

Università degli Studi di Padova
Dipartimento di Scienze Cardiologiche Toraciche Vascolari
Unità di Igiene e Sanità Pubblica
Laboratorio di Valutazione dei
Servizi Sanitari e della Promozione della Salute

Screening di Popolazione

Where are we now and what's next_

14.00 Saluti e presentazione

Vincenzo Baldo

Università degli Studi di Padova

14.10 Programmi di screening negli Stati Uniti: where are we now and what's next?

Mark H. Ebell

University of Georgia, US Preventive Services Task Force

15.00 Programmi di screening in Italia: where are we now and what's next?

Marco Zappa

*Valutazione Screening e Osservatorio Nazionale Screening
Istituto per lo studio e la prevenzione oncologica, Regione Toscana*

15.30 Programmi di Screening in Veneto: where are we now and what's next?

Adriana Montaguti

*Coordinamento Regionale Screening Oncologici
Direzione Prevenzione, Sicurezza Alimentare, Veterinaria, Regione Veneto*

16.00 Screening cardiovascolare: esperienze regionali a confronto

Federica Michieletto

Direzione Prevenzione, Sicurezza Alimentare, Veterinaria, Regione Veneto

Mara Morini

già Direttore Cure Primarie AUSL Bologna

Grazia Orizio

Dipartimento Cure Primarie ATS Brescia

16.30 Conclusioni

Manuel Zorzi

Registro dei Tumori del Veneto Regione Veneto

Alessandra Buja

Università degli Studi di Padova

Giovedì 18 maggio 2017

ore 14.00

**Aula A - Istituto di Igiene
via Loredan 18 — Padova**

*Segreteria organizzativa ed informazioni:
Alessandra Buja - alessandra.buja@unipd.it
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Marco Zappa



ISTITUTO PER LO STUDIO
E LA PREVENZIONE ONCOLOGICA



**OSSERVATORIO
NAZIONALE
SCREENING**



UNIVERSITÀ
DEGLI STUDI
DI PADOVA



DIPARTIMENTO DI SCIENZE
CARDIOLOGICHE
TORACICHE E VASCOLARI

UNITÀ DI IGIENE E
SANITÀ PUBBLICA
LABORATORIO DI VALUTAZIONE
DEI SERVIZI SANITARI E DELLA
PROMOZIONE DELLA SALUTE

topics

- 1) State of Art in Italy of screening programs (extension and participation)
- 2) Evaluation of screening performances as tool for quality assurance
- 3) Evaluation of effectiveness (Impact)
- 4) What's next :
 - HPV as primary test in cervical screening
 - DBT in Mammographic screening ?
 - Lung cancer screening ?

The Italian Context

- ➔ Mammographic screening is a Basic Healthcare Parameter (LEA) since 2001
- ➔ Guidelines are provided by the Minister of Health - Department of Prevention in agreement with Regional Governments
- ➔ Change in protocol are suggested by experts committee nominated by Ministry of Health
- ➔ Regional Governments are responsible for organization, management and quality assurance of screening programmes
- ➔ Since 2004 the National Centre for Screening Monitoring (ONS) has been charged with monitoring and promoting screening programmes nationwide

1) Screening programs in Italy

Mammographic screening

- ➔ 50-69 (74) aa MX biennial, double view double reading
- ➔ 45-49 aa MX annual

Cervical Screening

- ➔ 25-29 aa Pap test every 3yrs
- ➔ 30-64 aa HPV every 5 5yrs

Colorectal Screening

- ➔ 50-69aa FIT biennial
- ➔ 58 aa sigmoidoscopy once in a lifetime + FIT for non compliers subjects (Piedmont)

Extension and compliance to invitation

Two sources ;

- ➔ Annual survey by National Center for Screening Monitoring (ONS)
- ➔ PASSI a telephon survey on preventive attitudes carried on annually on a stratified sample of Italian population

Did you have a preventive cervical test in your life time?

If yes: when did you have the last one ?

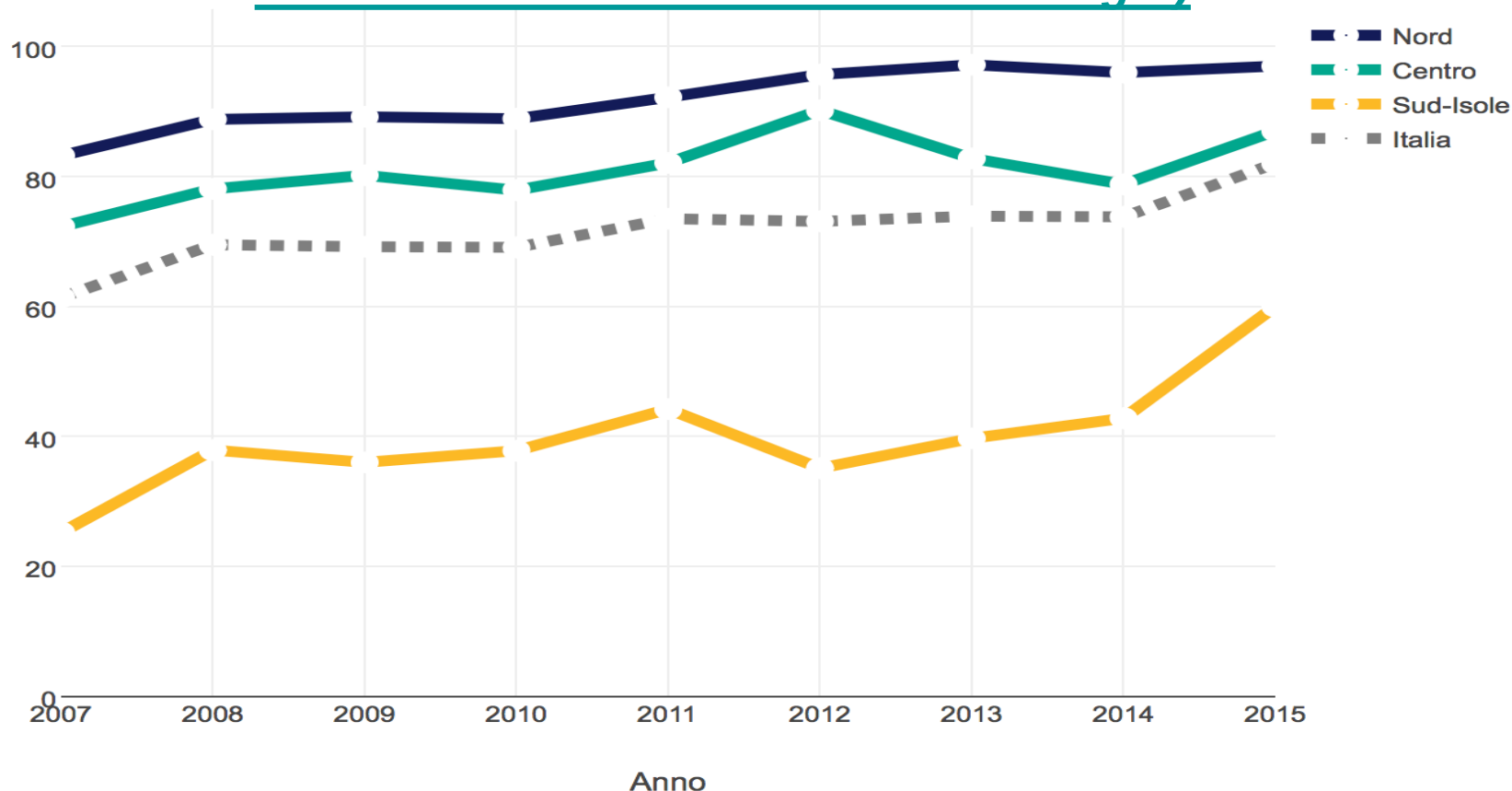
If yes: inside a screening programme (without any fee) or outside ?

Monitoring : Data Collection ONS survey

- Data come from every programme
- For every Region, a referent for data collection has been identified;
- Aggregated data collection by a structured questionnaire - referred to the previous year of activity
- A national datawarehouse based on individual record is on going

