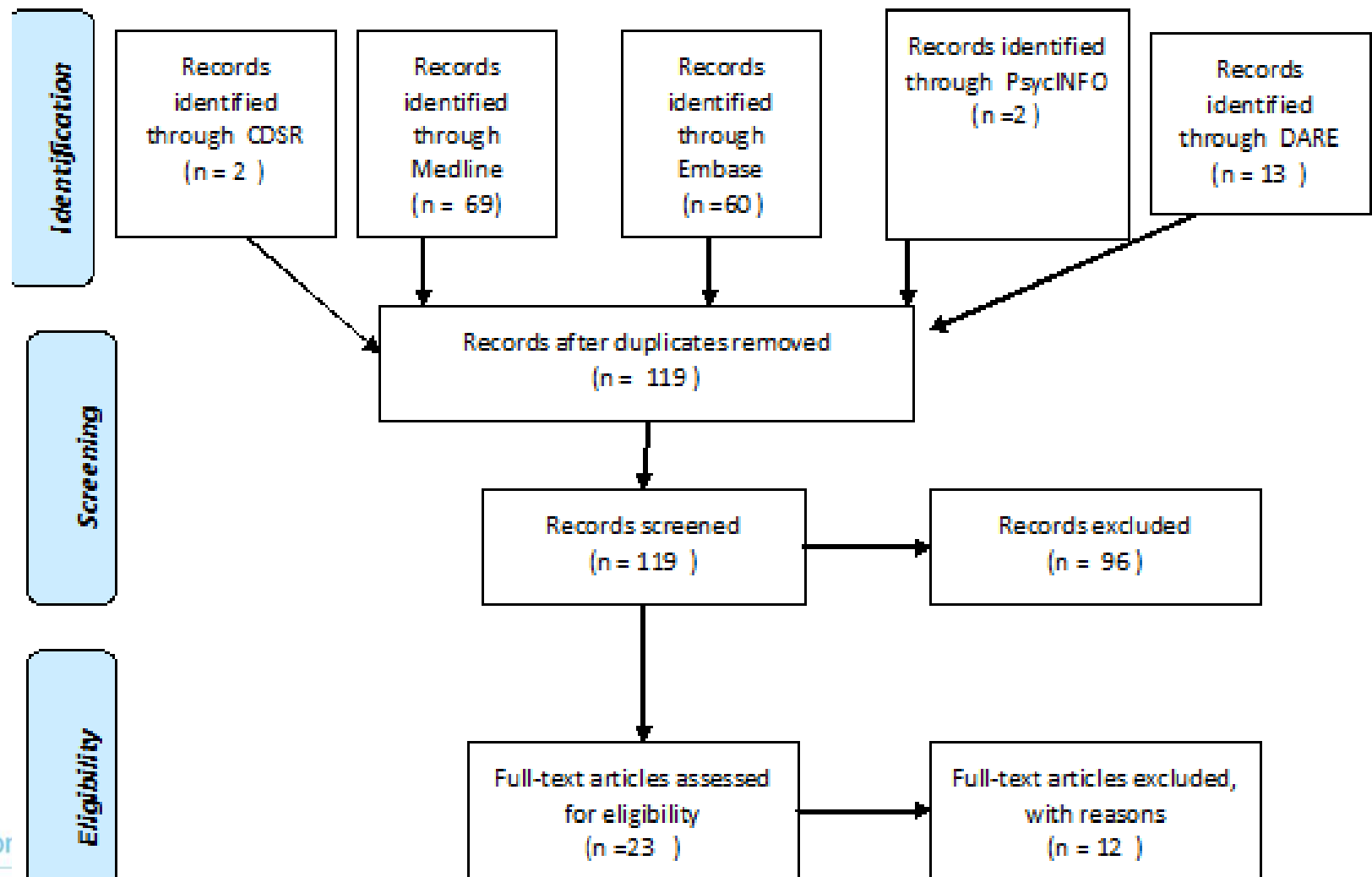
All the meta-analysis both of randomised controlled trials and observational studies found a statistically significant reduction in breast cancer mortality when all the age ranges are considered together.

