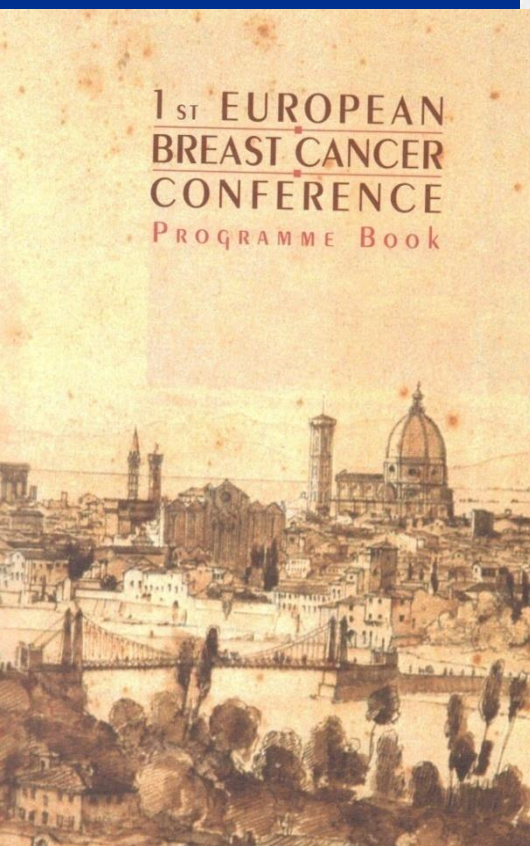


LIMITATIONS OF GUIDELINES IN DEVELOPED COUNTRIES

Prof Robert Mansel
Emeritus Professor
Cardiff University, UK
President EUSOMA

THE FIRST MOVES 1999



Pergamon

European Journal of Cancer, Vol. 35, No. 1, pp. 14-15, 1999
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PII: S0959-8049(98)00384-0

Position Paper

Florence Statement on Breast Cancer, 1998 Forging the Way Ahead for More Research on and Better Care in Breast Cancer

L. Cataliotti,¹ A. Costa,² P.A. Daly,³ L. Fallowfield,⁴ G. Freilich,⁵ L. Holmberg,⁶
M. Piccart,⁷ C.J.H. van de Velde⁸ and U. Veronesi²

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DEFINITIONS

- What is a breast centre/unit/clinic
- Who should be working in it
- What standards are required
- How can performance be measured
- Can quality indicators be applied to all breast centres

EUSOMA DEFINITION 2000

“The requirements of a specialist breast unit”



PERGAMON

European Journal of Cancer 36 (2000) 2288–2293

European
Journal of
Cancer

www.ejconline.com

Position Paper

The requirements of a specialist breast unit

EUSOMA

EUSOMA Secretariat, Viale B. d'Este 37, 20122 Milan, Italy

Received 24 February 2000; accepted 25 May 2000

EUSOMA DEFINITION

- **A single integrated Unit**
- **Sufficient cases to allow effective working and continuing expertise (150 minimum cases)**
- **Care by breast specialists in all the required disciplines working in multidisciplinary fashion in all areas**
- **Providing all the services necessary – from genetics and prevention, through the treatment of the primary tumour, to care of advanced disease and palliation.**
- **Patient support**
- **Data collection and Audit**

Controversial element - raises a challenge for small units and the private medical sector «office based practice»

B
R
E
A
S
T

U
N
I
T

Patient

Radiologist

Surgeon

Pathologist

**Medical
Oncologist**

RT

**Breast Care
Nurse**

Technician

**Data
Manager**

Geneticist

**Psycho-
oncologist**

Physiotherapist

Advocacy

What is the evidence for volume and MDT?

- No direct body of evidence for volume in breast cancer- better evidence for complex GI and Cardiac surgery
- Larger volume means specialisation and more complex cases
- MDT is linked with volume as small volume and MDT is not time or cost efficient.

WHAT IS THE EVIDENCE FOR MDT ?

- No direct RCT evidence
- Population comparisons in Scotland
- Hospital volume in Belgium
- Proxy of QA in sentinel node studies

RECENT STUDY ON SPECIALIST CARE- Scotland

- 13,722 women with breast cancer
- 1 health Board with specialist care compared with general hospital care
- After introduction of specialist care and MDT in 1995 specific breast cancer mortality fell by 18%
- This study used contemporaneous controls not historical comparisons

Kesson et al BMJ May 2012

HOSPITAL VOLUME IN BELGIUM

- Cancer registry study using 11 process quality indicators
- 25,000 BC pts between 2004-6
- Hospitals graded v.low (<50), low (50-99), med (100-149) and high (≥ 150)
- 5 year survivals were 75%, 79%, 80%, 83%
- Hazard Ratio for death was 1.42 in very low. Vrijens et al Breast 2012,21:261

