



# Valutazioni comparative SDO Registri: *vantaggi e svantaggi*



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Health & Consumer Protection  
Directorate-General

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# **European guidelines for quality assurance in breast cancer screening and diagnosis**

*Fourth Edition*

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## 1.9.2 Impact indicators

### Analysis of surrogate indicators

- Interval cancer rate
- Breast cancer detection rate
- Stage at diagnosis of screen-detected cancers
- Proportion of screen-detected invasive cancers  $\leq 10$  mm
- Proportion of screen-detected cancers that are invasive
- Proportion of screen-detected cancers with lymph node metastases

# Definizione di caso intervallo

## **Interval cancer:**

a primary breast cancer, which is diagnosed in a woman who had a screening, test, with/without further assessment, which was negative for malignancy, either:

before the next invitation to screening,

or within a time period equal to a screening interval for a woman who has reached the upper age limit for screening.

## **Interval cancer rate:**

the number of interval cancers diagnosed within a defined time period since the last negative screening examination per 10,000 women screened negative.

The rate of interval cancers can also be expressed as a proportion of the background (expected) breast cancer incidence rate in the screened group.

# I casi intervallo

- “The purpose of monitoring interval cancers is two fold. Radiological review of interval cancers is crucial since it serves both **quality assurance** and training (see Chapter 4 on Radiology). For evaluation purposes, monitoring interval cancers allows for the calculation of parameters providing an early **estimate of the impact** of the screening programme in modifying the appearance of the disease, and thereby its effects, in the population. Therefore, data collection and reporting should be directed to all cancers appearing in the target population.”

**Table 33: Early surrogate indicators by which the impact of a breast screening programme is assessed**

Surrogate indicator	Acceptable level	Desirable level	Screening programme 50-69
Interval cancer rate* / Background incidence rate* (%)			
• 0-11 months	30%	< 30%	
• 12-23 months	50%	< 50%	
Breast cancer detection rate*			
• Initial screening	3xIR	> 3xIR	
• Subsequent-regular screening	1.5xIR	> 1.5xIR	
Stage II+/Total cancers screen-detected (%)			
• Initial screening	NA	< 30%	
• Subsequent-regular screening	25%	< 25%	
Invasive cancers ≤10 mm/ Total invasive cancers screen-detected (%)			
• Initial screening	NA	≥ 25%	
• Subsequent-regular screening	≥ 25%	≥ 30%	
Invasive cancers/ Total cancers screen-detected (%)	90%	80-90%	
Node-negative cancers/ Total invasive cancers screen-detected (%)			
• Initial screening	NA	> 70%	
• Subsequent-regular screening	75%	> 75%	

IR = background incidence

NA = not applicable

# Strumenti

- I Registri Tumori
- Flussi informativi ospedalieri (SDO)
- Consultazione archivi dei laboratori di anatomia patologica
- Rilevazioni ad hoc

# Uso delle SDO per la stima d'incidenza del tumore della mammella



Journal of Clinical Epidemiology 61 (2008) 373–379

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**Journal of  
Clinical  
Epidemiology**

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A high positive predictive value algorithm using hospital administrative data identified incident cancer cases

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Table 2

Performance of algorithm for 2000 (training set) and 2001 (validation set), with the Piedmont Cancer Registry of Turin (PCRT) considered as the gold standard

	2000			2001		
	Breast	Colorectum	Lung	Breast	Colorectum	Lung
Total incident cases (PCRT data)	925 <sup>a</sup>	799	713	897 <sup>a</sup>	796	665
Total incident cases (hospital discharge abstracts for Turin residents)	765	642	685	743	655	682
Matched cases	687	577	554	688	576	537
Algorithm sensitivity (%) (95% CI)	74.3 (71.3–77.1)	72.2 (69.0–75.3)	77.7 (74.5–80.7)	76.7 (73.8–79.4)	72.4 (69.1–75.4)	80.8 (77.5–83.7)
Algorithm positive predictive value (%) (95% CI)	89.8 (87.4–91.8)	89.9 (87.3–92.1)	80.9 (77.7–83.7)	92.6 (90.5–94.4)	87.9 (85.2–90.3)	78.7 (75.5–81.7)

<sup>a</sup> Invasive and in situ cancer.

**Table 3**  
**False-positive cases of female breast, colorectal, and lung cancer, 2000**

Reason for incorrect classification	Breast		Colorectum		Lung	
	No.	%	No.	%	No.	%
<i>Coding error or clinical diagnosis misclassification</i>						
Benign cancer incorrectly scored as malignant	29	37	3	5	—	—
In situ cancer incorrectly scored as malignant	—	—	7	11	—	—
Secondary cancer incorrectly scored as primary	—	—	7	11	35	27
<i>Prevalent cases</i>						
Incidence before availability of hospital discharge abstracts (1995)	23	29	—	—	—	—
Incidence in 1995 and November 1999	4	5	8	12	43	33
Incidence in December 1999	6	8	18	28	17	13
Not resident in registry area	10	13	12	18	13	10
Not enough evidence according to PCRT criteria	—	—	10	15	23	17
Other	6	8	—	—	—	—
<b>Total</b>	<b>78</b>	<b>100</b>	<b>65</b>	<b>100</b>	<b>131</b>	<b>100</b>