When different age ranges are considered separately women for which the reduction in breast cancer mortality was greater is are those in the age range 60-69, but the results come only from two randomised trials. For the age range 40-49 and 50 -59 the reduction in mortality is statistically significant even if a little less than for all age ranges considered together. For women aged 70 -74 years one RCT and one quasi randomised trial provided results in favour of reduction of breast cancer mortality which are nearly statistically significant.

Results coming from observational studies and considering women invited to screening (ITT analysis) pooled in meta-analysis confirmed the effectiveness of breast screening on breast cancer mortality reduction, but the estimate of effect is greater. When only women who actually received mammography are included in the analysis (per protocol analysis) the estimate of mortality reduction is significantly greater (LEVEL OF EVIDENCE III-IV)

Appendix

PRISMA 2009 Flow Diagram – Fecal Occult Blood Test (FOBT)



JUSTIFICATION OF NEW RECOMMENDATION

- Scientifically justified prevention recommendation
- Relevant cancer burden in Europe related to recommendation
- Modifiable by the individual
- Communication possible in a way that it does not confuse the layman



ELSEVIER

Available at www.sciencedirect.com

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journal homepage: www.ejancer.info



Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012

J. Ferlay^{a,*}, E. Steliarova-Foucher^a, J. Lortet-Tieulent^a, S. Rosso^b,
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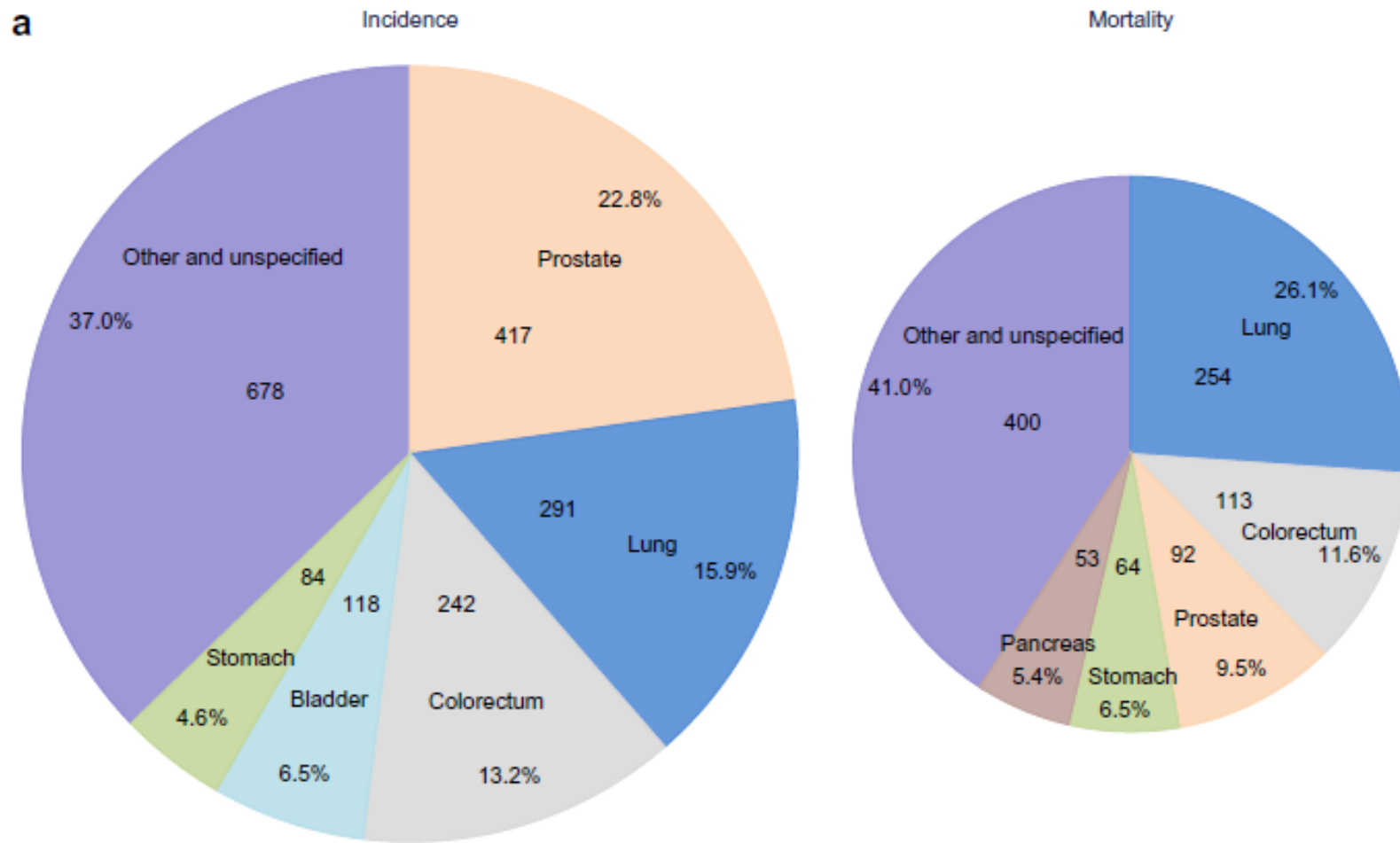
[International Agency for Research on Cancer](http://www.elsevier.com/locate/ejancer)