SURGICAL VOLUME

SURGICAL VOLUME INDEX

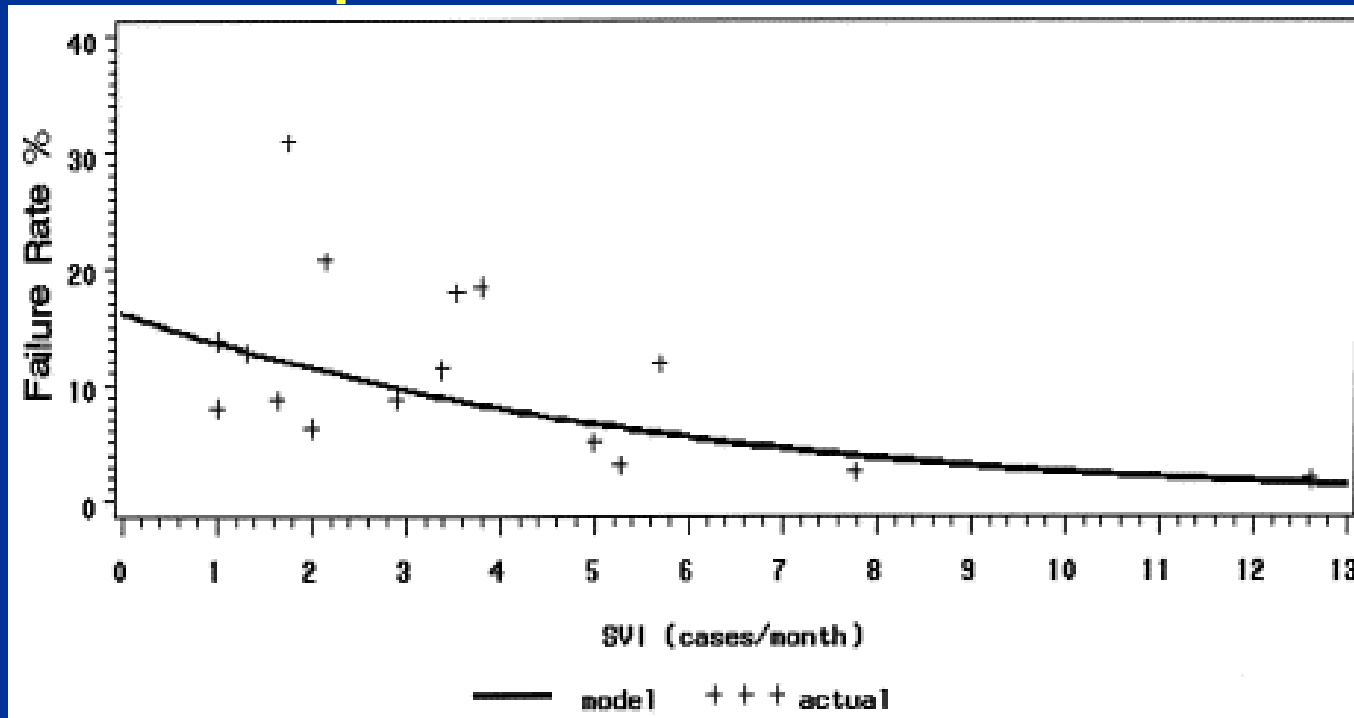
SLN IDENTIFICATION RATE

3-6 cases per month

>85%

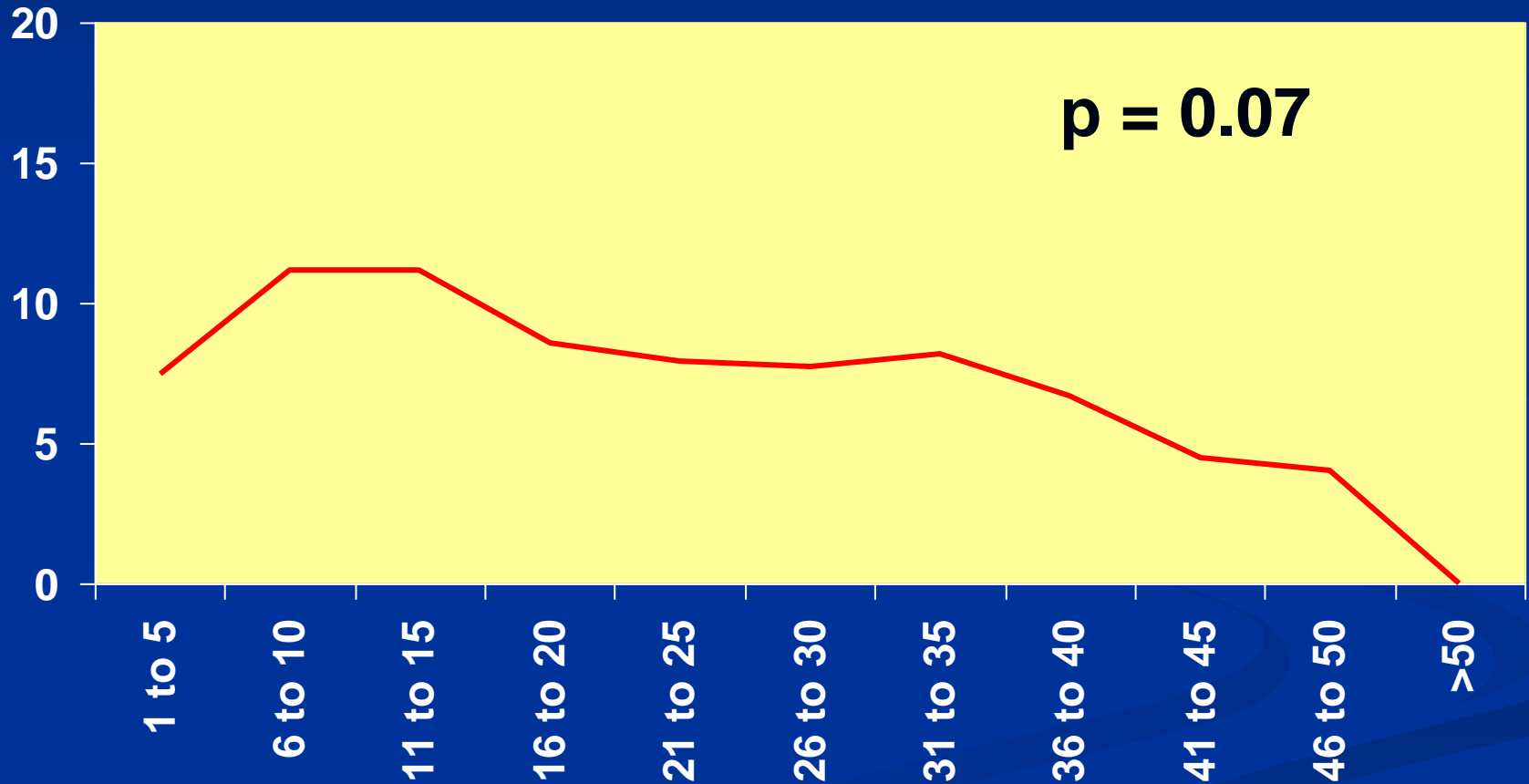
>6 cases per month

>95%



Cox et al. Ann Surg 2001

False Negative Rates by Surgeon Case Number



Overall false negative rate 8.9%

UK SCREENING PROGRAMME PREOPERATIVE DIAGNOSIS 1996-02 (Guidelines improve quality)

y 1276 since 1996/97.