Extension of Mammographic screening by italian macro-areas survey ONS

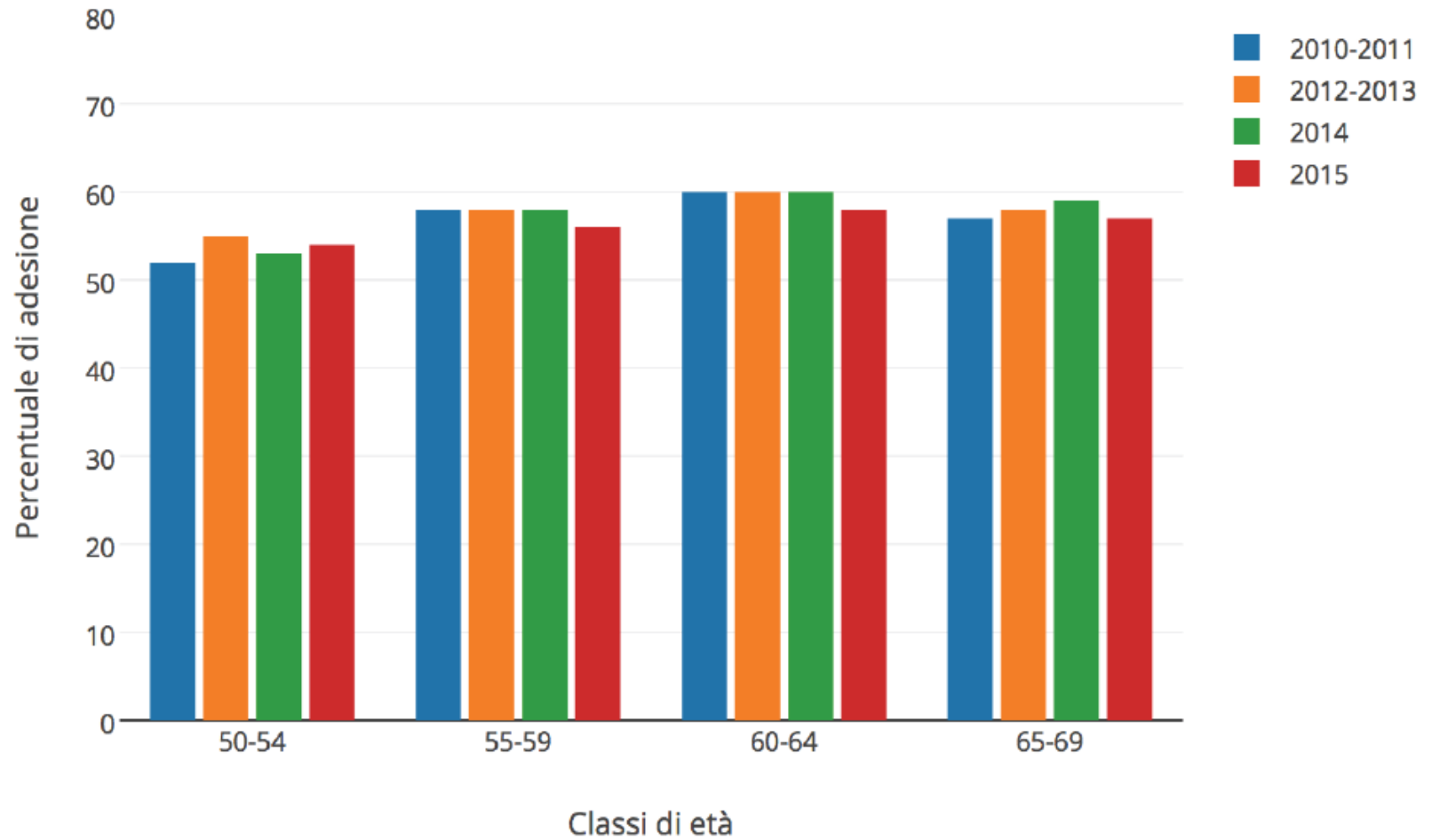
www.osservatorionazionale screening.it



% of women 50-69 yrs old regularly invited

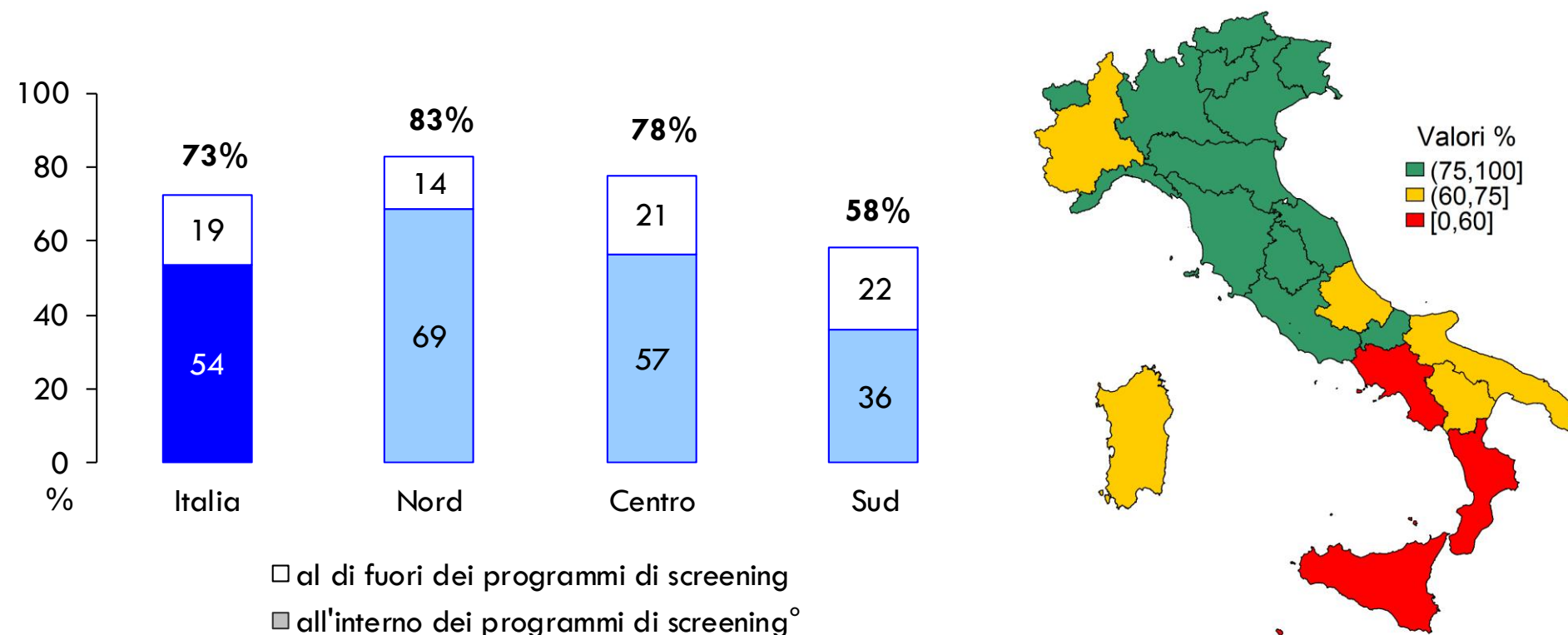
Mammographic screening

Compliance by age



survey PASSI 2014-2016

% of women aged 50-69 referring a MX in the last two years

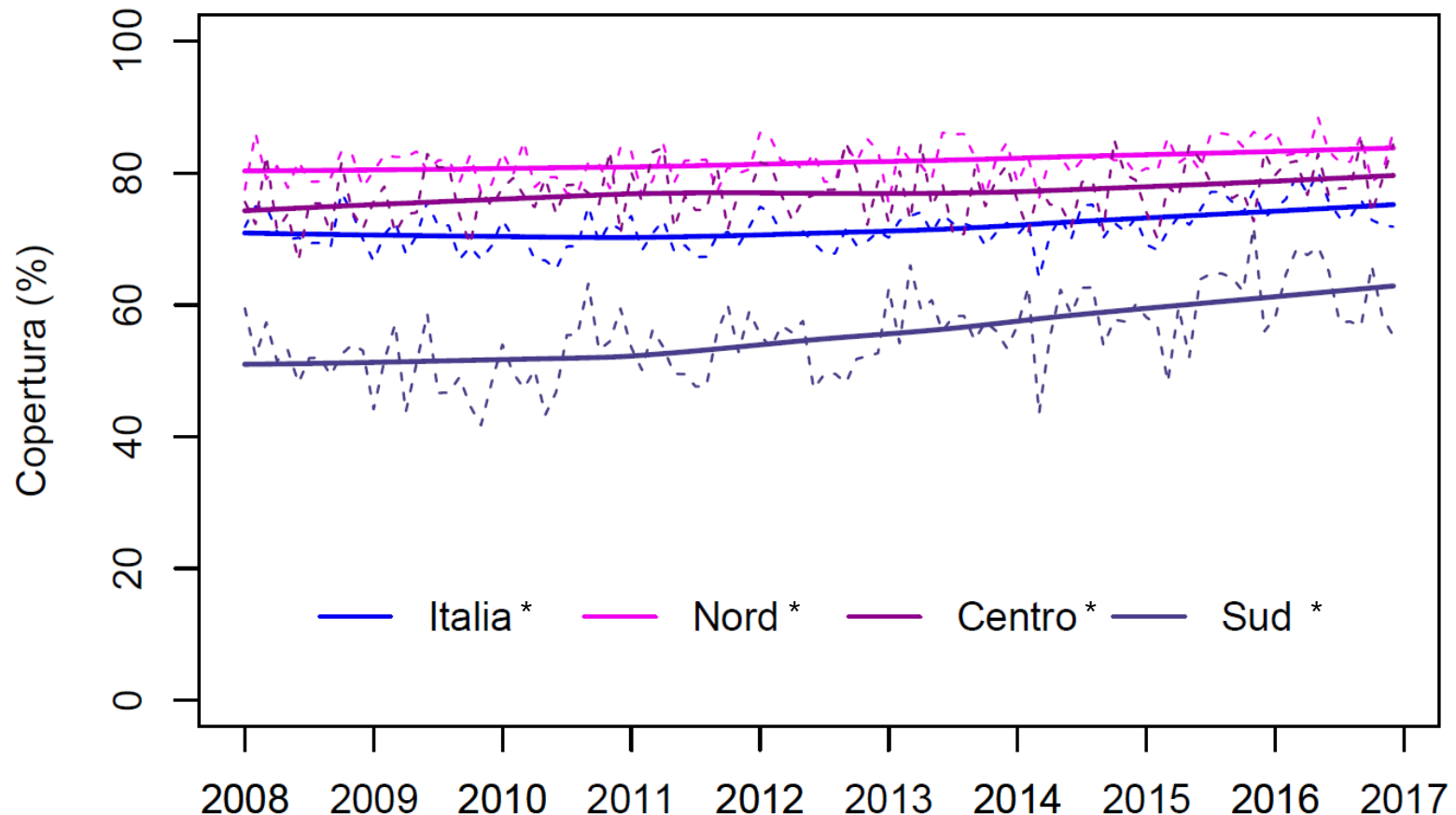


° Comprende anche altre offerte gratuite (ad esempio articolo 85 della legge 338/2000 - finanziaria 2001)

survey PASSI 2008-2016

% of women aged 50-69 referring a preventive MX in the last two years

Serie temporale (destagionalizzata)

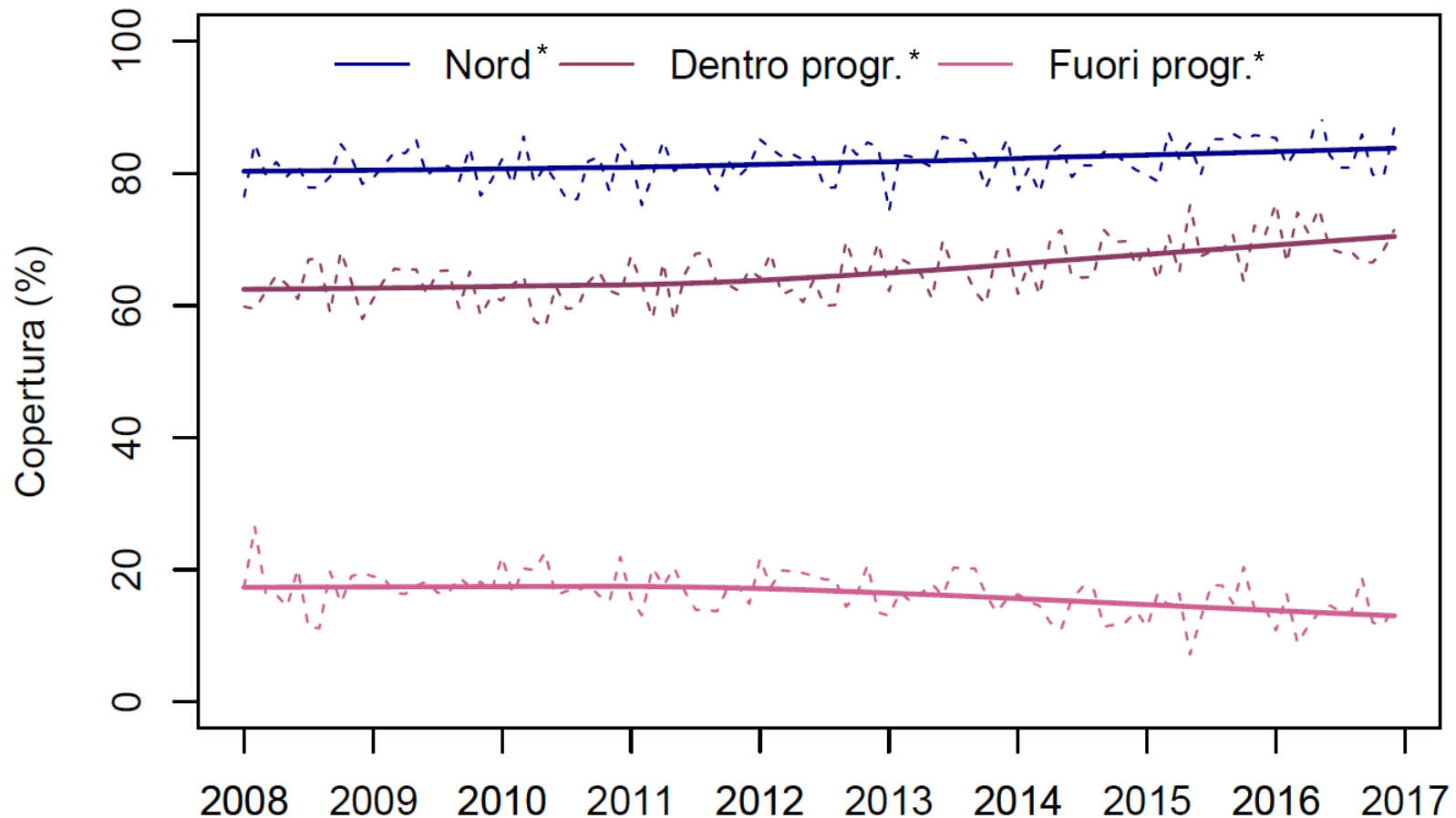


* $p\text{-value} < 0,05$

survey PASSI 2008-2016

% of women aged 50-69 referring a preventive MX in the last two years
(inside or outside screening programs) **Northern Italy**