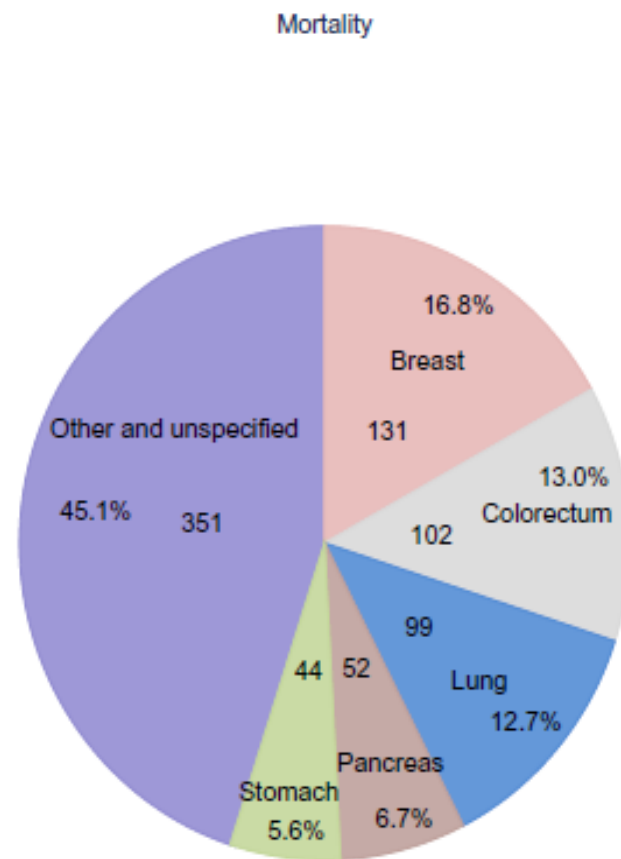
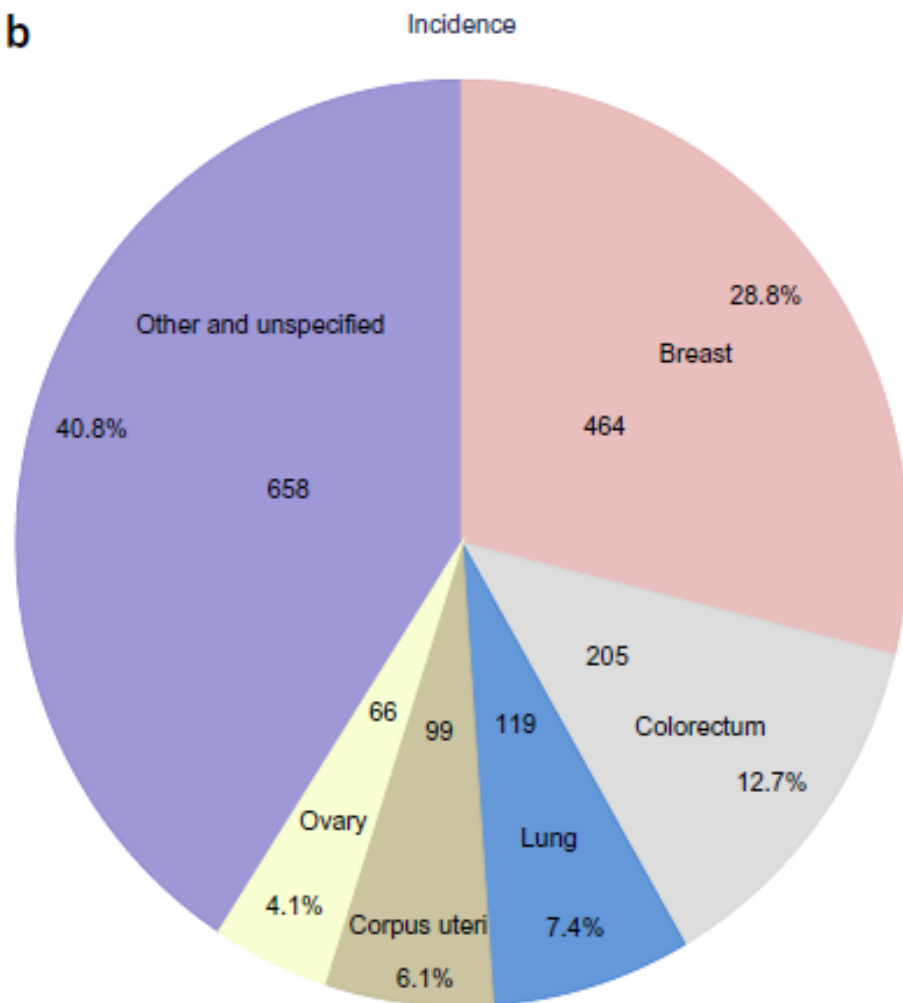
Estimated numbers of new cancer cases and deaths in 27 EU member states in 2012