| 6 YEAR COMPARISON: PRE-OPERATIVE DIAGNOSIS RATES | | | | | | |
|---|-------------------------------------|-----------------------------------|-----------|-------------|-----------------|----------------------------------|
| Total cancers | Number of cancers with C5 and/or B5 | % with pre-operative diagnosis by | | | | Pre-operative diagnosis rate (%) |
| | | C5 only | C5 and B5 | C5 (+/- B5) | B5 only (no C5) | |
| 7310 | 4576 | - | - | 45 | 17 | 63 |
| 8215 | 5866 | - | - | 42 | 29 | 71 |
| 8002 | 6449 | - | - | 36 | 44 | 81 |
| 8906 | 7590 | - | - | 31 | 54 | 85 |
| 10079 | 8775 | 19 | 8 | - | 60 | 87 |
| 10191 | 9043 | 13 | 9 | - | 66 | 89 |

1996

1999

2002

from Scotland are absent in 1998/99 and 1999/00

2012 = >95 %

WHY DO WE NEED GUIDELINES?

- They bring best evidence into practice faster
- They standardise procedures ? More cost effective
- They reduce chance of poor practice due to peer review of each case

ALMANAC randomised trial

Axillary operating time

| | Standard axillary surgery | SLNB |
|----------------------|----------------------------------|-----------------------|
| High caseload | 17 mins (19.0, 2-221) | 15 mins (17.2, 2-135) |
| Low caseload | 25 mins (12.7, 6-70) | 20 mins (19.9, 5-113) |

Median axillary operating time (SD, range)

ALMANAC randomised trial

Return to daily activities

| | Standard axillary surgery | SLNB |
|---------------|---------------------------|------------------|
| High caseload | 79.0% | 82.3% |
| Low caseload | 62.6% | 70.5% |
| p-value | <0.001 | <0.001 |

Percentage of patients returning to normal daily activities at 1 month

ALMANAC randomised trial

Return to normal paid work

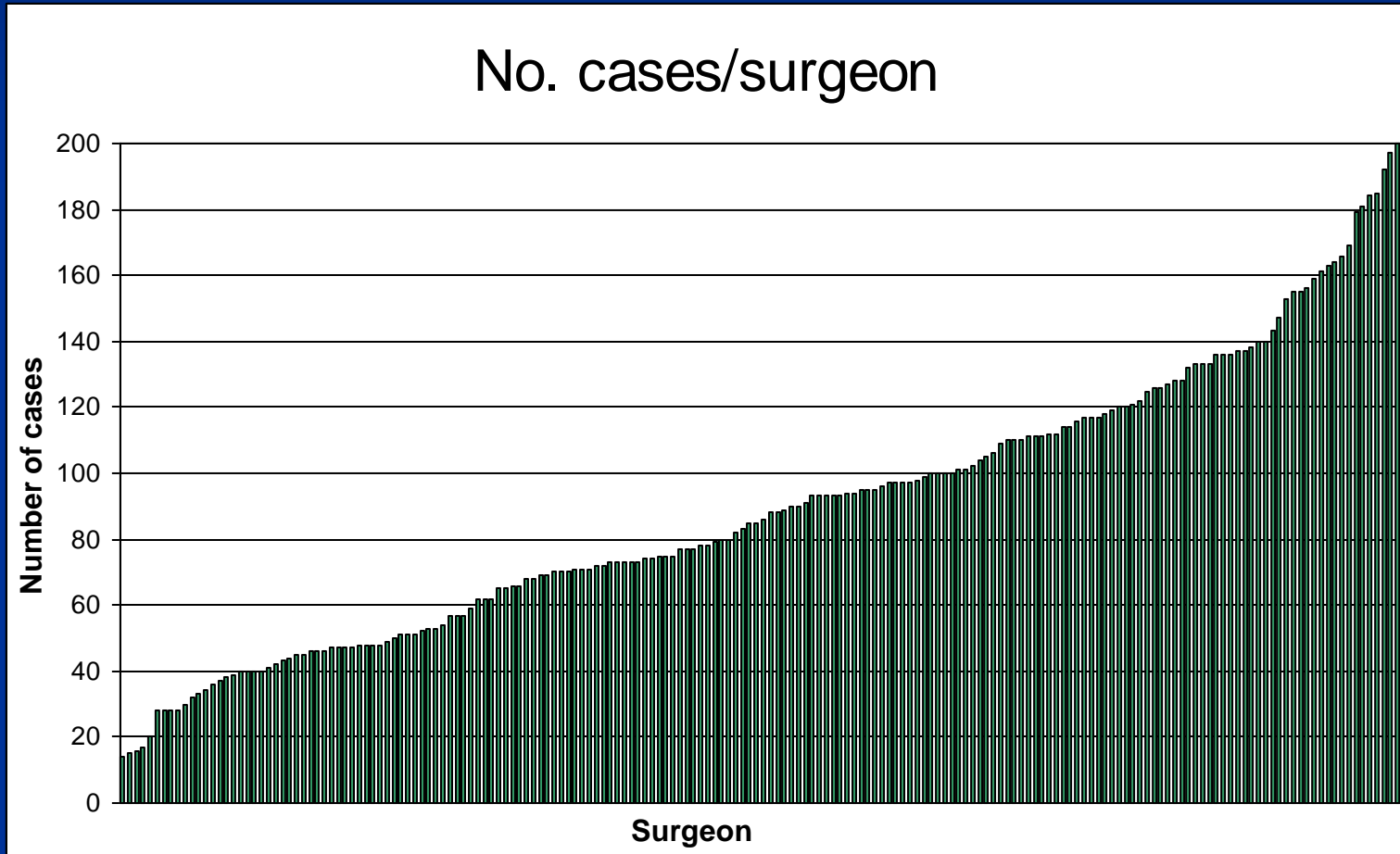
| | Standard axillary surgery | SLNB |
|---------------|---------------------------|------------------|
| High caseload | 58.6% | 62.7% |
| Low caseload | 25.8% | 24.2% |
| P-value | <0.001 | <0.001 |