Serie temporale (destagionalizzata) – Regioni del Nord

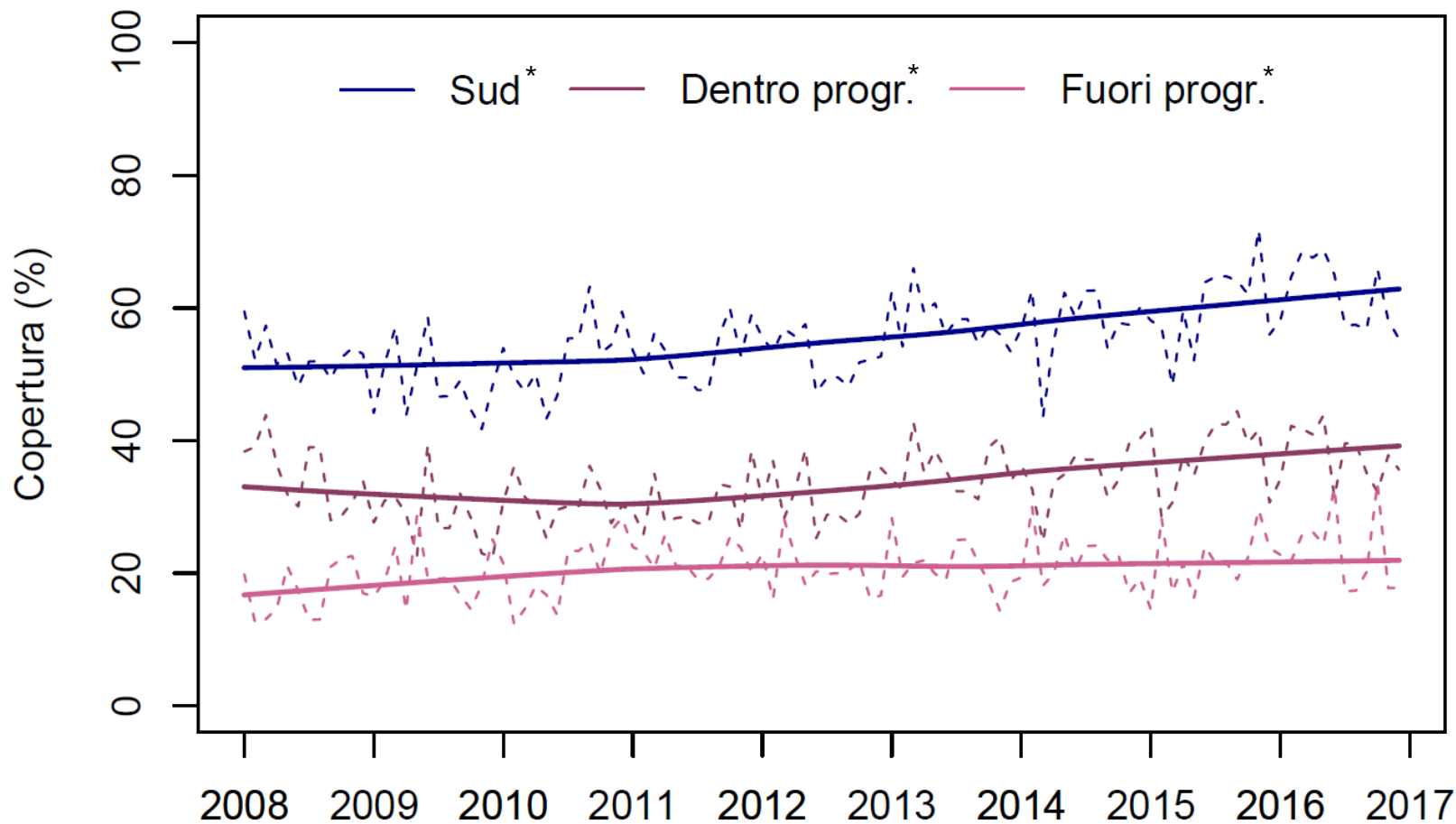


* $p\text{-value} < 0,05$

survey PASSI 2008-2016

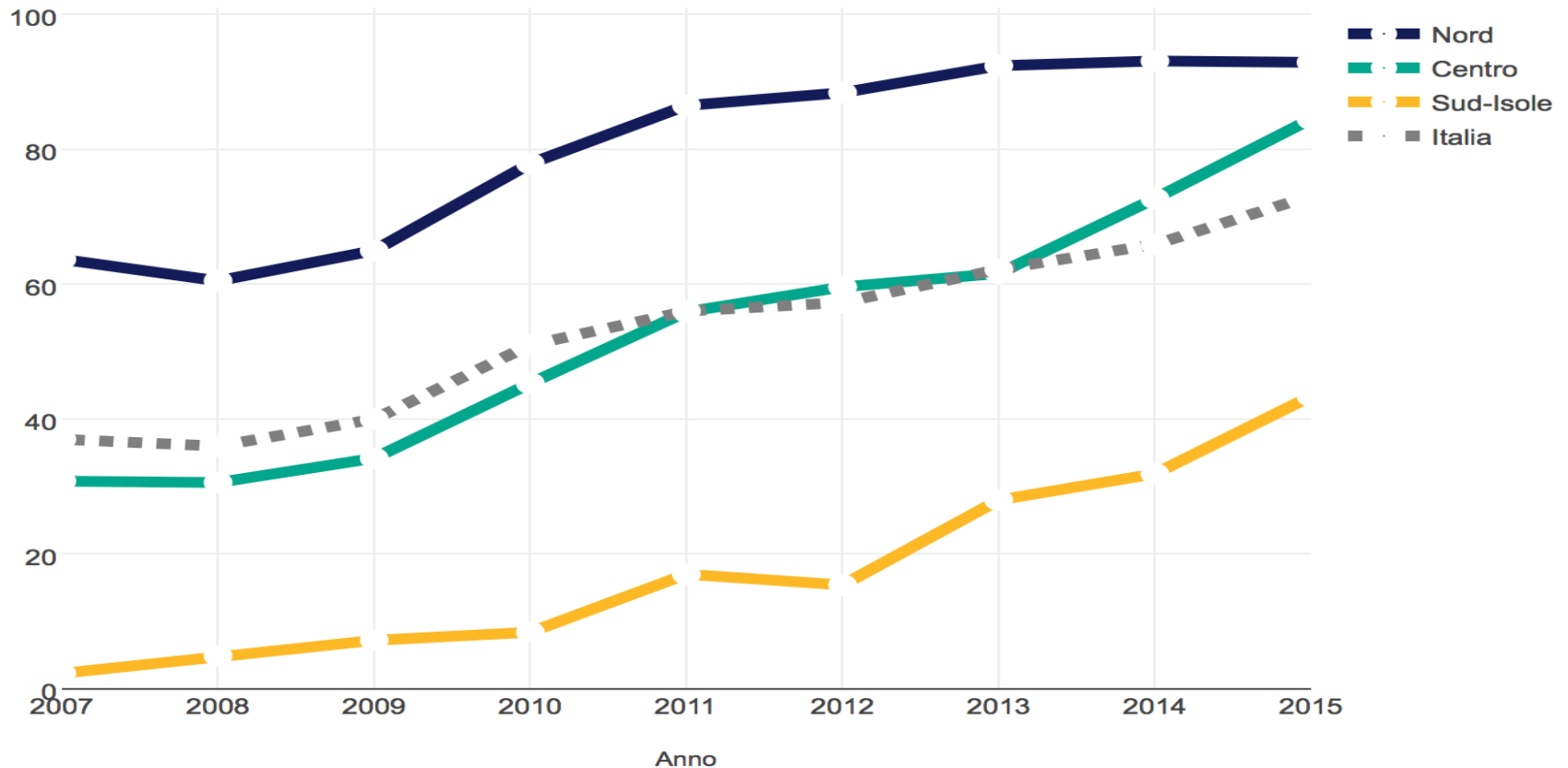
of women aged 50-69 referring a preventive MX in the last two years
(inside or outside screening programs) **Southern Italy**

Serie temporale (destagionalizzata) – Regioni del Sud



* $p\text{-value} < 0,05$

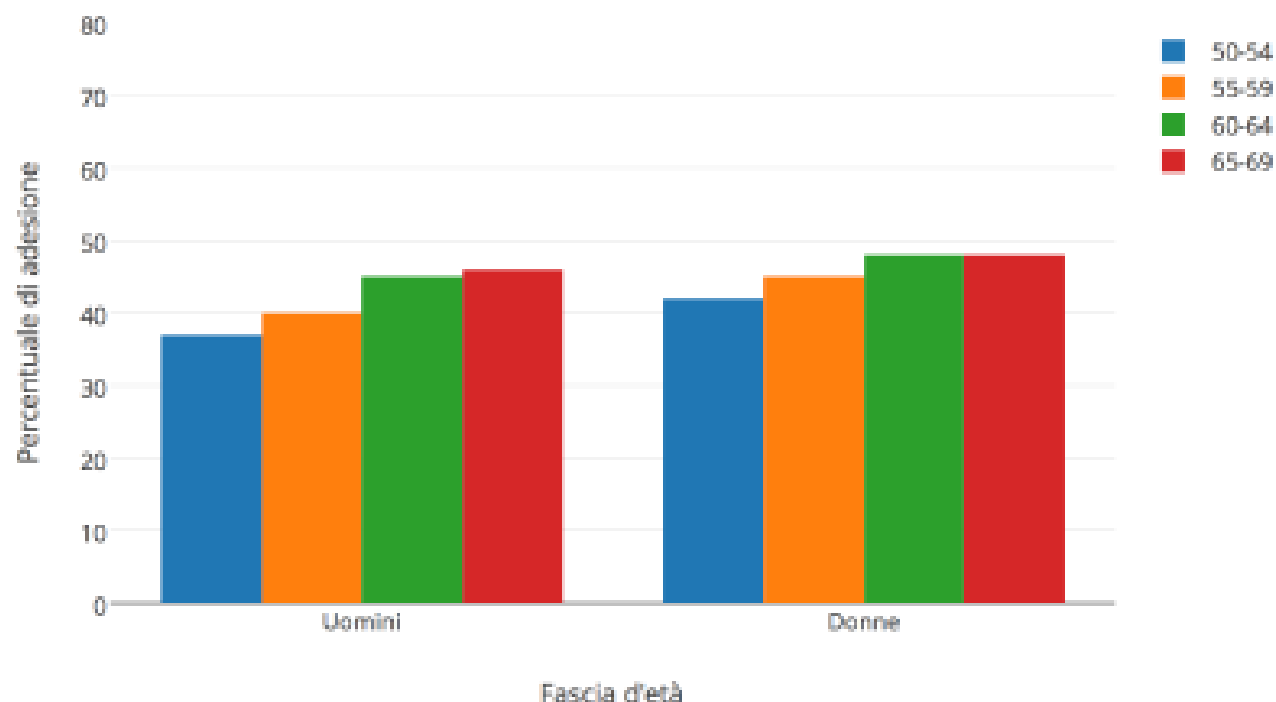
Extension of Colorectal screening by italian macro-areas survey ONS



% of subjects 50-69 yrs old regularly invited from 2006 to 2015)

Colorectal screening

Compliance by age - 2015 *survey ONS*

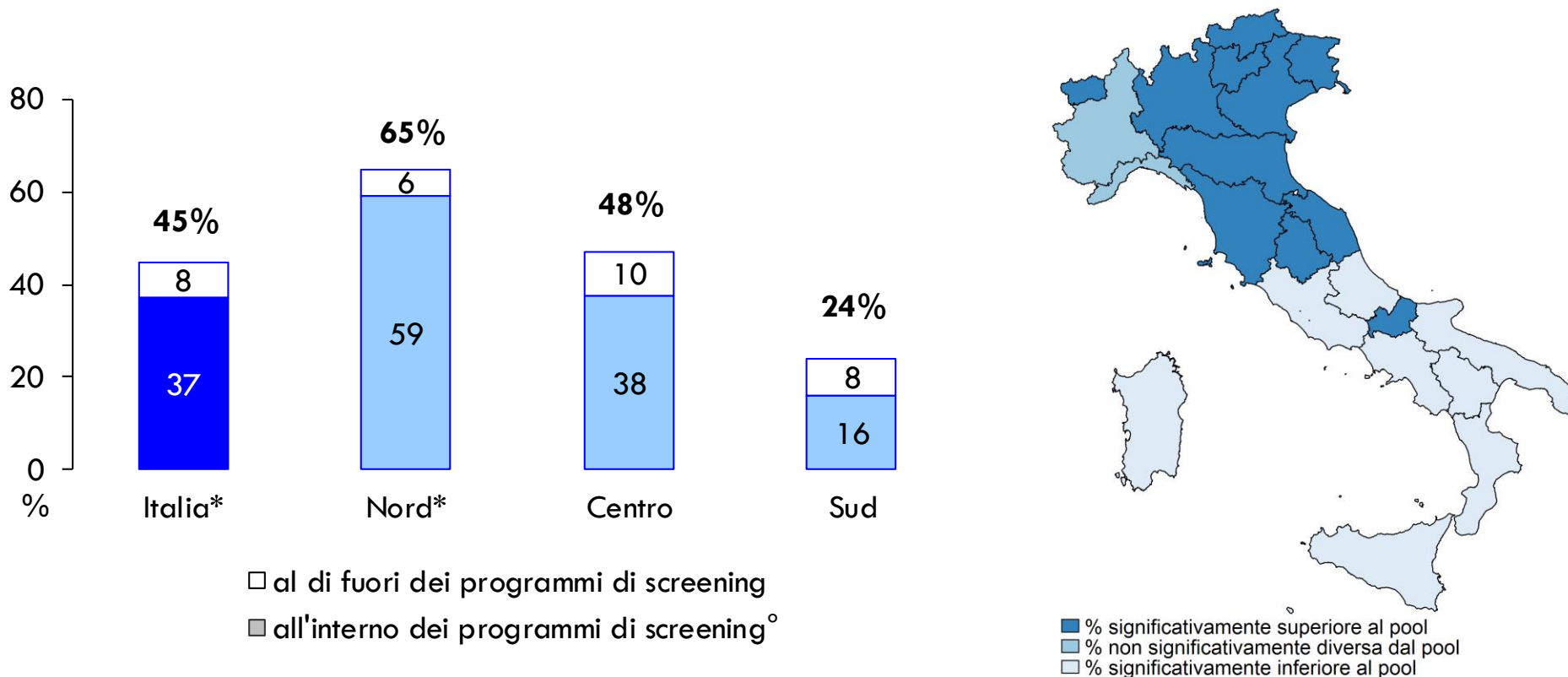


Adesione allo screening coloretale per fasce d'età



PASSI 2014-2016

% of subjects aged 50-69 referring a preventive colorectal test in recommended period



Sangue occulto preventiva entro gli ultimi due anni o colonscopia/rettosigmoidoscopia entro gli ultimi cinque anni