(Ferlay et al EJC 2013)

Cancer Site	New Cases	Deaths
• Colon and rectum	342,000	150,000
• Lung	310,000	265,000
• Breast	310,000	91,000
• Cervix	33,000	13,000
• Prostate	360,000	71,000



b



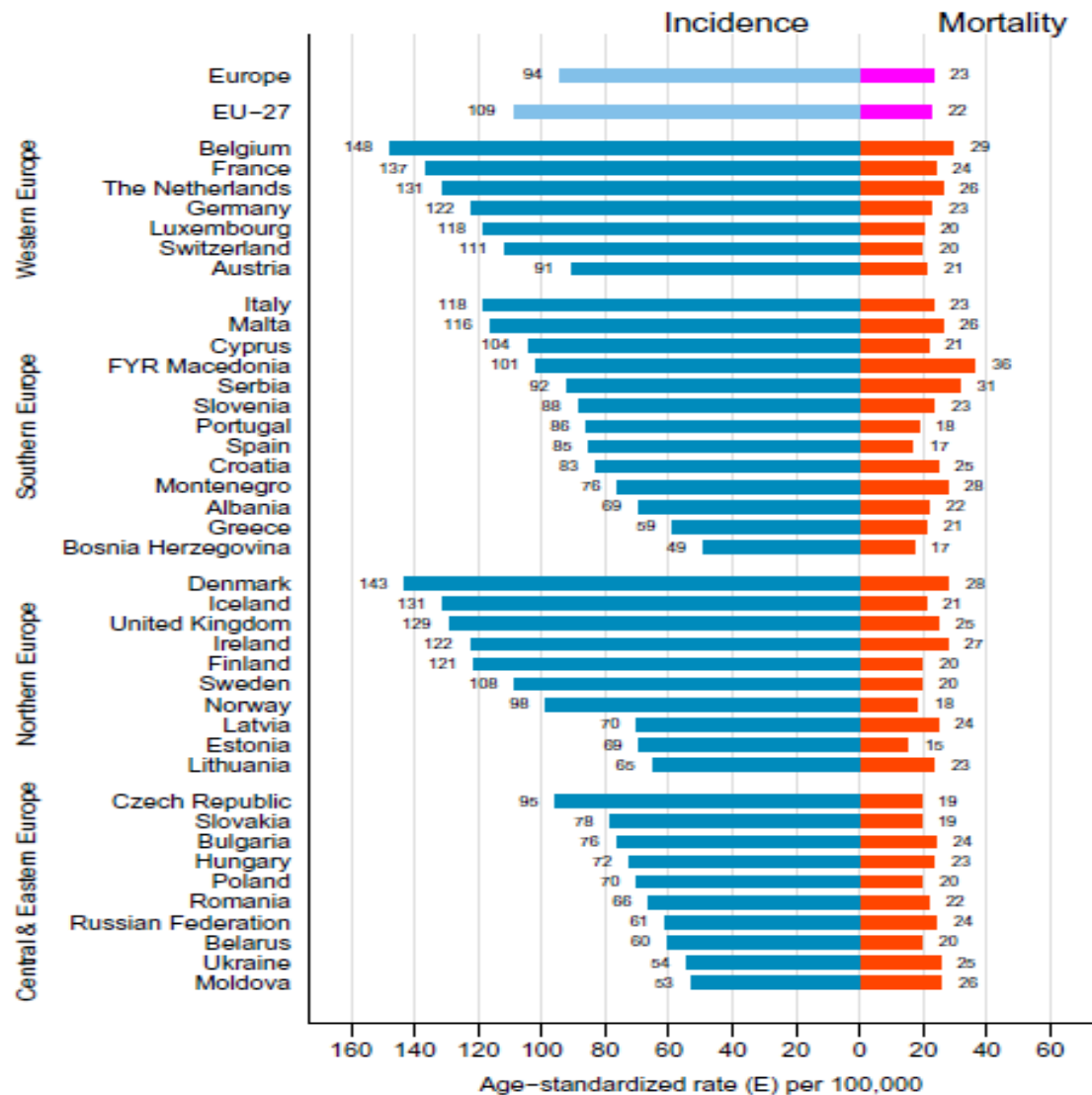


Fig. 5. Age-standardised incidence and mortality rates by area and country in Europe 2012: breast cancer.