Table 4

False-negative cases of female breast, colorectal, and lung cancer, 2000

Reason for incorrect classification	Breast		Colorectum		Lung	
	No.	%	No.	%	No.	%
<i>Coding error or clinical diagnosis misclassification</i>						
Personal history of cancer (same site)	5	2	2	1	1	1
Malignant cancer incorrectly scored as benign or of uncertain behavior	21	9	18	8	—	—
Other primary cancer diagnosis	2	1	6	3	3	2
<i>Not included in hospital discharge abstracts database</i>						
Private hospitalization	60	25	13	6	—	—
No hospital discharge abstract	7	3	5	2	—	—
Biopsy in outpatient care	4	2	27	12	18	11
<i>Algorithm criteria not met</i>						
Not surgical	80	33	53	24	—	—
Percutaneous biopsy only	8	3	—	—	—	—
Metastases in primary diagnosis	4	2	36	16	37 <sup>a</sup>	23
Only ICD-9-CM 162.xx as secondary diagnosis	—	—	—	—	21	13
Ascertained through death certificate only	8	3	8	4	16	10
First hospitalization in 1999	11	5	—	—	—	—
First hospitalization in 2001	19	8	40	18	52	33
Other	9	4	14	6	11	7
Total	238	100	222	100	159	100

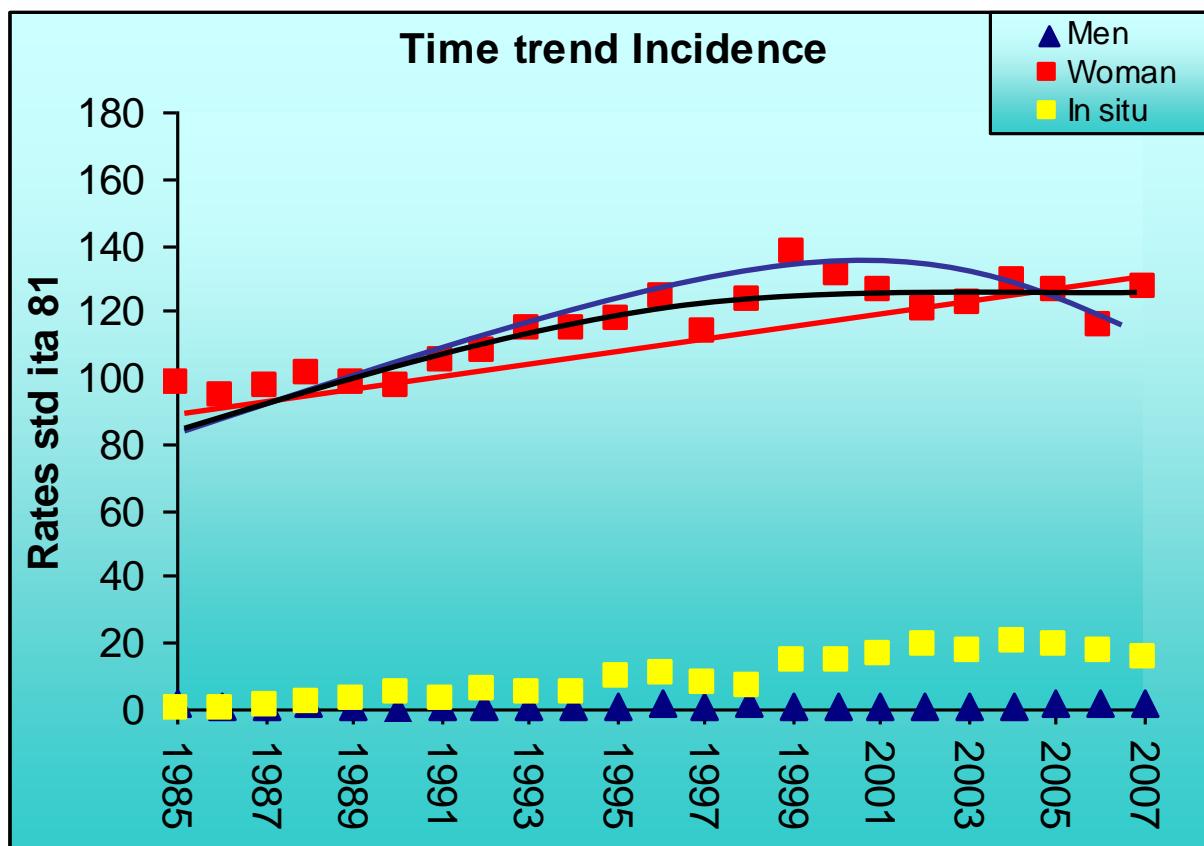
# Studio dell'effetto della parziale identificazione dei casi intervallo: Ipotesi e Parametri

- Background incidence:
  - Pre-screening
  - Fase di prevalenza
  - Screening maturo
- Detection rate di base
- Sensibilità del metodo (SDO)