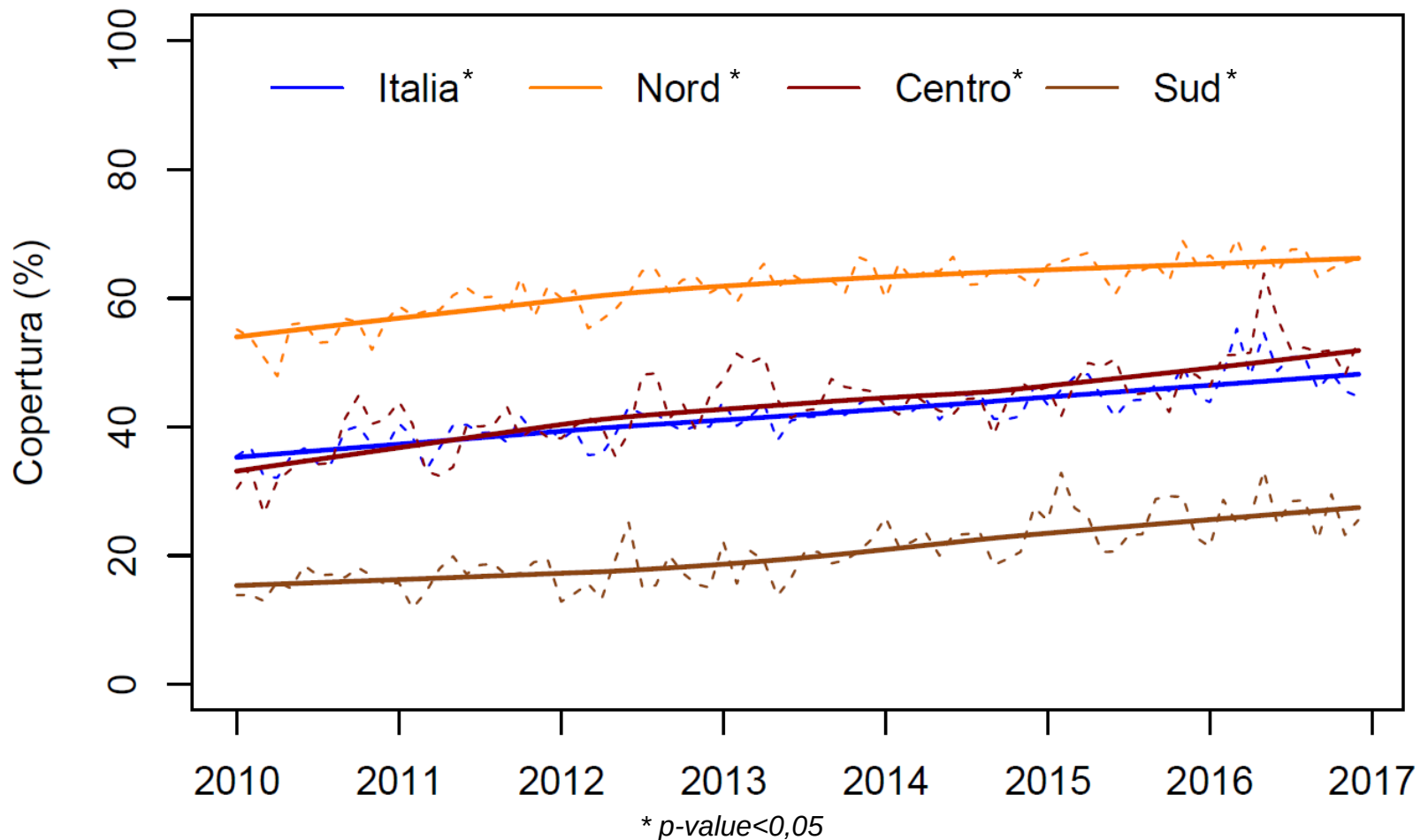
° Comprende anche altre offerte gratuite (ad esempio articolo 85 della legge 338/2000 - finanziaria 2001)

* Il dato relativo al Piemonte non è confrontabile con quello delle altre Regioni per le diverse modalità di organizzazione dello screening; per questo il Piemonte contribuisce al dato nazionale con un algoritmo dedicato che tiene conto del diverso protocollo di screening

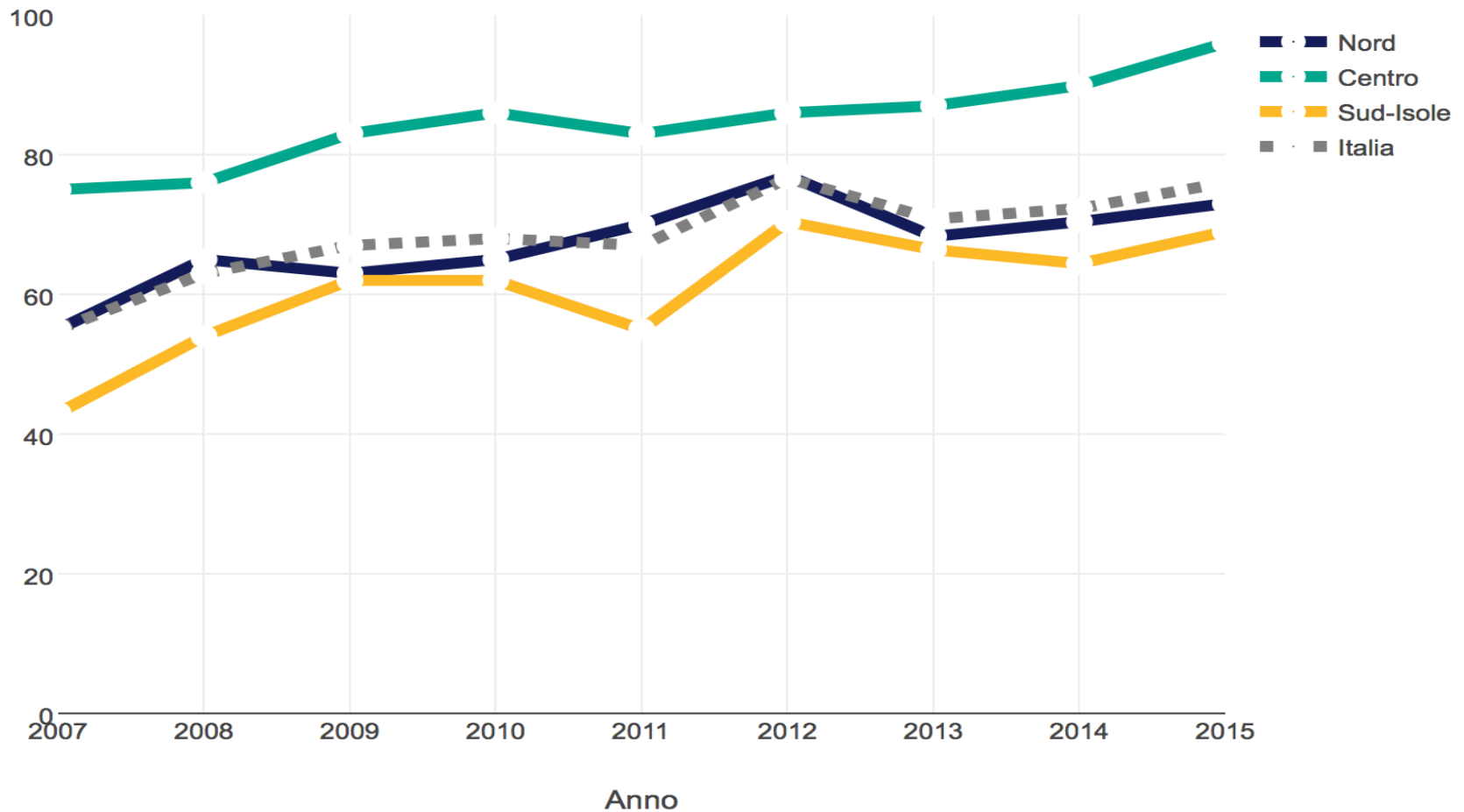
PASSI survey 2010-2016

of subjects aged 50-69 referring a preventive colorectal test in recommended period

Serie temporale (destagionalizzata)



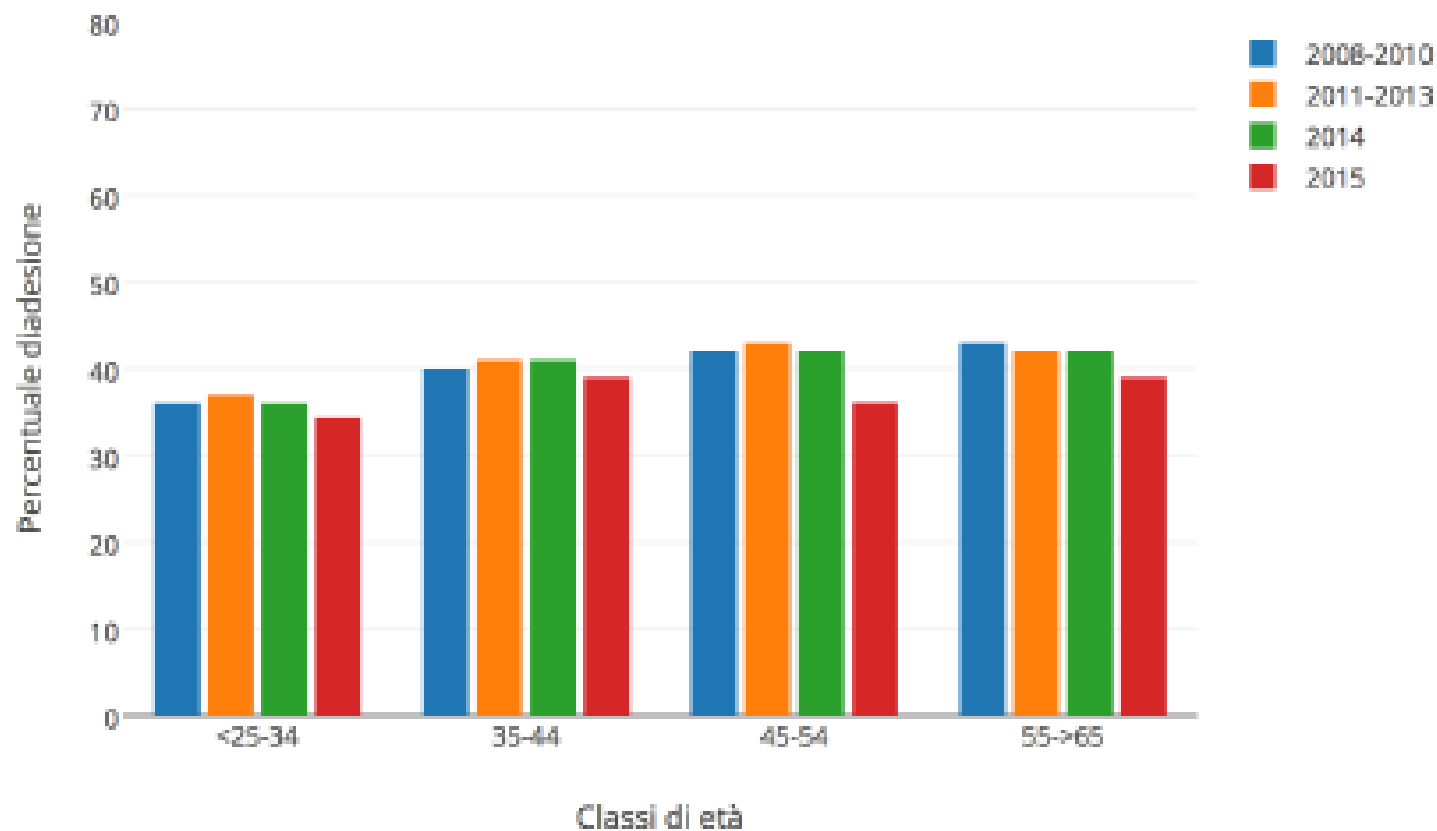
Extension of Cervical screening by macro-areas