Percentage of patients returning to normal paid work at 3 months

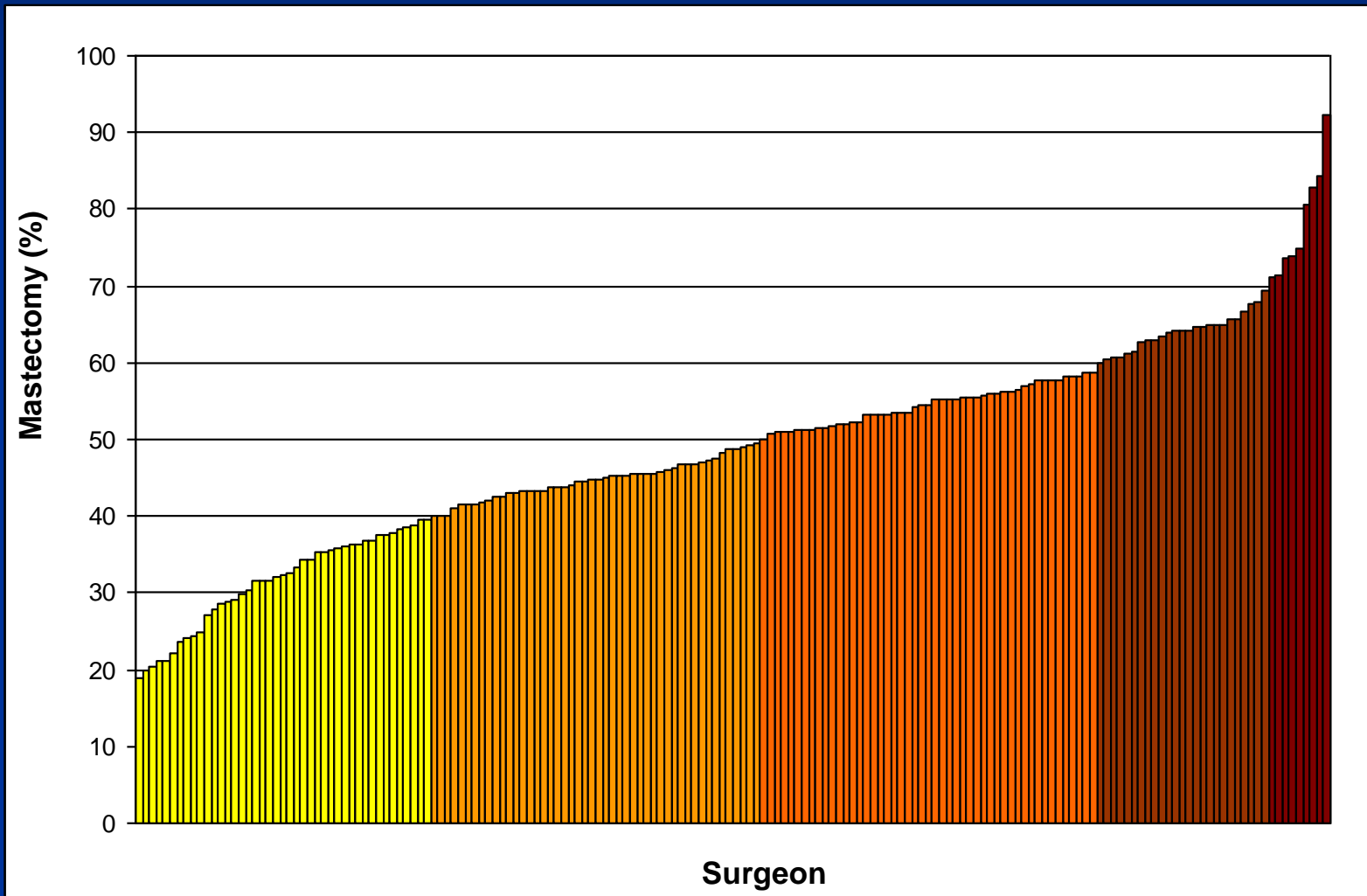
VARIATIONS IN PRACTICE

- UK screening data
- Dutch audit evidence
- UK National mastectomy audit
- Scottish regional data