# Background Incidence

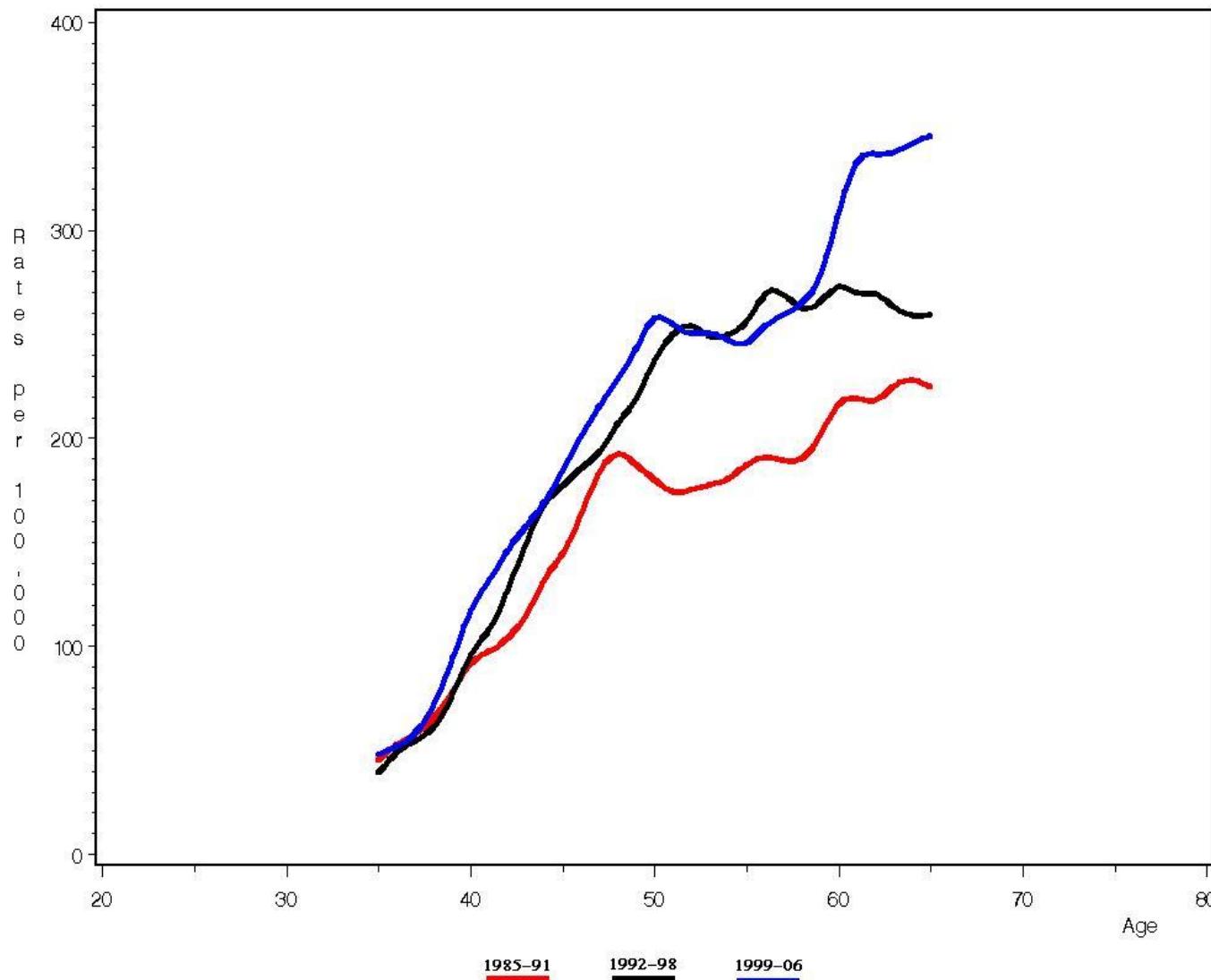
Piedmont Cancer Registry  
City of Turin (910,504 inhabitants at 31.12.2009)