% of women 25-64 yrs old regularly invited

Screening Cervical Screening

Compliance to invitation



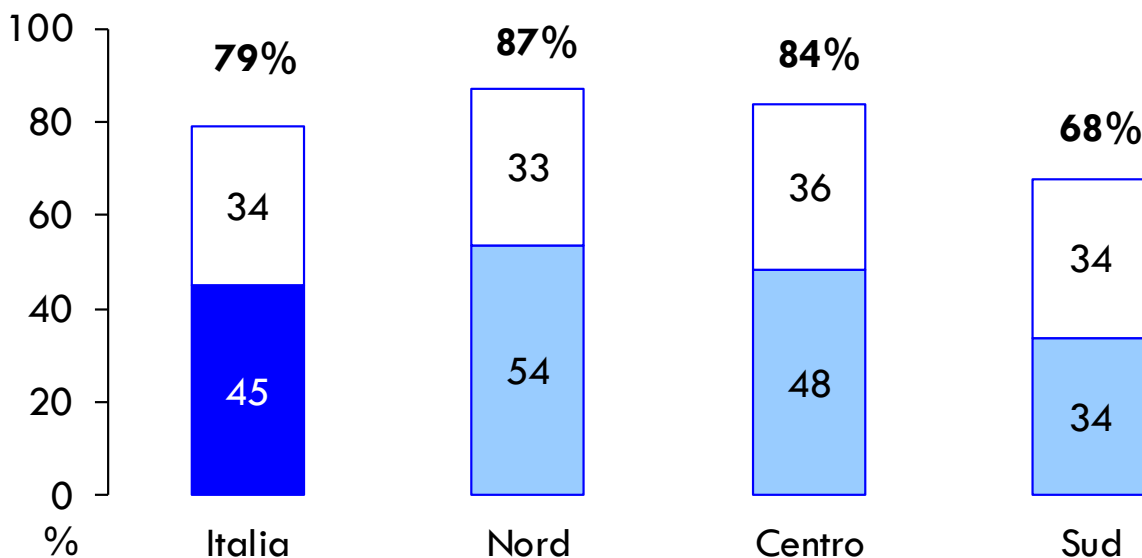
% of HPV DNA as primary test Survey ONS

% di donne invitate a screening con ricerca Hpv come test primario §			Adesione al test Hpv
2012	ITALIA	8,1%	42%
	Nord	9,3%	50,7%
	Centro	4%	36,4%
	Sud e Isole	9,2%	30,9%
2013	ITALIA	11,5%	42,3%
	Nord	9,8%	50,7%
	Centro	13,4%	40,3%
	Sud e Isole	12,4%	34,4%
2014	ITALIA	13,1%	47,2%
	Nord	11,3%	49,3%
	Centro	18,8%	45,8%
	Sud e Isole	11,1%	46,4%
2015	ITALIA	16%	50,1%
	Nord	17,6%	52,6%
	Centro	20,4%	51,2%
	Sud e Isole	10,2%	42,3%

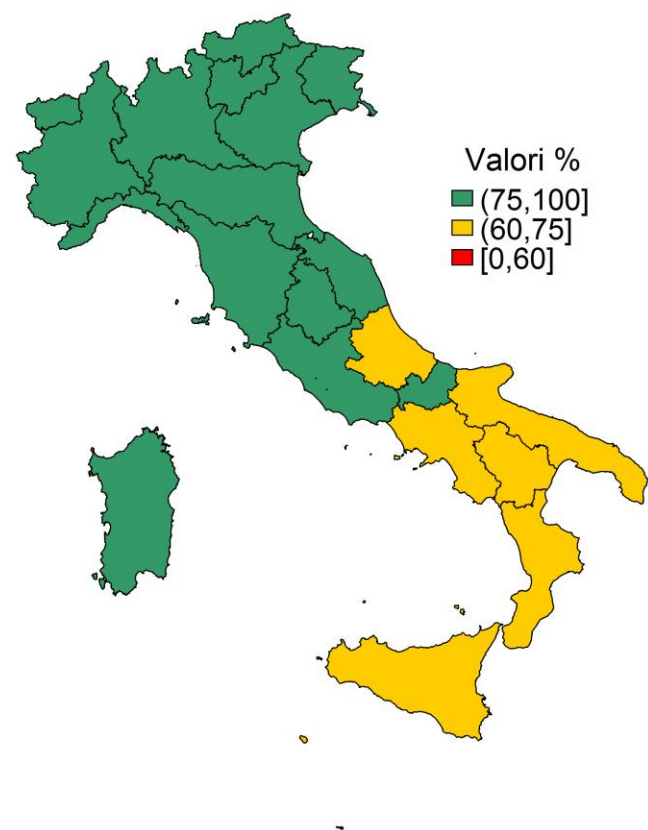
§ tra tutte le invitate a screening cervicale.

PASSI 2014-2016

% of women aged 25-64 referring a preventive cervical test in the recommended period



□ al di fuori dei programmi di screening
■ all'interno dei programmi di screening°

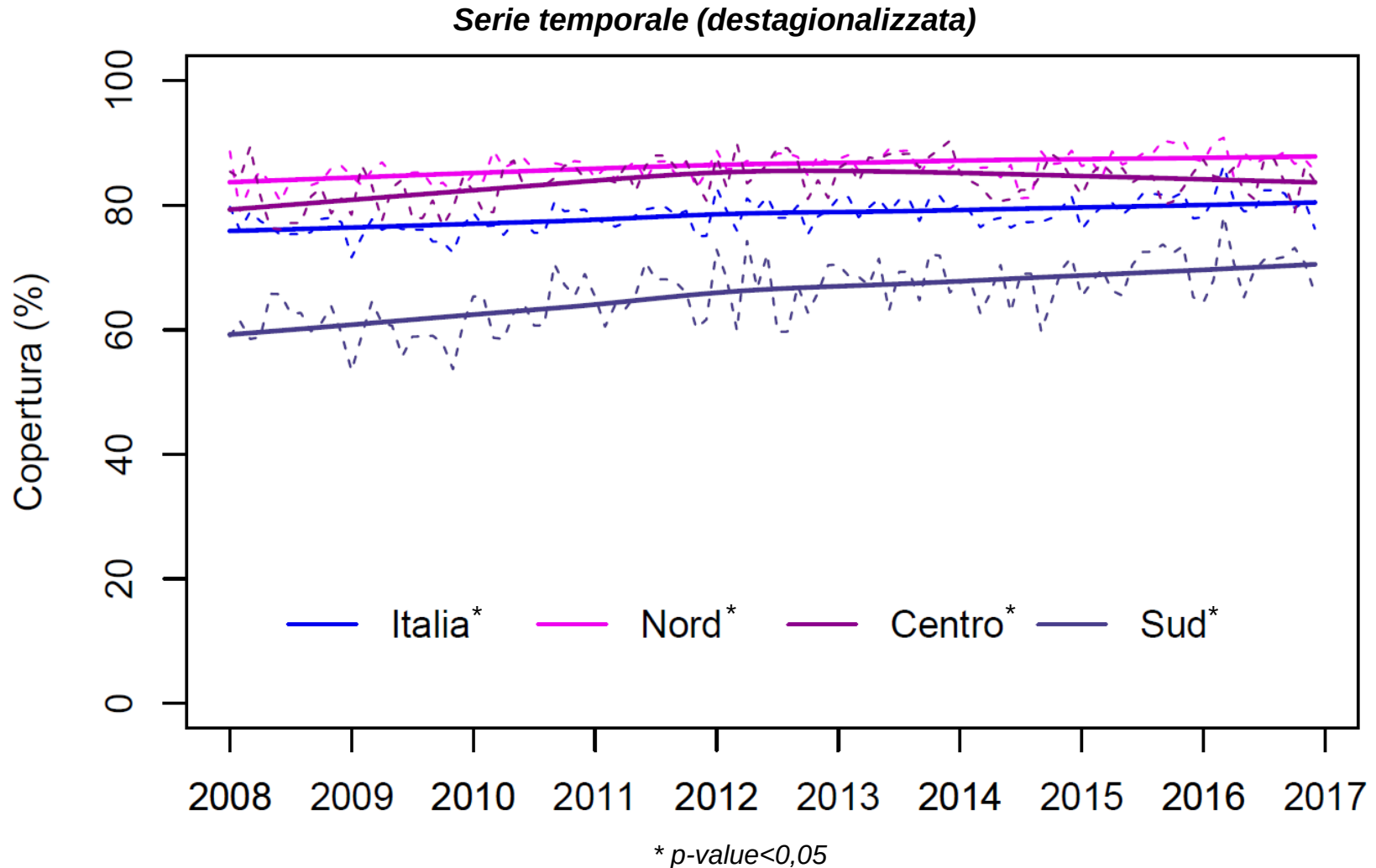


* Pap test o HPV test entro i tempi raccomandati

° Comprende anche altre offerte gratuite (ad esempio articolo 85 della legge 338/2000 - finanziaria 2001)

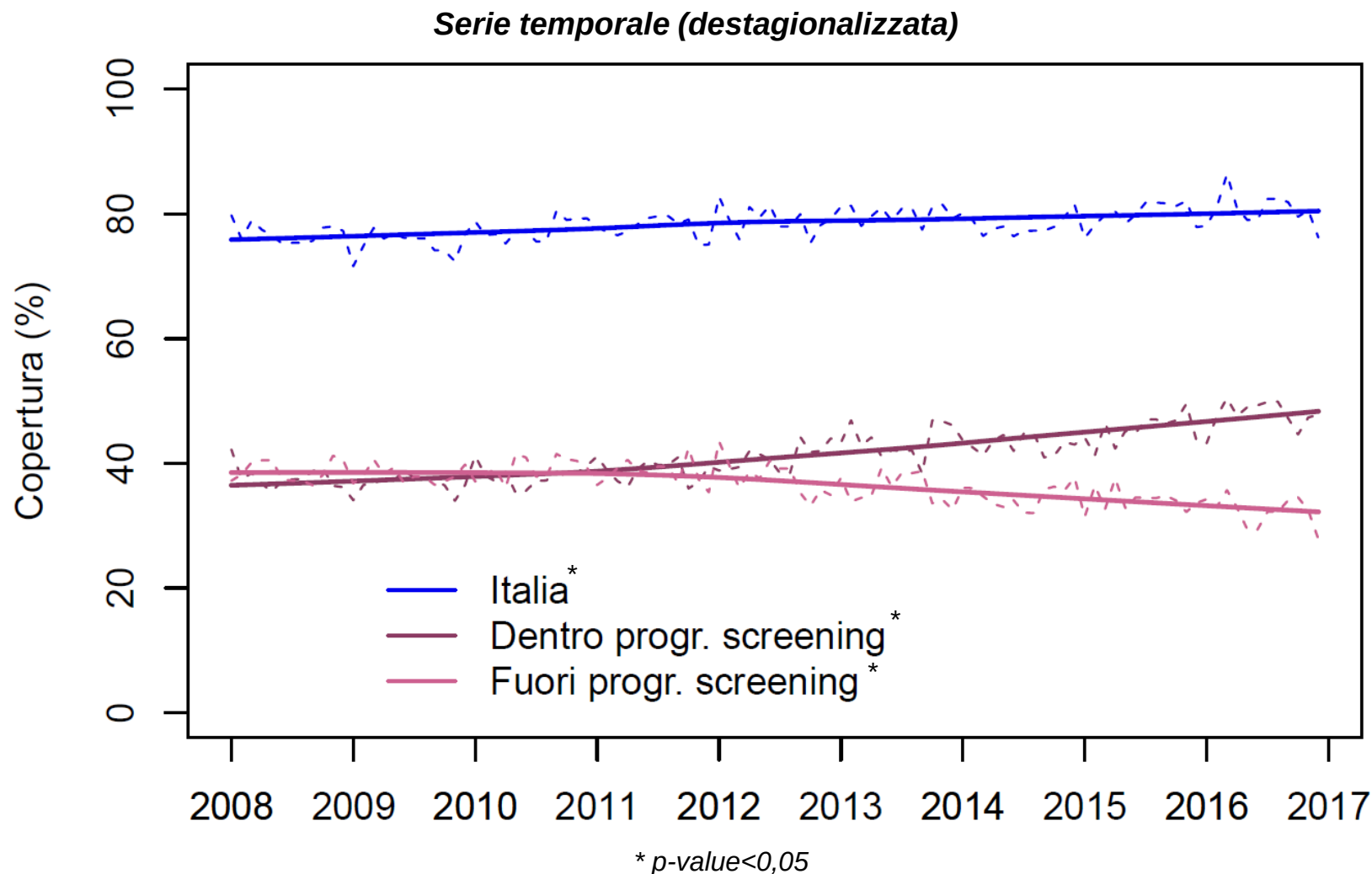
Survey PASSI 2008-2016

% of women aged 25-64 referring a preventive cervical test in the recommended period