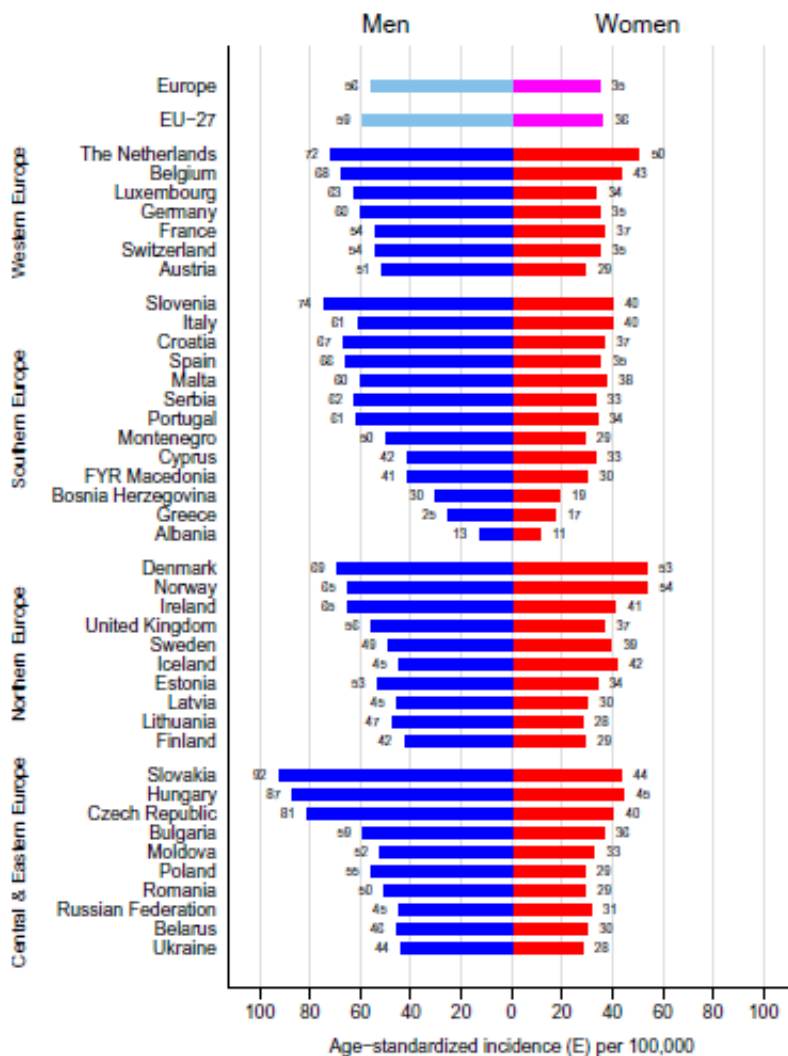


Fig. 6a. Age-standardised incidence rates by sex, area and country in Europe 2012: colorectal cancer.