## BREAST - ICD-10: C 50



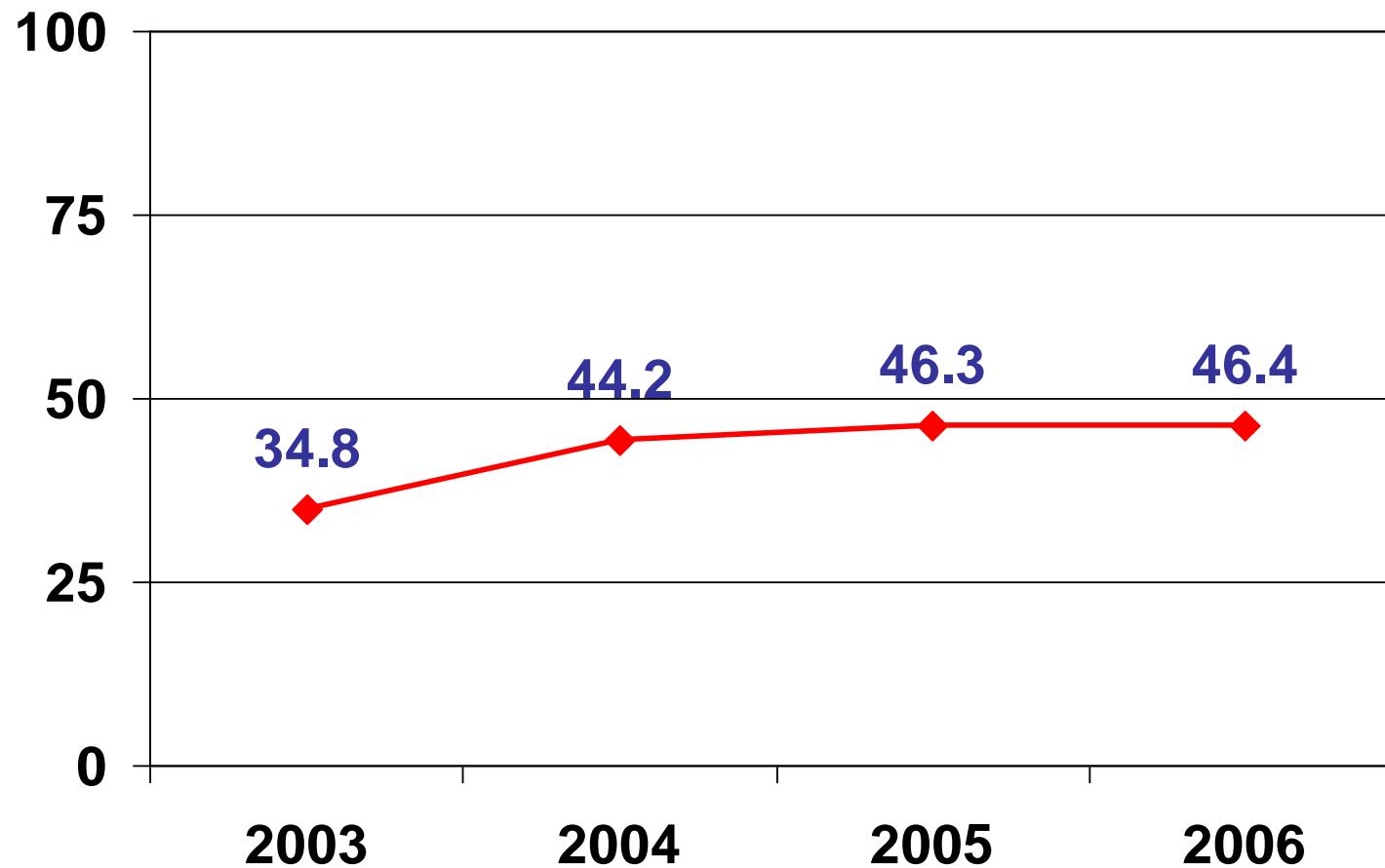
# Breast cancer

Annual age-specific rates (truncated) by period



# Piedmont Region Mammography Screening Programme

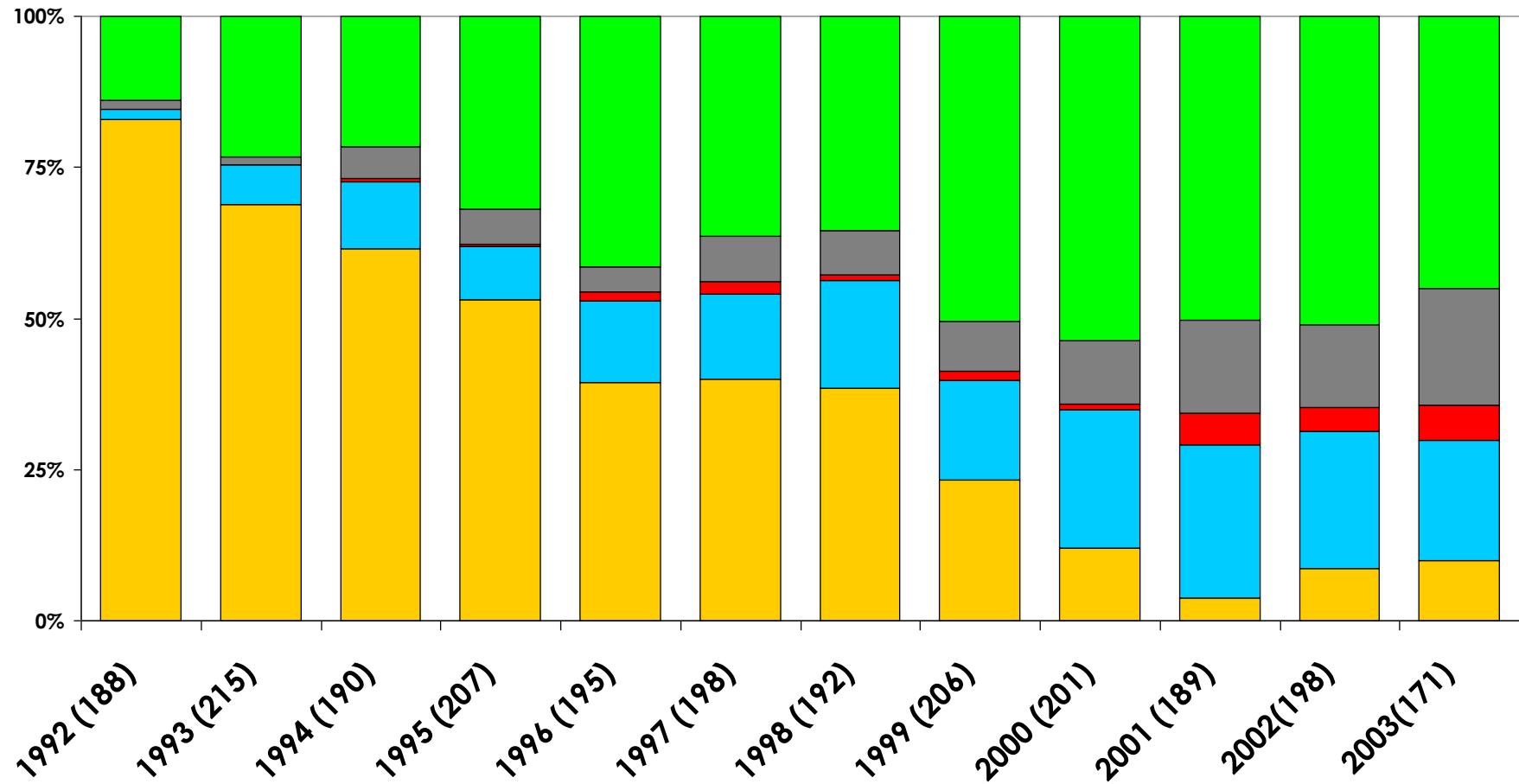
## Examination Coverage % by Year



# Impatto dello screening

## Cancri incidenti a Torino (registro tumori)

Donne 50-59 anni in cinque categorie per storia di screening 1992-2003



874 non invitata

351 mai aderenti

44 non aderenti ultimo invito

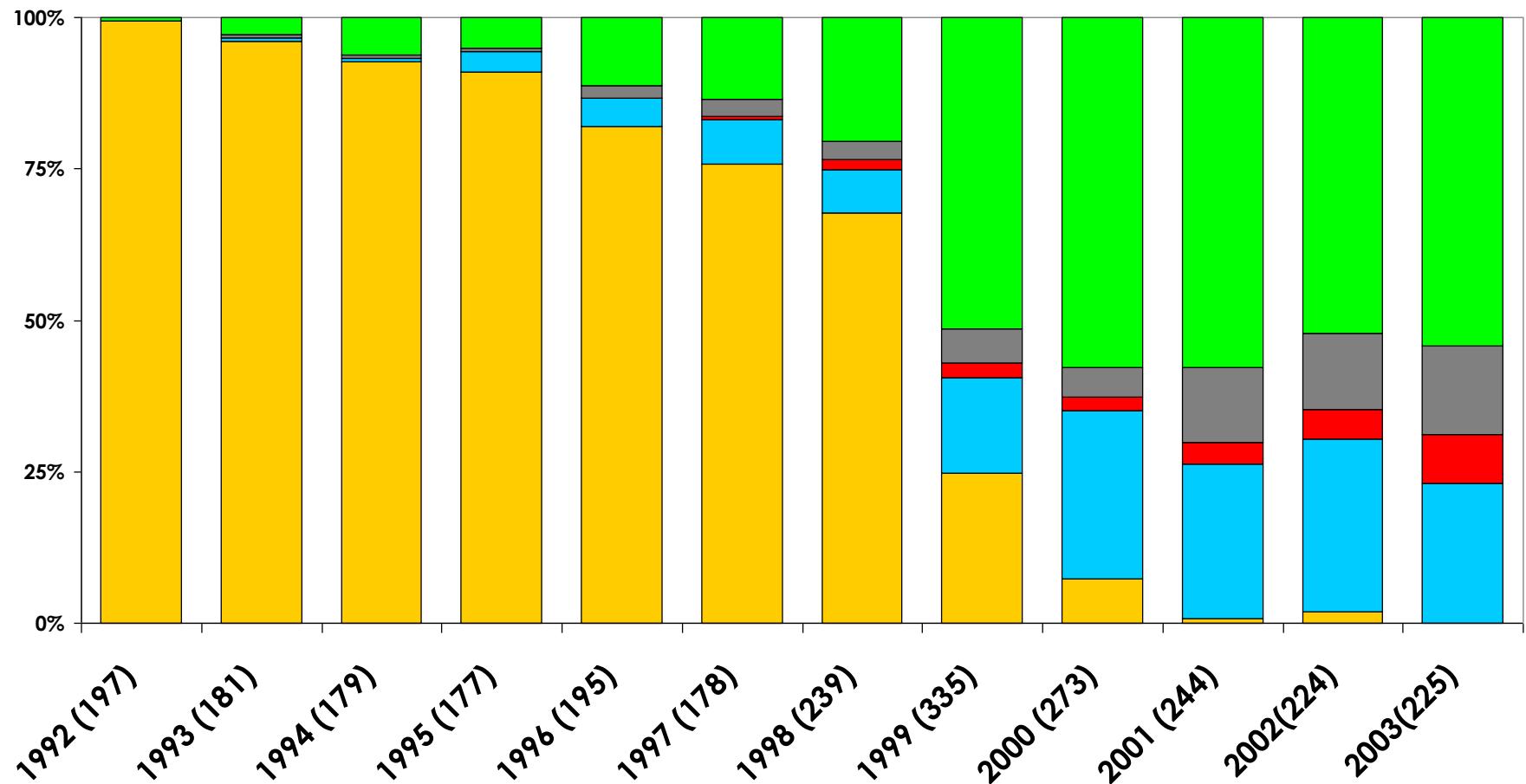
192 casi intervallo

889 screen detected