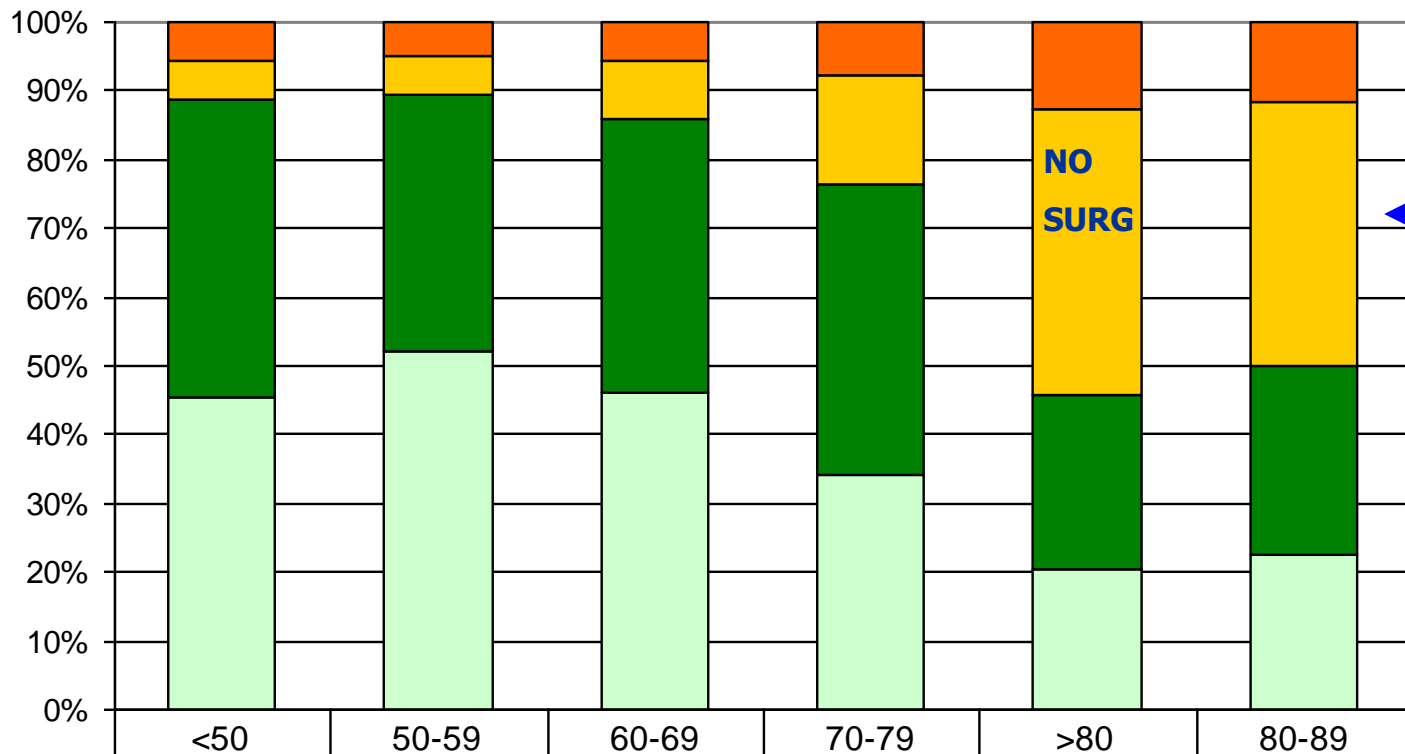
Number of cases treated by each surgeon



Variation in mastectomy rates

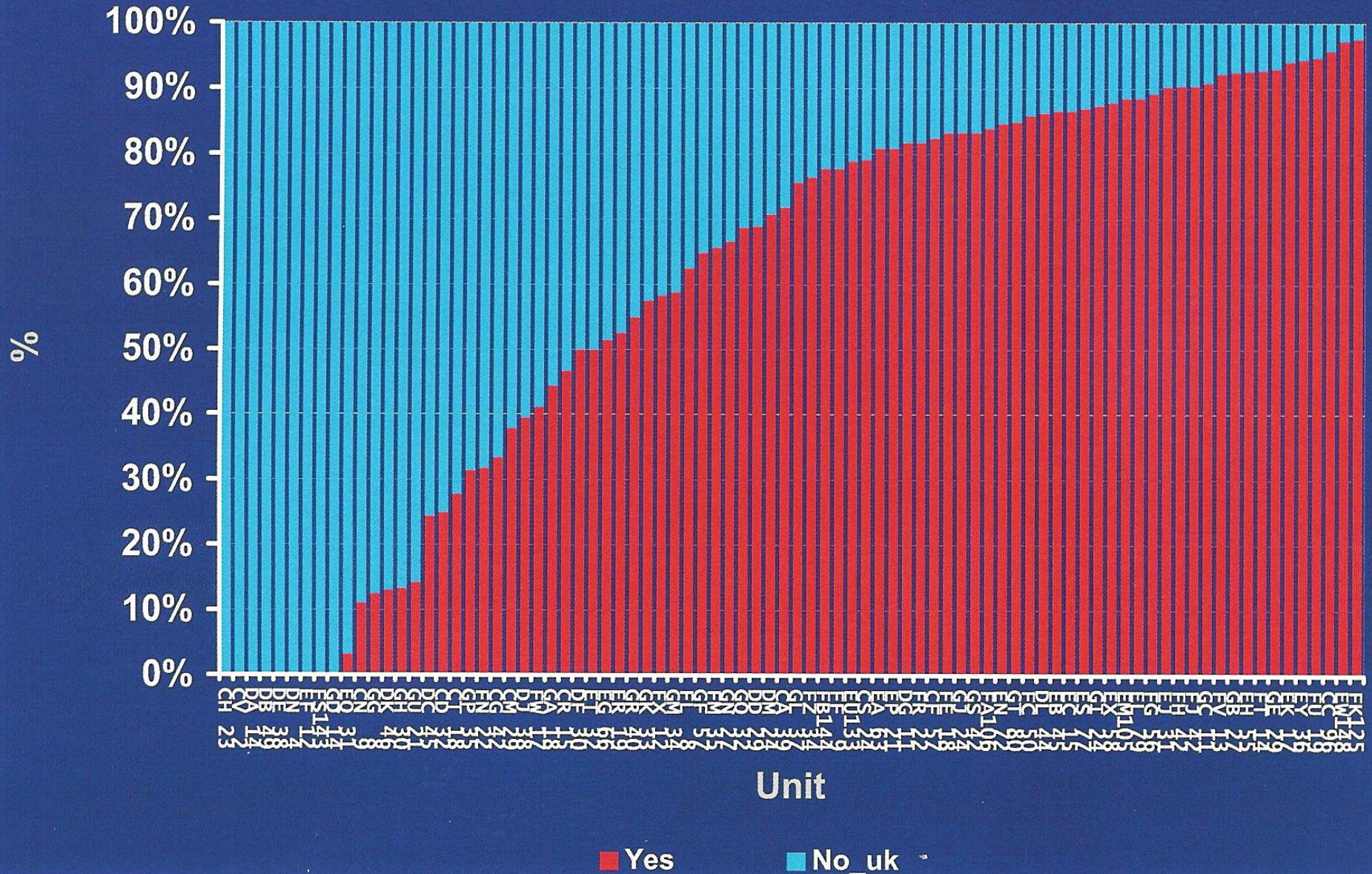


Surgical treatment: variation with age (UK)



| | | | | | | |
|--------------|------|------|------|------|-----|-----|
| Unknown | 207 | 204 | 186 | 242 | 286 | 224 |
| No Surgery | 206 | 222 | 271 | 506 | 941 | 734 |
| Mastectomy | 1562 | 1494 | 1308 | 1348 | 574 | 531 |
| Conservation | 1651 | 2102 | 1502 | 1084 | 460 | 430 |