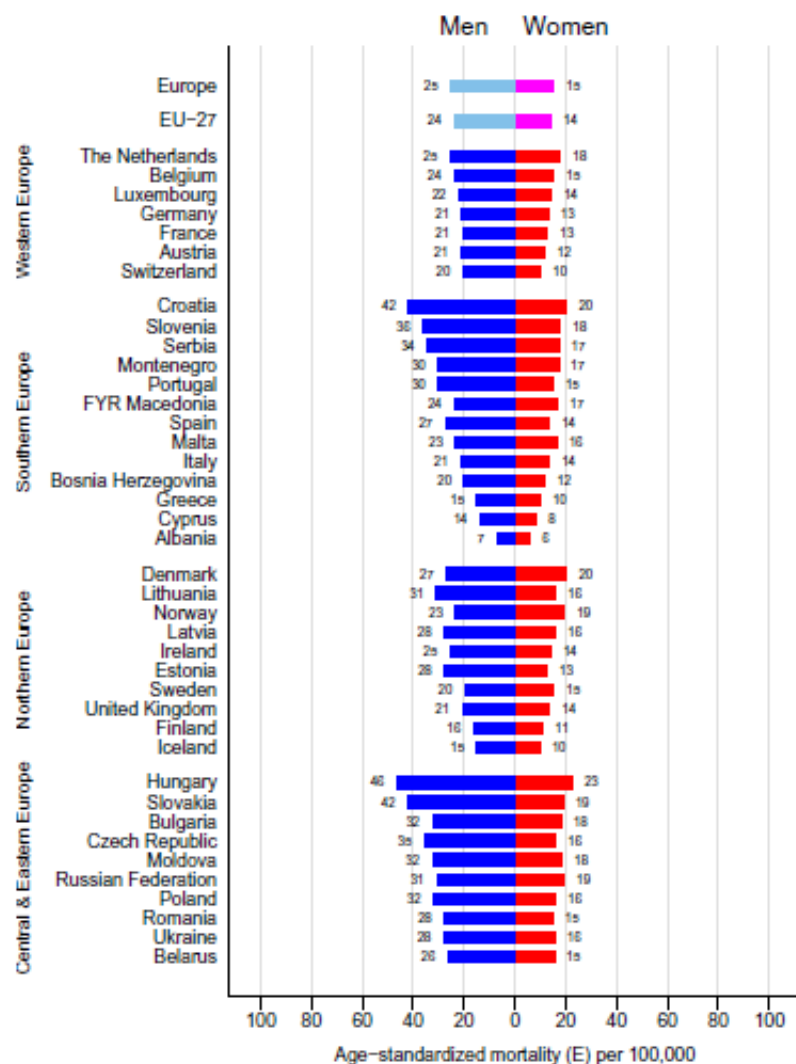


Fig. 6b. Age-standardised mortality rates by sex, area and country in Europe 2012: colorectal cancer.