# Impatto dello screening

## Cancri incidenti a Torino (registro tumori)

Donne 60-69 anni in cinque categorie per storia di screening 1992-2003



1263 non invitee

354 mai aderenti

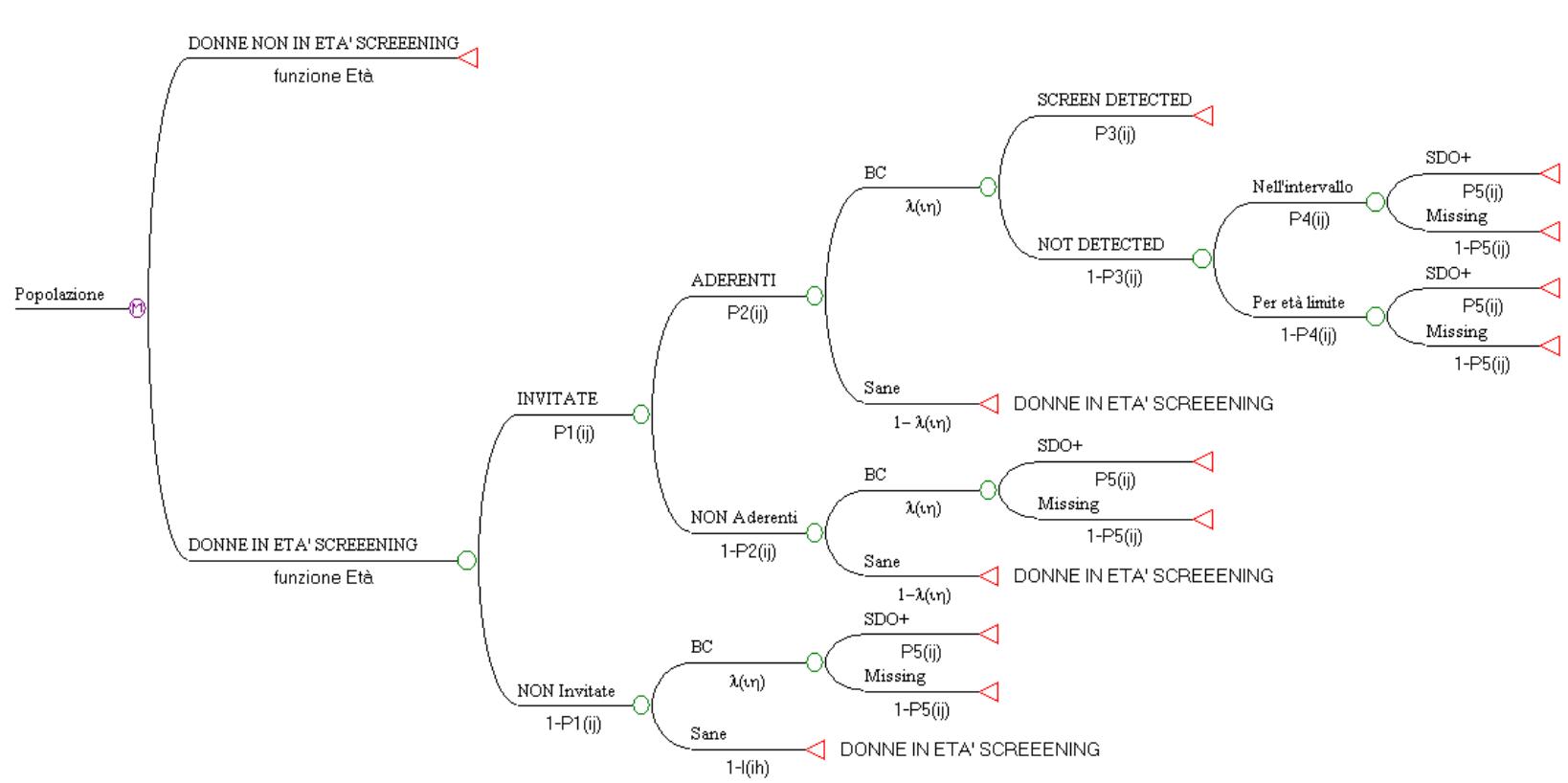
57 non aderenti ultimo invito

142 casi intervallo

831 screen detected

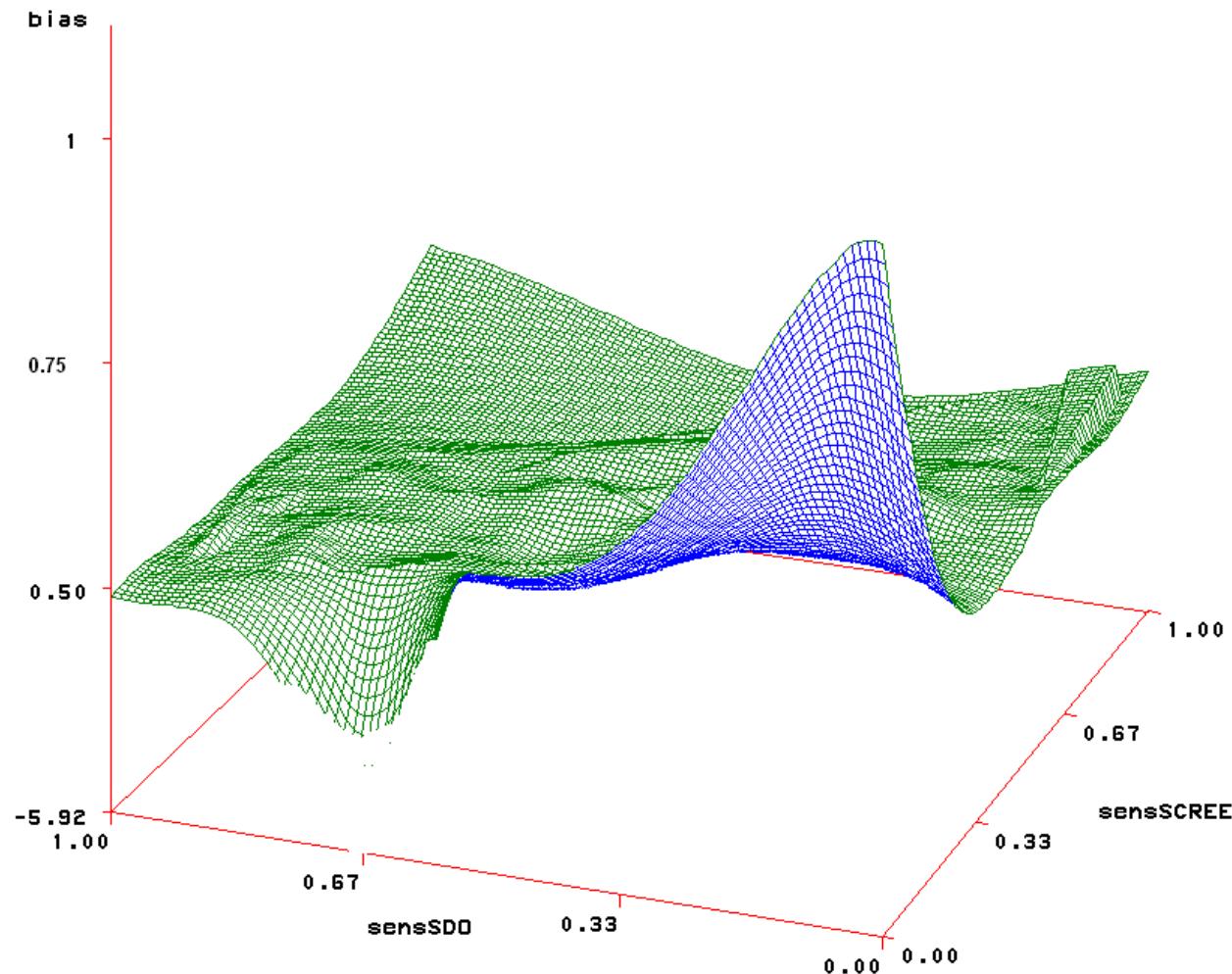


 Simulazione 1



C/E, 1/2

# Risultati della simulazione



# Misura del tasso dei casi intervallo

Research paper 87

## A pooled analysis of interval cancer rates in six European countries

Sven Törnberg, Levent Kemetli, Nieves Ascunce, Solveig Hofvind, Ahti Anttila, Brigitte