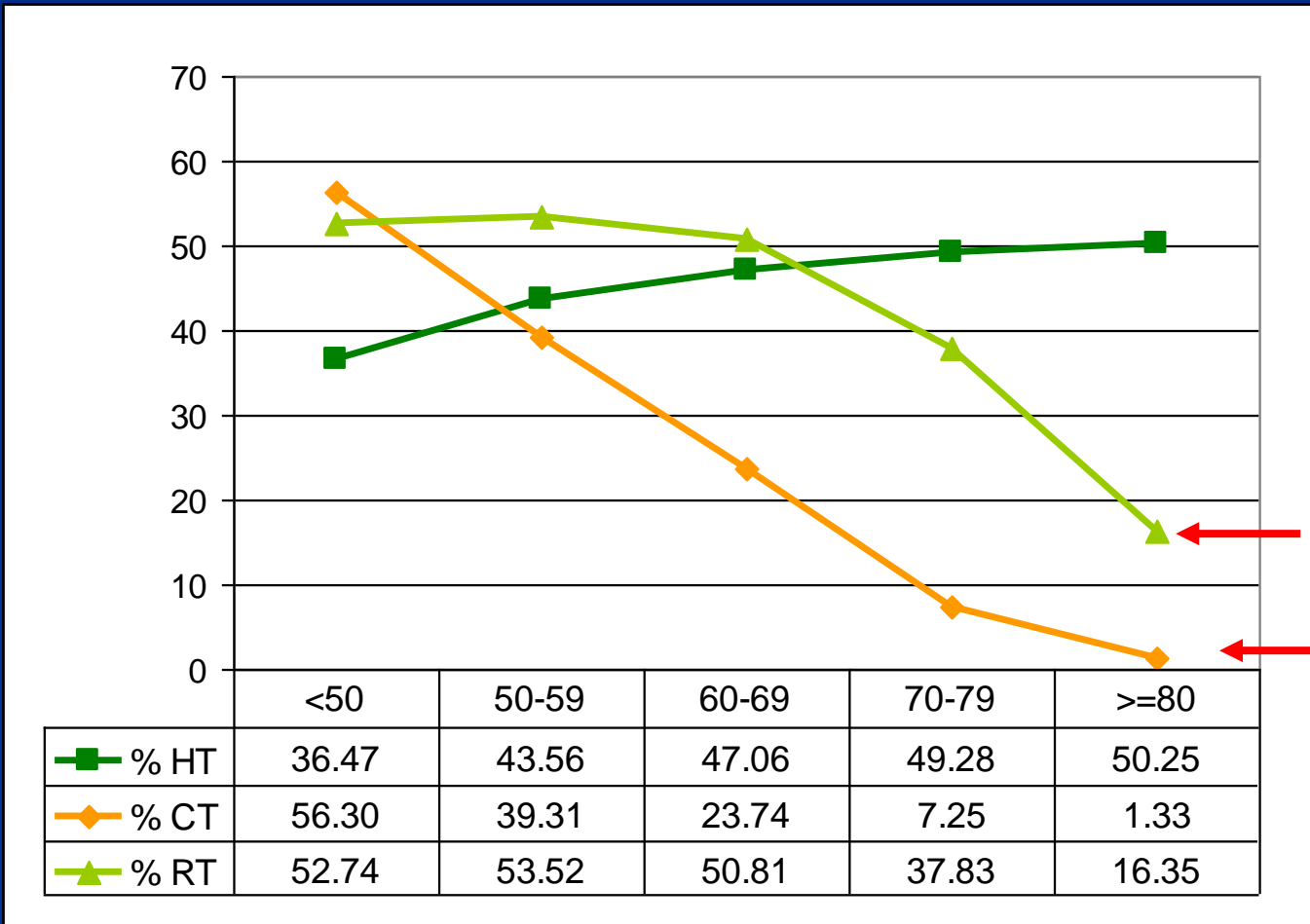
Radiotherapy (local or site unknown) following Breast Conservation Surgery for Invasive Breast Cancer





Variation in adjuvant treatment with age

15,166
invasive
cancers

UK West
Midlands



UNDERTREATMENT OF THE ELDERLY

| Report | Year | No surgery | 5 yr survival | 10 yr survival |
|---|-----------|-----------------------------|--------------------------|--|
| UK 2 nd National cancer report | 2007 | 10% 65-74yrs 26% 80 yrs> | 86% <50yrs 62% >80yrs | |
| SEER JCO 2011 | 1980-1997 | | | 50-64yrs  15% ≥ 75yrs  7.5% |

UK NATIONAL AUDIT 2011

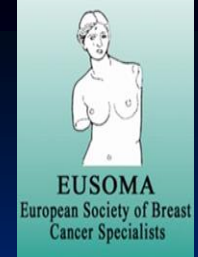
Headline results

- 21% reconstruction rate post MX
- 18% readmitted for complications
- Only 50% satisfied with pre op information

PROMS findings

- Only 59% satisfied with unclothed appearance (immediate reconstruction)
- 76% satisfied with unclothed app (delayed)

EUSOMA



EUROPEAN JOURNAL OF CANCER 46 (2010) 2344–2356



ELSEVIER

available at www.sciencedirect.com



journal homepage: www.ejconline.com



Position Paper

Quality indicators in breast cancer care

M. Rosselli Del Turco ^{a,*}, A. Ponti ^b, U. Bick ^c, L. Biganzoli ^d, G. Cserni ^e, B. Cutuli ^f,
T. Decker ^g, M. Dietel ^c, O. Gentilini ^h, T. Kuehn ^k, M.P. Mano ^j, P. Mantellini ⁱ, L. Marotti ^a,
P. Poortmans ^l, F. Rank ^m, H. Roe ⁿ, E. Scaffidi ^h, J.A. van der Hage ^o, G. Viale ^p, C. Wells ^q,
M. Welnicka-Jaskiewicz ^r, Y. Wengstöm ^s, L. Cataliotti ^t