Survey PASSI 2008-2016

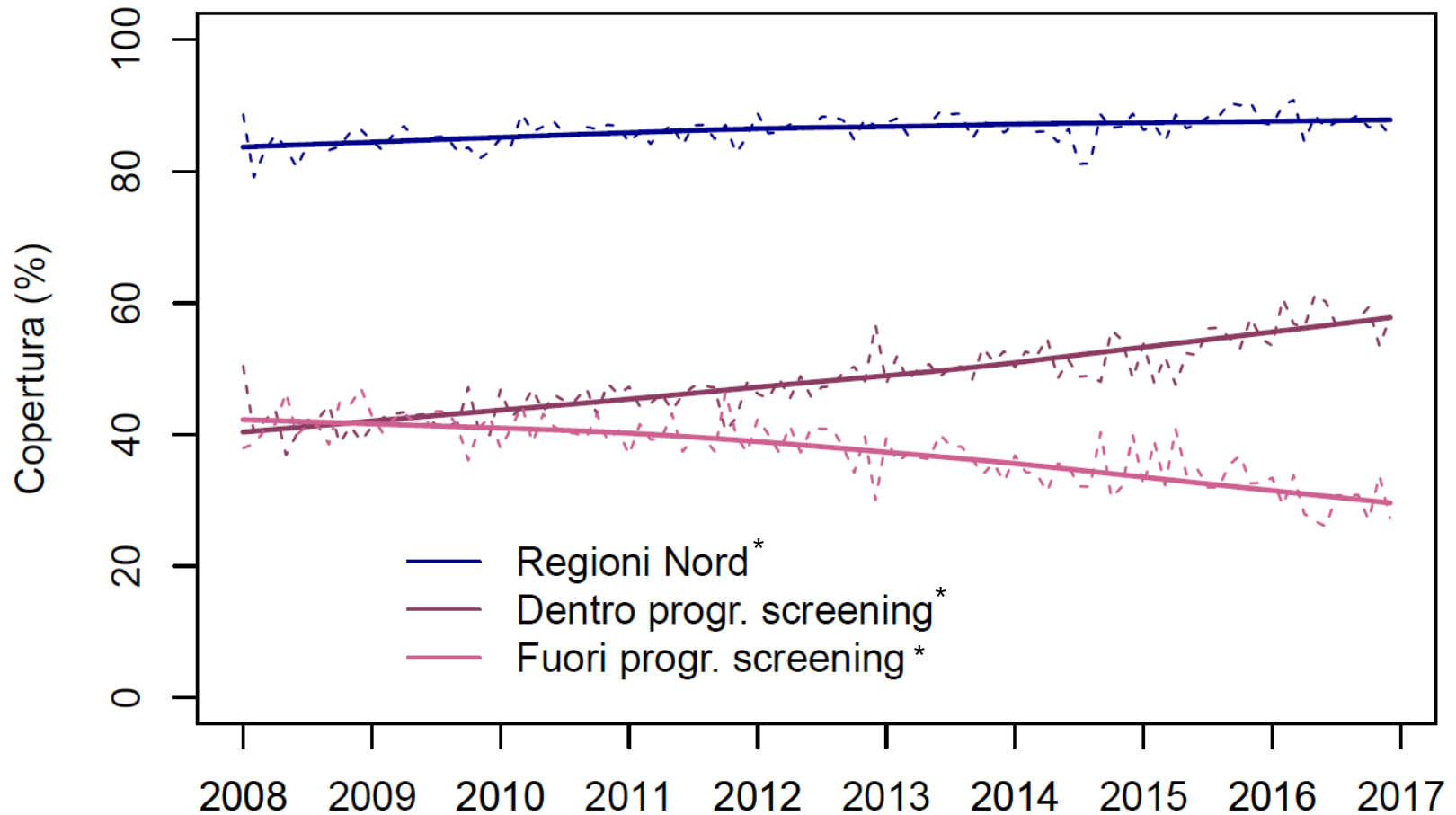
% of women aged 25-64 referring a preventive colorectal test in recommended period inside or outside the screening programme



PASSI 2008-2016

% of women aged 25-64 referring a preventive test for cervical cancer in the recommended period **Northern Italy**

Serie temporale (destagionalizzata) – Regioni del Nord

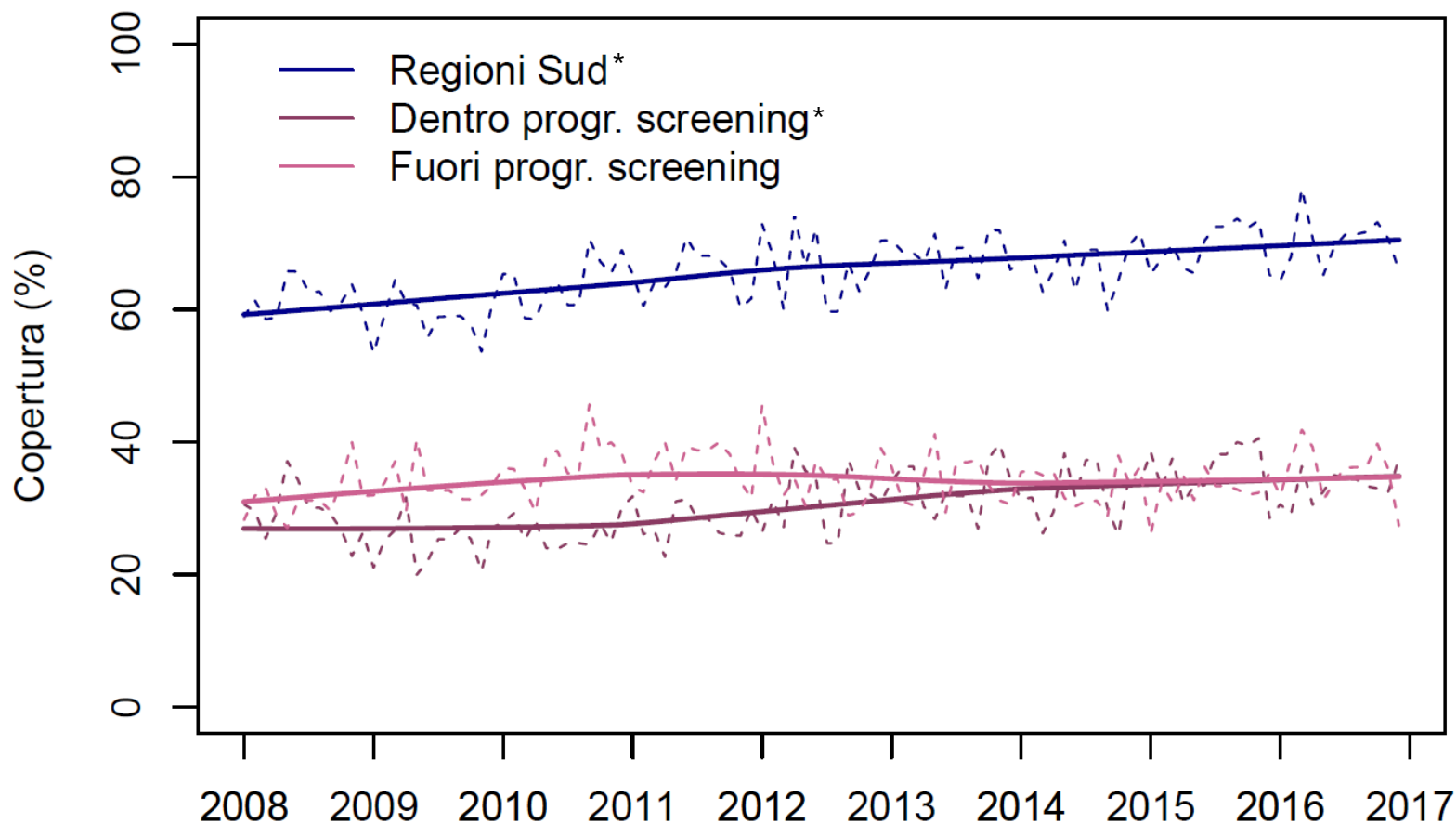


* $p\text{-value} < 0,05$

Survey PASSI 2008-2016

% of women aged 25-64 referring a preventive test for cervical cancer in the recommended period **Southern Italy**

Serie temporale (destagionalizzata) – Regioni del Sud



* $p\text{-value} < 0,05$

2) Monitoring for quality assurance

- A screening programme should guarantee a path not only a test
- ➔ Each step should be monitored and evaluated
- ➔ The National center for Screening monitoring (ONS) has been charged by ministry of Health of certifying and evaluating the performances of screening programmes

mammographic screening

Dati nazionali di attività di screening mammografico 2010-2015

	2010-2011	2012-2013	2014	2015
Numero totale di donne invitate	5.150.652	5.312.947	2.778.387	3.162.602
Numero di donne aderenti all'invito (% su donne invitate)	2.842.013 (55%)	3.044.984 (57%)	1.577.666 (57%)	1.728.339 (55%)
Media aderenti per anno	1.421.007	1.522.492		
Numero di donne esaminate*	2.772.433	2.975.296	1.565.430	
Numero di donne richiamate per approfondimenti (% su donne esaminate)	149.936 (5,4%)	172.377 (5,8%)	91.494 (5,8%)	
Numero di biopsie benigne	1.722	1.582	896	
Numero di carcinomi diagnosticati allo screening	12.392	13.511	7.383	
Numero di carcinomi duttali in situ diagnosticati allo screening	1.499	1.751	1.001	
Numero di carcinomi invasivi ≤ 10 mm diagnosticati allo screening	3.715	4.137	2.158	

*La differenza fra aderenti ed esaminate deriva dal fatto che in alcuni rari casi i programmi non hanno riportato le informazioni sulle performance diagnostiche.

Certification

- National Health Care Parameter (LEA)
- *Number of people examined as a consequence of a screening invitation*

Target annual eligible population

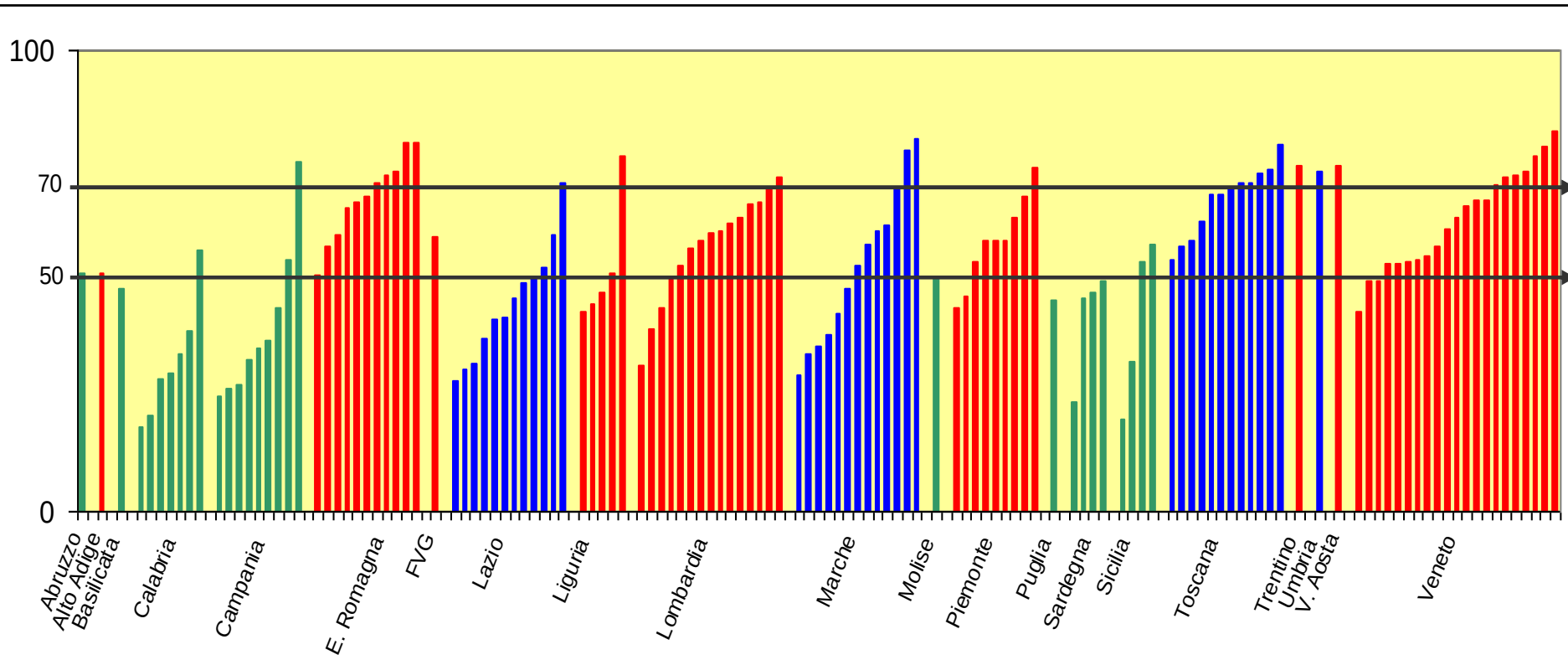
➔ *Quality and timeliness of information are also evaluated*

Cervice									
REGIONE	2009	score	2010	score	2011	score	2012	score	
Abruzzo	13,0%	1	17,1%	1	9,2%	1	38,1%	3	Abruzzo
Valle d'Aosta	57,2%	5	65,4%	5	61,9%	5	51,4%	5	Valle d'Aosta
Basilicata	58,1%	5	61,6%	5	41,6%	3	33,8%	3	Basilicata
Prov. Aut. Bolzano	0,0%	0	0,0%	1	30,3%	3	33,3%	3	Bolzano
Calabria	18,5%	1	17,3%	1	15,8%	1	16,5%	1	Calabria
Campania	15,6%	1	12,7%	1	12,8%	1	13,1%	1	Campania
Emilia Romagna	56,0%	5	57,0%	5	64,3%	5	62,2%	5	Emilia Romagna
Friuli Venezia Giulia	46,3%	3	44,3%	3	58,5%	5	61,5%	5	Friuli Venezia Giulia
Lazio	17,7%	1	16,8%	1	17,3%	1	17,3%	1	Lazio
Liguria	0,0%	0	0,0%	0	1,2%	0	8,0%	1	Liguria
Lombardia	10,8%	1	11,4%	1	10,4%	1	12,2%	1	Lombardia
Marche	40,3%	3	34,1%	3	41,5%	3	39,0%	3	Marche
Molise	19,7%	1	14,5%	1	9,2%	1	13,0%	1	Molise
Piemonte	41,8%	3	40,3%	3	43,2%	3	43,6%	3	Piemonte
Puglia	15,3%	1	15,8%	1	12,6%	1	16,2%	1	Puglia
Sardegna	22,7%	1	23,0%	1	29,5%	3	27,6%	3	Sardegna
Sicilia	5,2%	1	13,1%	1	14,5%	1	18,1%	1	Sicilia
Toscana	42,5%	3	46,7%	3	50,3%	5	54,1%	5	Toscana
Prov. Aut. Trento	43,0%	3	36,3%	3	51,3%	5	61,7%	5	Trentino
Umbria	47,7%	3	41,5%	3	42,9%	3	66,3%	5	Umbria
Veneto	36,3%	3	39,8%	3	57,4%	5	71,6%	5	Veneto

Quality assurance

- The evaluation of ons survey is based on
 - benchmarking
 - indicators
- We are able to identify outlier parameters between Regions and within each Region

Mammographic screening: compliance to invitation between Regions and within each Region.