Séradour, Eugenio Paci, Cathrine Guldenfels, Edward Azavedo, Alfonso Frigerio, Vitor Rodrigues and Antonio Ponti

Table 4 ICR/EIR by time since a negative screening examination

Country/project	Expected incidence 50–69/10000	No. of tests	1–12 months			13–24 months			>24 months		Total 1–24 months	
			No. of IC	IC rate/ 10 000	ICR/EIR	No. of IC	ICR/ 10000	ICR/EIR	No. of IC	ICR/ 10 000	ICR/ 10 000	ICR/EIR (2 years)
Navarra (E)	16.2	126 318	27	2.1	0.13	79	6.3	0.39	12	0.9	8.4	0.26
Firenze (I)	22.2	49 148	19	3.9	0.17	56	11.4	0.51	NA	NA	15.3	0.34
Torino (I) <sup>a</sup>	20.2	41 911	23	5.5	0.25	42	10.0	0.45	NA	NA	15.5	0.35
Four counties (N)	20.0	126 779	57	4.5	0.22	190	15.0	0.75	NA	NA	19.5	0.49
Stockholm (S) <sup>b</sup>	25.8	458 292	334	7.3	0.28	631	13.8	0.53	24	0.5	21.1	0.41
Pirkanmaa (SF) <sup>c</sup>	13.1	64 803	42	6.5	0.49	71	11.0	0.84	4	0.6	17.4	0.67
Marseille (F)	20.1	140 086	75	5.4	0.27	169	12.1	0.60	59	4.2	17.4	0.43
Strasbourg (F)	22.6	168 186	116	6.9	0.31	243	14.4	0.64	NA	NA	21.3	0.47
Total	20.0	1 175 523	693	5.9	0.29	1481	12.6	0.63	99	0.8	18.5	0.46

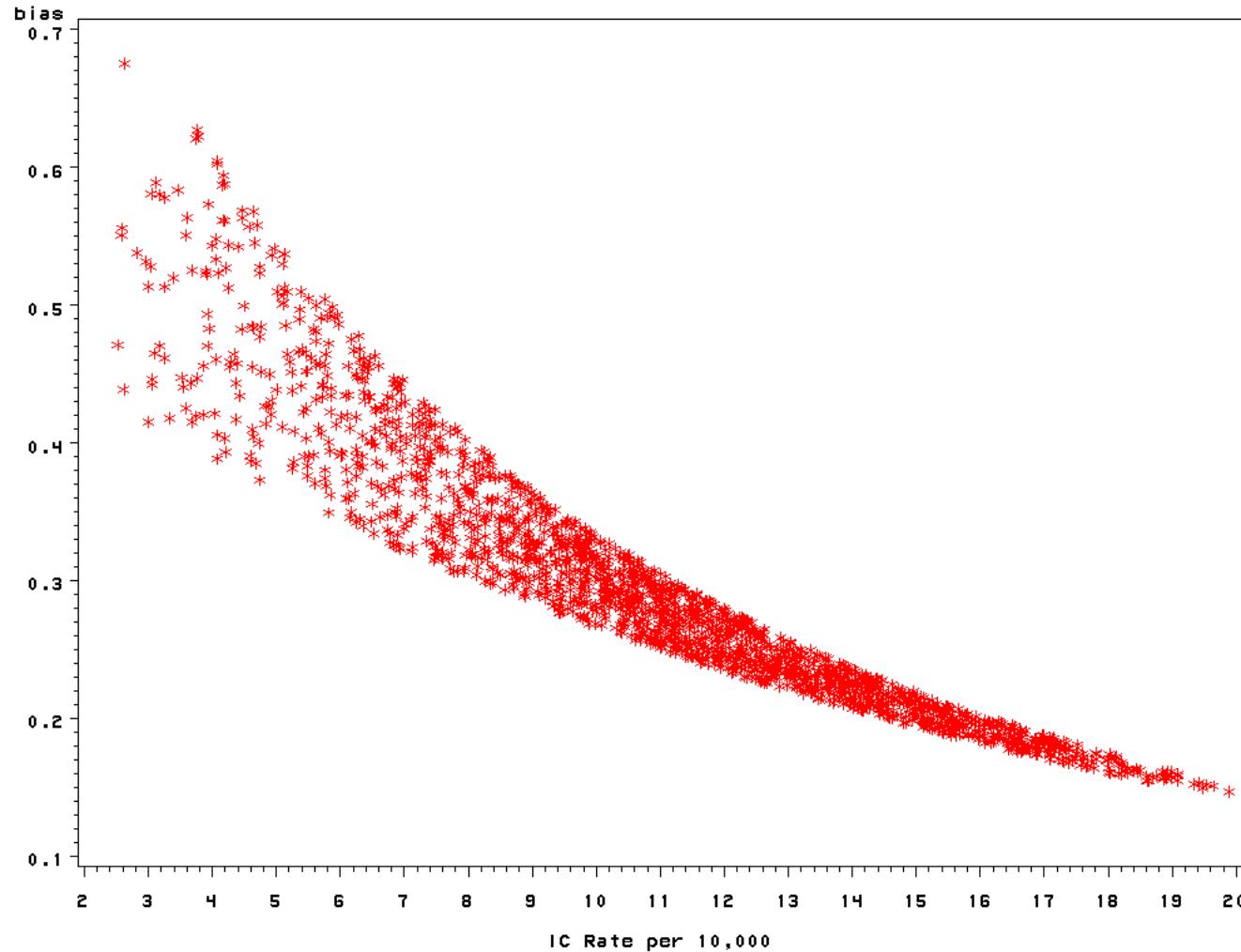
ICR/EIR, interval cancer rate/expected incidence ratio; NA, not available.