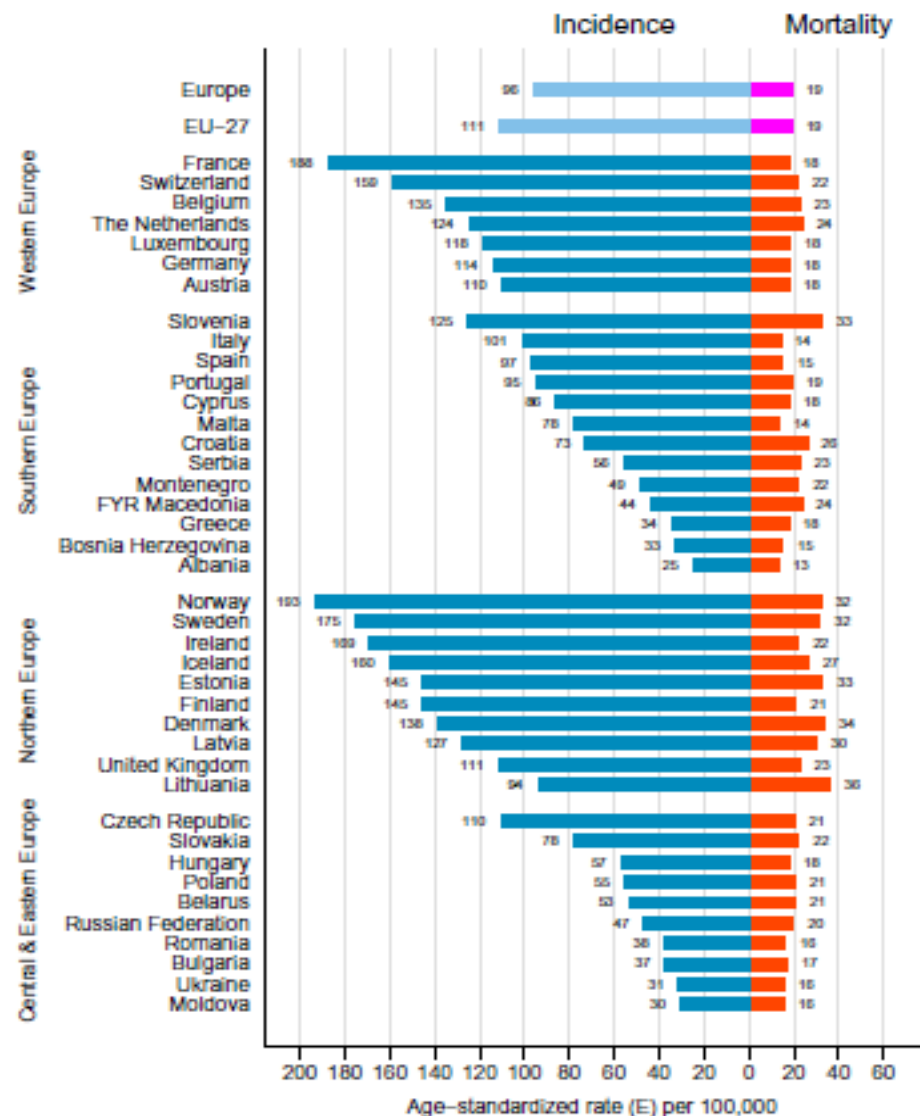


Fig. 7. Age-standardised incidence and mortality rates by area and country in Europe 2012: prostate cancer.