Compliance to colonoscopy (%) and cecum intubation in FIT positive subjects Tuscany - 2010

Programmi	SOF +	N. colonscopie	N. colonscopie complete	% adesione colonscopia [§]	% colonscopie complete
Massa e Carrara	1.171	1.013	967	86,5	95,5
Lucca	391	331	312	84,7	94,3
Pistoia	114	104	101	91,2	97,1
Prato	537	444	430	82,7	96,8
Pisa	991	543	419	54,8	77,2
Livorno	964	780	730	80,9	93,6
Siena	802	688	653	85,8	94,9
Arezzo	913	700	651	76,7	93,0
Grosseto	589	444	414	75,4 (81,5)	93,2
Firenze	1.603	1.175	1.089	73,3	92,7
Empoli	643	562	555	87,4	98,8
Viareggio	298	237	231	79,5	97,5
Regione Toscana	9.016	7.021	6.552	77,9	93,3

Complete colonoscopy stratified for each reference endoscopic unit. Florentine District, 2006-2010

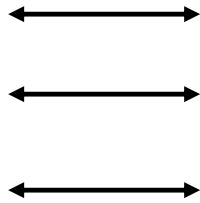
	2006	2007	2008	2009	2010	totale
Endoscopic unit	%	%	%	%	%	%
A	94.0	97.5	97.6	97.8	97.6	96.8
B	92.4	94.6	93.1	93.6	96.1	94.0
C	86.7	87.4	95.6	89.4	91.6	89.8
D	36.2	68.6	57.6	54.1	72.0	57.2
E	100.0	94.1	92.3	100.0	100.0	97.1
F	100.0	96.6	97.2	95.2	99.1	97.2
G	90.4	92.9	100.0	87.5	64.3	88.4
H	86.8	97.4	94.1	89.7	91.5	92.0
Totale**	90.5	94.7	93.6	93.5	94.9	93.4

*prima o seconda colonscopie complete

3) Evaluation of Effectiveness (Impact)

- To evaluate the impact of screening program on the entire population not only on screened subjects

**Cancer
Registry**



**Screening
archives
SCREENING
(invitations,
exams)**

By linkage with screening archive all cases are classified according to modality of diagnosis:

- screen-
detected*
- 1) Screen detected at first test
 - 2) Screen detected at repeat screening
 - 3) Cancer occurred after a negative test
 - 4) Cancer occurred in subject invited but not attending
 - 5) Cancer in subject not yet invited
- Includes
Interval cancers*

Design and methods

- Comparisons of area with different start of the program
- Comparison of trend pre vs post the start of the program
- Comparison of attenders Vs not attenders
- Incidence based mortality
- Case control studies
-

Mammographic Screening

Evaluated the impact on

- Specific mortality
- Overdiagnosis
- Rate of Conservative treatment
-

→ Euroscreening working group
(JMS J Med Screen. 2012;19 Suppl 1)

The impact of mammographic screening on breast cancer mortality in Europe: a review of observational studies

Mireille Broeders, Sue Moss, Lennarth Nyström, Sisse Njor, Håkan Jonsson, Ellen Paap, Nathalie Massat, Stephen Duffy, Elsebeth Lynge and Eugenio Paci, for the EUROSCREEN Working Group

J Med Screen 2012;19 Suppl 1:14–25
DOI: 10.1258/jms.2012.012078

See end of article for authors' affiliations

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Accepted for publication
14 June 2012

Objectives To assess the impact of population-based mammographic screening on breast cancer mortality in Europe, considering different methodologies and limitations of the data.

Methods We conducted a systematic literature review of European trend studies ($n = 17$), incidence-based mortality (IBM) studies ($n = 20$) and case-control (CC) studies ($n = 8$). Estimates of the reduction in breast cancer mortality for women invited versus not invited and/or for women screened versus not screened were obtained. The results of IBM studies and CC studies were each pooled using a random effects meta-analysis.

Results Twelve of the 17 trend studies quantified the impact of population-based screening on breast cancer mortality. The estimated breast cancer mortality reductions ranged from 1% to 9% per year in studies reporting an annual percentage change, and from 28% to 36% in those comparing post- and prescreening periods. In the IBM studies, the pooled mortality reduction was 25% (relative risk [RR] 0.75, 95% confidence interval [CI] 0.69–0.81) among invited women and 38% (RR 0.62, 95% CI 0.56–0.69) among those actually screened. The corresponding pooled estimates from the CC studies were 31% (odds ratio [OR] 0.69, 95% CI 0.57–0.83), and 48% (OR 0.52, 95% CI 0.42–0.65) adjusted for self-selection.

Conclusions Valid observational designs are those where sufficient longitudinal individual data are available, directly linking a woman's screening history to her cause of death. From such studies, the best 'European' estimate of breast cancer mortality reduction is 25–31% for women invited for screening, and 38–48% for women actually screened. Much of the current controversy on breast cancer screening is due to the use of inappropriate methodological approaches that are unable to capture the true effect of mammographic screening.



Original Research

Advanced breast cancer rates in the epoch of service screening: The 400,000 women cohort study from Italy



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Susanna Baracco ^c, Cinzia Campani ^{d,e}, Debora Canuti ^f, Claudia Cirilli ^g,
Natalina Collina ^b, Giovanni Maria Conti ⁱ, Enza Di Felice ^{d,e},
Fabio Falcini ^f, Maria Michiara ^j, Rossella Negri ^k, Alessandra Ravaioli ^b,
Priscilla Sassoli de' Bianchi ^l, Monica Serafini ⁱ, Manuel Zorzi ^c,
Adele Caldarella ^a, Luigi Cataliotti ^m, Marco Zappa ^{a,*}, IMPACT
COHORT Working Group¹

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^k Mammography Screening Center, Local Health Unit, Modena 41124, Italy

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Received 4 October 2016; received in revised form 7 December 2016; accepted 20 December 2016

Table 3

Observed and expected breast cancer cases (total invasive and T2+) among attenders and non-attenders to mammography screening in central and northern Italy.

Screening exposure	Stage	No. BC cases		O/E (95% CI)
		Observed (O)	Expected (E)	
Attenders	All invasive	9609	8146	1.18 (1.16–1.20)
	T2 or larger	1970	2852	→ 0.69 (0.66–0.72)
Non-attenders	All invasive	4203	3804	1.11 (1.07–1.14)
	T2 or larger	1539	1365	1.13 (1.07–1.19)
Invited (attenders + non-attenders)	All invasive	13,812	11,950	1.16 (1.14–1.18)
	T2 or larger	3509	4217	→ 0.83 (0.80–0.86)

Colorectal screening

Evaluated the impact of colorectal screening on

- Specific mortality
- Incidence
- Stage shift

ORIGINAL ARTICLE

Impact on colorectal cancer mortality of screening programmes based on the faecal immunochemical test