Summary Table of Quality Indicators in Breast Cancer Care

| Indicator | Level of evidence | Mandatory/ Recomm. | Minim/ Target standard |
|---|-------------------|--------------------|------------------------|
| 1. Completeness of clinical and imaging diagnostic work-up (Proportion of women with breast cancer who pre-operatively underwent mammography, ultrasound and physical examination) | III | M | 90% 95% |
| 3. Proportion of women with breast cancer (invasive or in situ) who had a pre-operative definitive diagnosis (B5 or C5) | III | M | 80% 90% |
| 4b Proportion of invasive cancer cases with primary surgery, for which the following prognostic/predictive parameters have been recorded: histological type, grading, ER & PR, HER 2, pathological stage (T and N), size in mm for the invasive component, peritumoral vascular invasion, distance to nearest radial margin | II | M | 95% 98% |
| <i>Surgery and loco-regional treatment</i> | | | |
| 8. Multidisciplinary discussion (proportion of cancer patients to be dicussed) | IV | M | 90% 99% |
| 9. c Proportion of patients (invasive cancers) and a clinically negative axilla (+US ±FNA/CNB) who had sentinel lymph-node biopsy | II | M | 90% 95% |
| 9d Proportion of patients with invasive cancer and axillary clearance performed with at least 10 lymph nodes examined | III | M | 95% 98% |

QUALITY INDICATORS BC SURGERY

- MDT discussion (90%)- **IV**
- 1 operation (80)- **III**
- SNB in Negative axilla (90)- **II**

Associated with surgery

- Post op RT after WLE (90)- **I**
- Post MX RT after Ax nodes pos (90)- **I**
- Adjuvant chemo/hormone therapy (90) -**I**

EUSOMA Network web data system

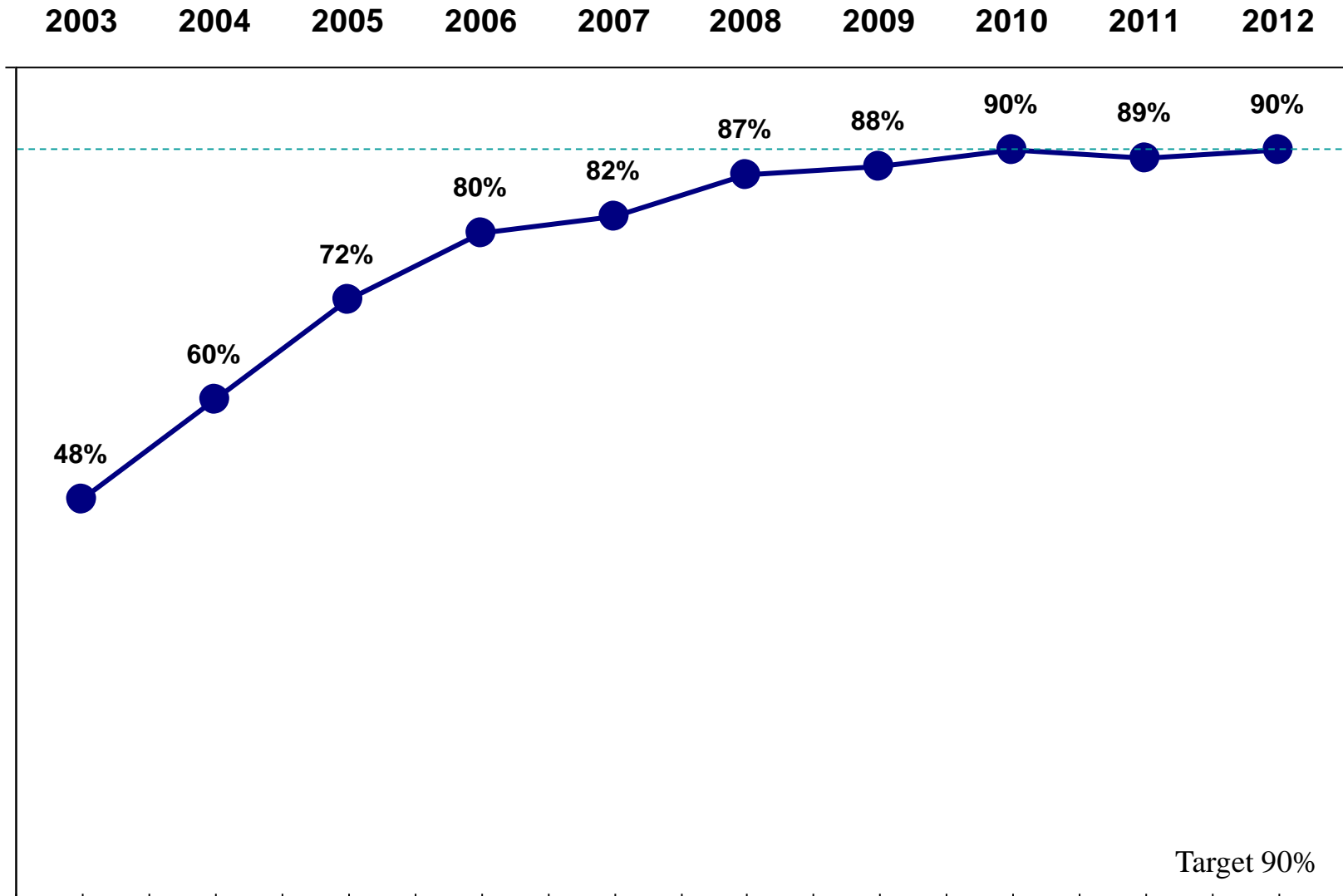
Quality indicators 2003-2012 in certified Units