JUSTIFICATION OF NEW RECOMMENDATION

- Scientifically justified prevention recommendation
- Relevant cancer burden in Europe related to recommendation
- Modifiable by the individual
- Communication possible in a way that it does not confuse the layman

Modifiable by the individual

- The EU citizen may decide, according to ECAC, to know more from QA (and from scientific justification – level 3):
 - **if invited to screen**, he/she can
 1. accept or refuse the invitation based on an informed decision according to personal values.
 2. act as a citizen in order to improve the screening programme: effectiveness, equity, appropriateness, quality assurance.
 - **If not invited**, he/she may act as a citizen in order to introduce a cancer screening programme based on the ECAC and the EU guidelines for cancer screening

JUSTIFICATION OF NEW RECOMMENDATION

- Scientifically justified prevention recommendation
- Relevant cancer burden in Europe related to recommendation
- Modifiable by the individual
- Communication possible in a way that it does not confuse the layman

Communication possible in a way that
it does not confuse the layman

- Consistency between subsequent versions.

Q&As

QAs could be divided in 4 Groups

- **G1:** Questions which could be answered through “common sense” or specific knowledge but that do not need to be based on updated evidence
- **G2:** Questions for which updated evidence is needed and PICOS have been formulated and answered
- **G3:** Questions for which updated evidence is needed and **no** PICOS have been formulated and answered: so the needed updated evidence is not available.
- **G4:** Questions to which is hard to answer (i.e. different policy)

General questions (i.e. applicable to all types of cancer screening)

- What is screening? **G1**
- What is an 'organized' screening programme? **G1**
- Why is screening recommended only for certain types of cancer? **G2**
- Why is prostate screening not included in the recommendations? **G2**
- If I am invited to attend screening, how will I know whether this is part of an 'organised' screening programme?" **G4**
- I am not aware of/I have not heard of any screening programme in my country, what should I do? **G4**
- Why is there no organised bowel or breast or cervical cancer screening programme in my country? **G4**
- What can I do if we do not have invitations in our country? **G4**
- Why should I wait for an invitation to attend? **G1**
- I have received an invitation to attend screening, can I refuse? **G1**
- What does the screening examination cost or is it free? **G4**
- Will screening cause cancer? **G2**
- I would like to attend screening, what should I do? **G4**

Specific questions:

The questions and answers below are grouped under sub-headings and will be formulated to address a specific type of cancer screening (bowel, breast or cervical). Questions and answers will be presented separately on the ECAC website for each type of cancer screening (bowel, breast or cervical).

- **When to attend**
- At what age should I start? **G2**
- At what age should I stop? **G2**
- How often should I attend screening? **G2**
- My last screening test result was negative: why should I re-attend screening? **G2**
- My screening test was negative, but I have noticed something (for example with my breasts), should I wait for the next invitation to screening or should I do something now? **G1**

Reasons to attend:

- I have not noticed or felt any problem/change with my breasts (or my bowel or cervix), do I need to attend screening? **G1**
- Can I get a cancer after a negative screening exam/after attending screening? **G2**
- If I attend will my risk of contracting bowel/breast/cervical cancer be reduced? **G2**
- If I attend, will my risk of dying from bowel/breast/cervical cancer be reduced? **G2**
- If a cancer is detected in screening what is my chance of surviving? **G2**
- Specific to cervical: I have been vaccinated against HPV, should I still attend cervical cancer screening? **G3**
- My mother and/or my grandmother had breast cancer, what should I do? **G3**

Methods for cancer screening

- What is an HPV? or What is a pap-smear/smear test? or What is an FOBT/FIT test? What is sigmoidoscopy ? or What is a mammography? **G1**
- Is there any other effective screening method? Is there a better method for screening? **G3**
- Is it possible for me to choose the test? **G4**
- Specific to bowel cancer screening: Is it better to use FIT or FOBT or sigmoidoscopy? **G2**
- How can I be sure that the screening test is reliable/of good quality? **G4**

Other questions

- Is there any harm/risk from screening? **G2**
- How long do I need to wait for my results? **G4**
- What will happen if I have an abnormal test? **G1**
- Will screening cause unnecessary (diagnostic and therapeutic) procedures: is it (harmful / painful)? **G2**
- Specific to breast cancer screening: I have heard about overdiagnosis in breast cancer screening. What is it? **G2**