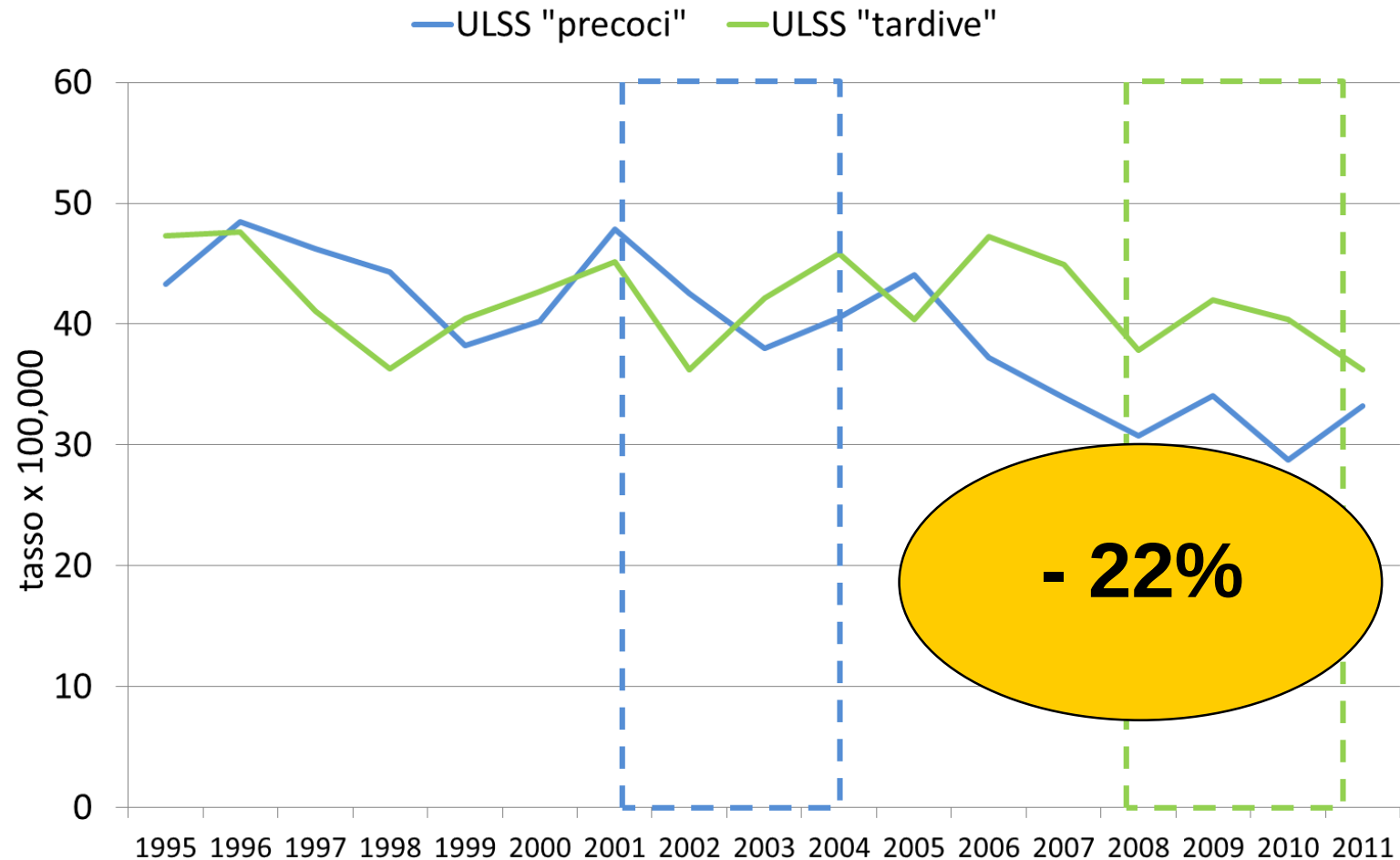


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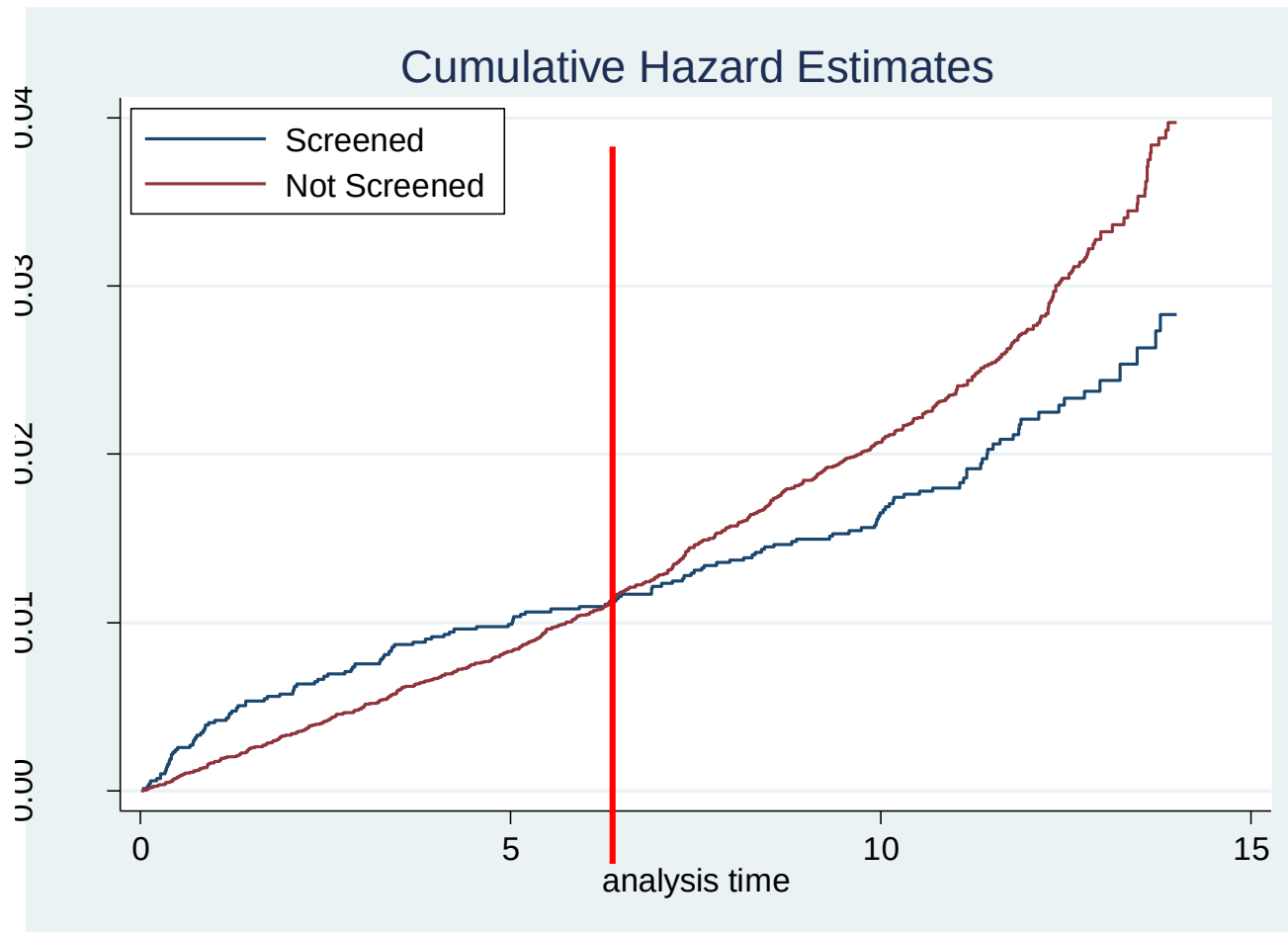
To cite: Zorzi M, Fedeli U, Schievano E, et al. *Gut* 2015;**64**:784–790.

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Standardized mortality rates from colorectal cancer in “early” and “late” ULSS



Cumulative risk of colorectal Cancers (screened vs not screened)



- Coorte degli screenati: 141 cancro, 78023 person-years, FUP medio 11.2 anni.
- Coorte dei non screenati: 661 cancro, 285945 person-years, FUP medio 10.6 anni.

Screening cervicale

- Evaluated the impact on
- Incidence
- Stage shift
- Istological type



Contents lists available at ScienceDirect

Preventive Medicine

journal homepage: www.elsevier.com/locate/ypmed

Changes in cervical cancer incidence following the introduction of organized screening in Italy



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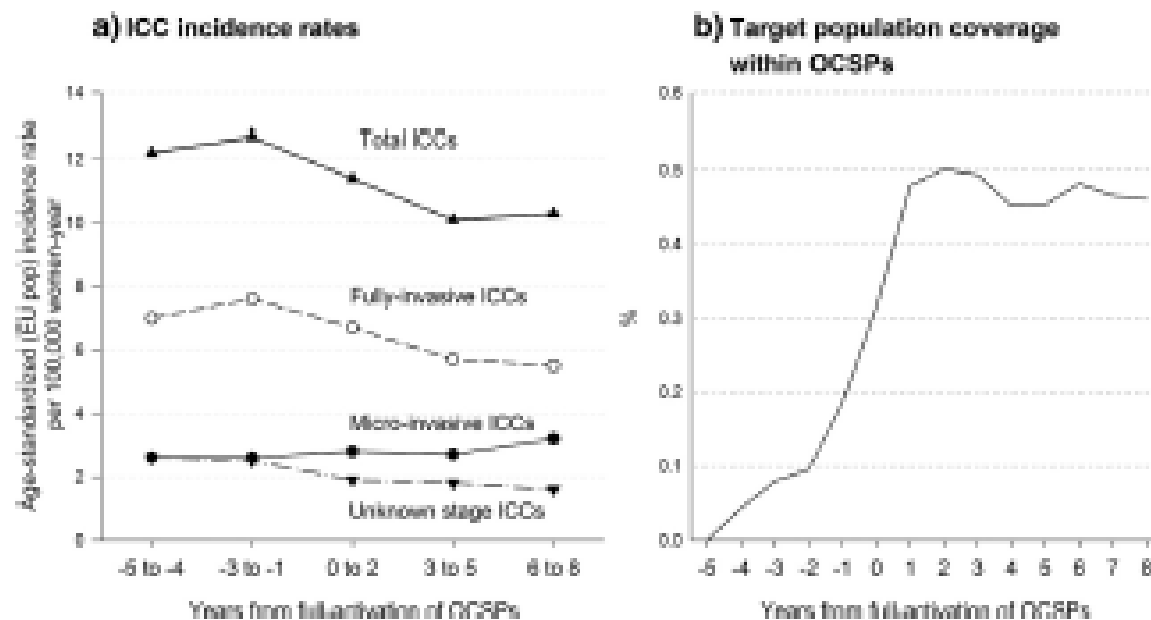


Fig. 1. (a) Invasive cervical cancer (ICC) age-standardized (European pop.) incidence rates (per 100,000 women-year) by stage at diagnosis and (b) proportion (%) of target women (25–49 years) having had a Pap smear within organized cervical screening programs (OCSPs) in the previous 3 years in the study area, according to years from full activation of OCSPs, Italy, women aged 25–49 years, 1995–2008. *Calendar year during which at least 40% of target women had been invited to OCSPs.

4) What 's the next

- HPV as primary test in cervical screening
- DBT in Mammographic screening ?
-
- Lung cancer screening ?

HPV 2015-2016 Italy

- ➔ The National Preventive Plan of Prevention :
“Within 2018 all the screening programmes have to moved towards HPV based “
- ➔ Consensus conference on “ screening in vaccinated populations”
- ➔ Manual of Indicators for evaluating HPV based programme
- ➔ Expert Commission every six months evaluates if new commercial HPV assays are acceptable for organized screened programme
- ➔ So far 75% of Regions are just moving towards the new test

Digital Breast Tomosynthesis (DBT)

- Two Randomized clinical trials are on going (Reggio Emilia and Torino)
- Two pilot programs are ongoing (Verona , Trento)

First results

DBT as compared to Digital Mammography *

- Increase in cancer detection rate (.5 to 2.7*1000)
- Reduction in false positive recal rate (.8 to 3.6*100)

Open questions

- Overdiagnosis
- Increase detection rate of benign lesions
- Radiation exposure
- Increasing reading time

*Houssami N Expert Rev Med Devices 2015

Lung cancer screening

- Easy to identify high risk population
- Very high risk

➔ Smoking cessation !!!

Lung Cancer screening

Annals of Internal Medicine



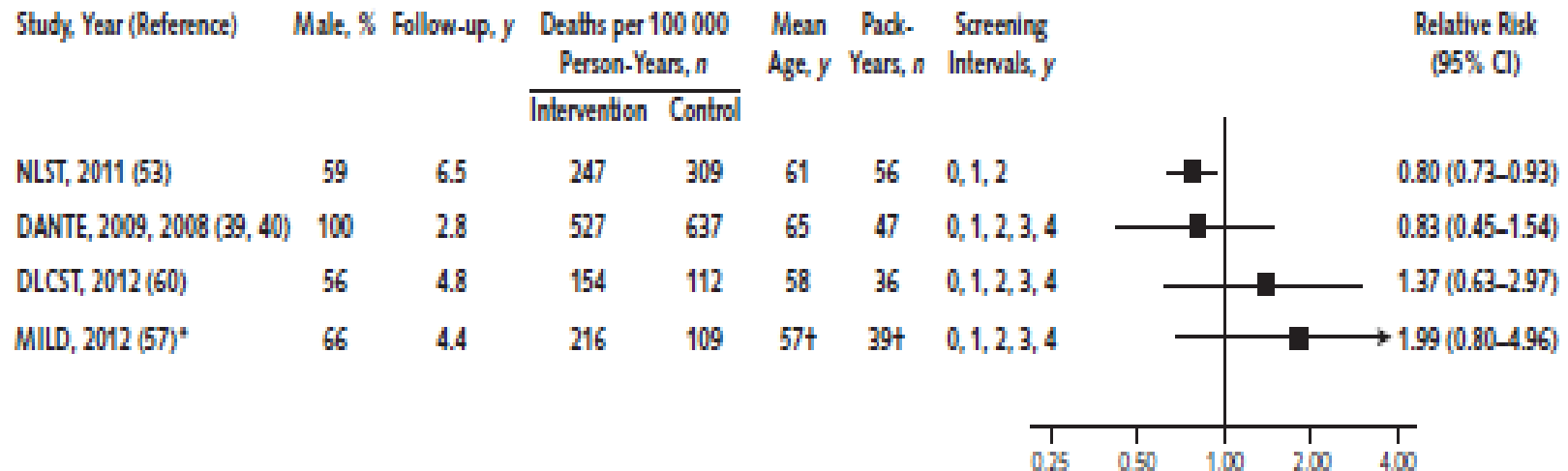
SCREENING FOR LUNG CANCER

CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	Asymptomatic adults aged 55 to 80 y who have a 30 pack-year smoking history and currently smoke or have quit smoking within the past 15 y
Recommendation	Screen annually for lung cancer with low-dose computed tomography. Discontinue screening when the patient has not smoked for 15 y. Grade: B

In Europe diverging results

Figure 1. Trial results for lung cancer mortality.



ORIGINAL ARTICLE

Mortality, survival and incidence rates in the ITALUNG randomised lung cancer screening trial

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► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/thoraxjnl-2016-209825>).

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Received 7 December 2016

Revised 6 February 2017

Accepted 9 March 2017

ABSTRACT

Background ITALUNG is contributing to the European evaluation of low-dose CT (LDCT) screening for lung cancer (LC).

Methods Eligible subjects aged 55–69 years, smokers or ex-smokers (at least 20 pack-years in the last 10 years), were randomised to receive an annual invitation for LDCT screening for 4 years (active group) or to usual care (control group). All participants were followed up for vital status and cause of death (at the end of 2014) and LC incidence (at the end of 2013). Pathological and clinical information was collected from the Tuscan Cancer Registry data.

Results 1613 subjects were randomly assigned to the active group and 1593 to the control group. At the end of the follow-up period 67 LC cases were diagnosed in the active group and 71 in the control group (rate ratio (RR)=0.93; 95% CI 0.67 to 1.30). A greater proportion of stage I LC was observed in the active group (36% vs 11%, $p<0.001$). Non-significant reductions of 17% (RR=0.83; 95% CI 0.67 to 1.03) for overall mortality and 30% (RR=0.70; 95% CI 0.47 to 1.03) for LC-specific mortality were estimated.

Key messages

What is the key question?

► After the positive results of the National Lung Screening Trial in the USA, the efficacy of lung cancer screening with low-dose CT (LDCT) is still debatable in Europe.

What is the bottom line?

► Despite the lack of statistical significance, the outcomes of the ITALUNG trial suggest that LDCT screening could reduce lung cancer and overall mortality and does not show overdiagnosis after an adequate follow-up period.

Why read on?

► The results of the ITALUNG trial, which is part of the European Randomised Trials Collaboration, make an important contribution to the assessment of the benefit-to-harm ratio of lung cancer screening in Europe.

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Italung : main results

- No overdiagnosis
- $RR=0.7$ (95% CI 0.47-1.03) for Lung cancer mortality