<sup>a</sup>Expected incidence for Torino was based on the ages 50–64 years.

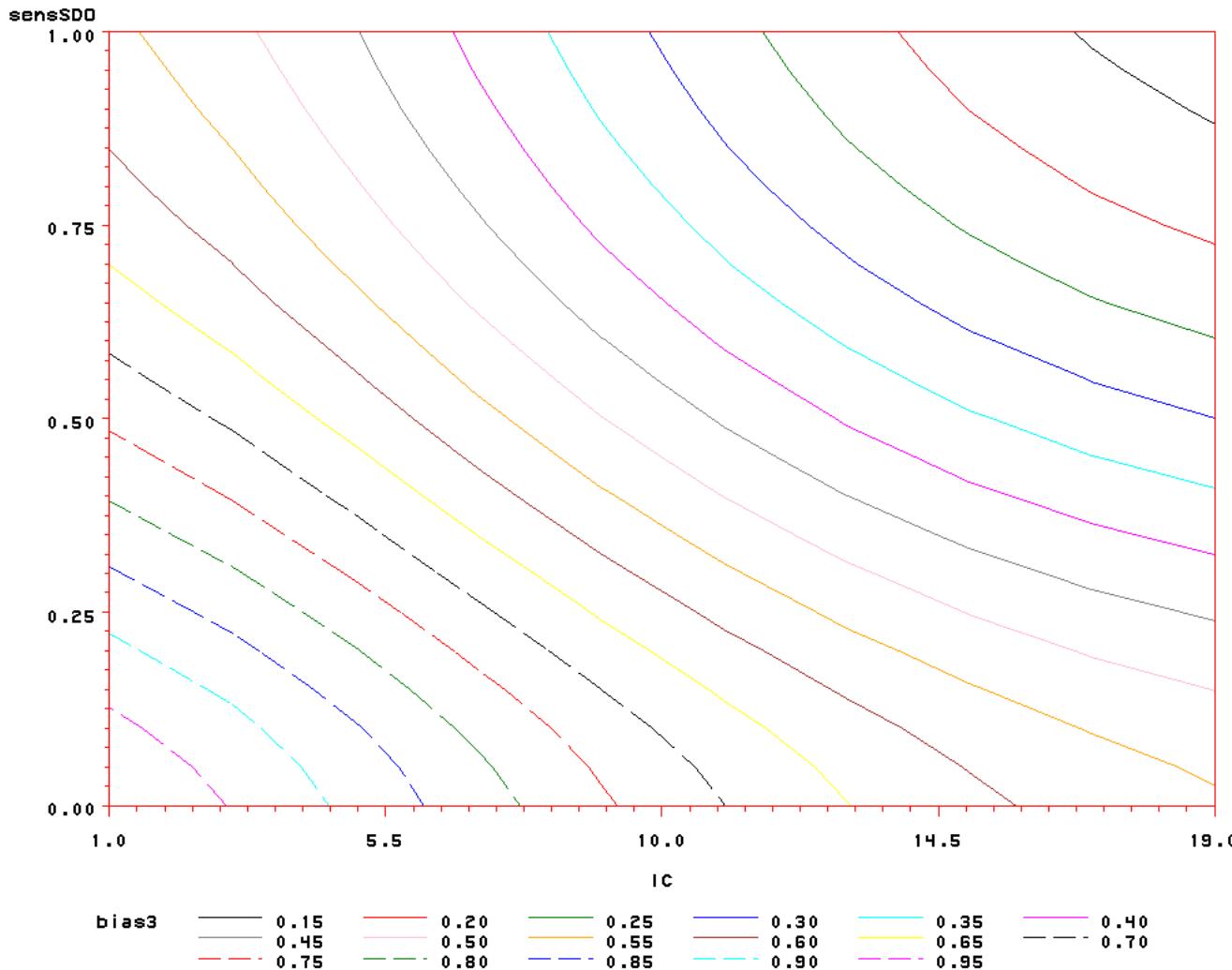
<sup>b</sup>Expected incidence for Stockholm was based on 1985–1988 for the period 1989–1991. When expected incidence was extrapolated to the entire period 1989–1998, the ratio was 23.7/10 000.

<sup>c</sup>Expected incidence for Pirkanmaa was based on the ages 50–59 years.

# Relazione fra bias e tasso di casi intervallo



# Stima del bias data sensibilità delle SDO e tasso di casi Intervallo



# Conclusioni

- E' indispensabile disporre di una stima dell'errore di misura intrinseco al sistema di rilevazione:
  - Definire le procedure per calcolare i casi intervallo
  - Definire l'incidenza attesa di riferimento (od alcuni scenari d'interesse)
  - Calcolare il bias dello strumento di rilevazione
  - Stimare per via diretta, campionaria o per simulazione l'effetto sul valore misurato

Grazie per l'attenzione