EUSOMA database – 48 units – 43256 invasive cancers

| | | | | | | | | | |
|----|---|---------------|---|--------------|---|--------------------|-------|------|------|
| 1 | Cancers with a pre-operative diagnosis (B5 or C5) | 32438 / 38989 | = | 83.2% | ✗ | 1523 miss. (3.8%) | 32438 | 1523 | 6551 |
| 2 | Invasive ca with hist.type, grading, ER/PR, stage & size recorded | 33085 / 35794 | = | 92.4% | ✗ | 0 miss. | 33085 | | 2709 |
| 3 | Non-invasive ca with size, hist.pattern & grading recorded | 3778 / 4794 | = | 78.8% | ✗ | 0 miss. | 3778 | | 1016 |
| 4 | Invasive ca with axillary clearance with >= 10 LNs examined | 13119 / 14922 | = | 87.9% | ✗ | 613 miss. (3.9%) | 13119 | 613 | 1803 |
| 5 | M0 invasive ca receiving postoperative RT after BCT | 19609 / 20721 | = | 94.6% | ✗ | 2612 miss. (11.2%) | 19609 | 2612 | 1112 |
| 6 | Invasive ca <= 3 cm (incl. DCIS component) treated with BCT | 19612 / 24502 | = | 80% | ✓ | 743 miss. (2.9%) | 19612 | 743 | 4890 |
| 7 | Non-invasive ca <= 2 cm treated with BCT | 2245 / 2668 | = | 84.1% | ✓ | 151 miss. (5.4%) | 2245 | 151 | 423 |
| 8 | DCIS with no axillary clearance | 4030 / 4308 | = | 93.5% | ✗ | 27 miss. (0.6%) | 4030 | 27 | 278 |
| 9 | Endocrine sensitive invasive ca receiving HT | 22994 / 24324 | = | 94.5% | ✓ | 6481 miss. (21%) | 22994 | 6481 | 1330 |
| 10 | ER- (T > 1 cm or N+) invasive ca receiving adjuvant CT | 3670 / 4035 | = | 91% | ✓ | 500 miss. (11%) | 3670 | 500 | 365 |
| 11 | Invasive ca receiving just 1 operation (excl. reconstruction) | 28518 / 35521 | = | 80.3% | ✗ | 55 miss. (0.2%) | 28518 | 55 | 7003 |
| 12 | DCIS receiving just 1 operation (excl. reconstruction) | 2775 / 4455 | = | 62.3% | ✗ | 3 miss. (0.1%) | 2775 | 3 | 1680 |
| 13 | Invasive ca pN0 not receiving axillary clearance (SLN only) | 16439 / 21549 | = | 76.3% | ✗ | 7 miss. (0%) | 16439 | 7 | 5110 |

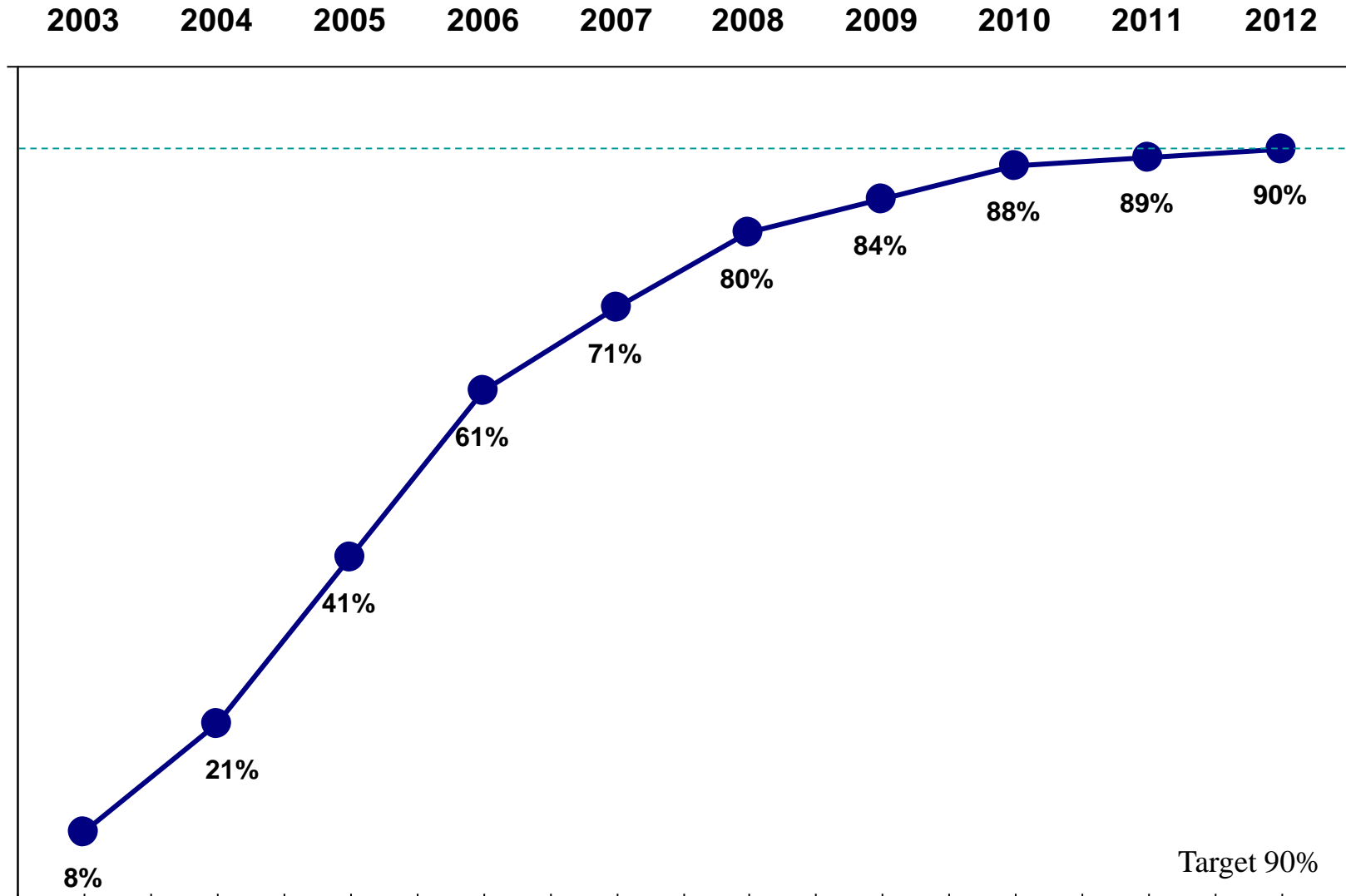
EUSOMA Network web data system

1 - Cancers with a pre-operative diagnosis (B5 or C5)



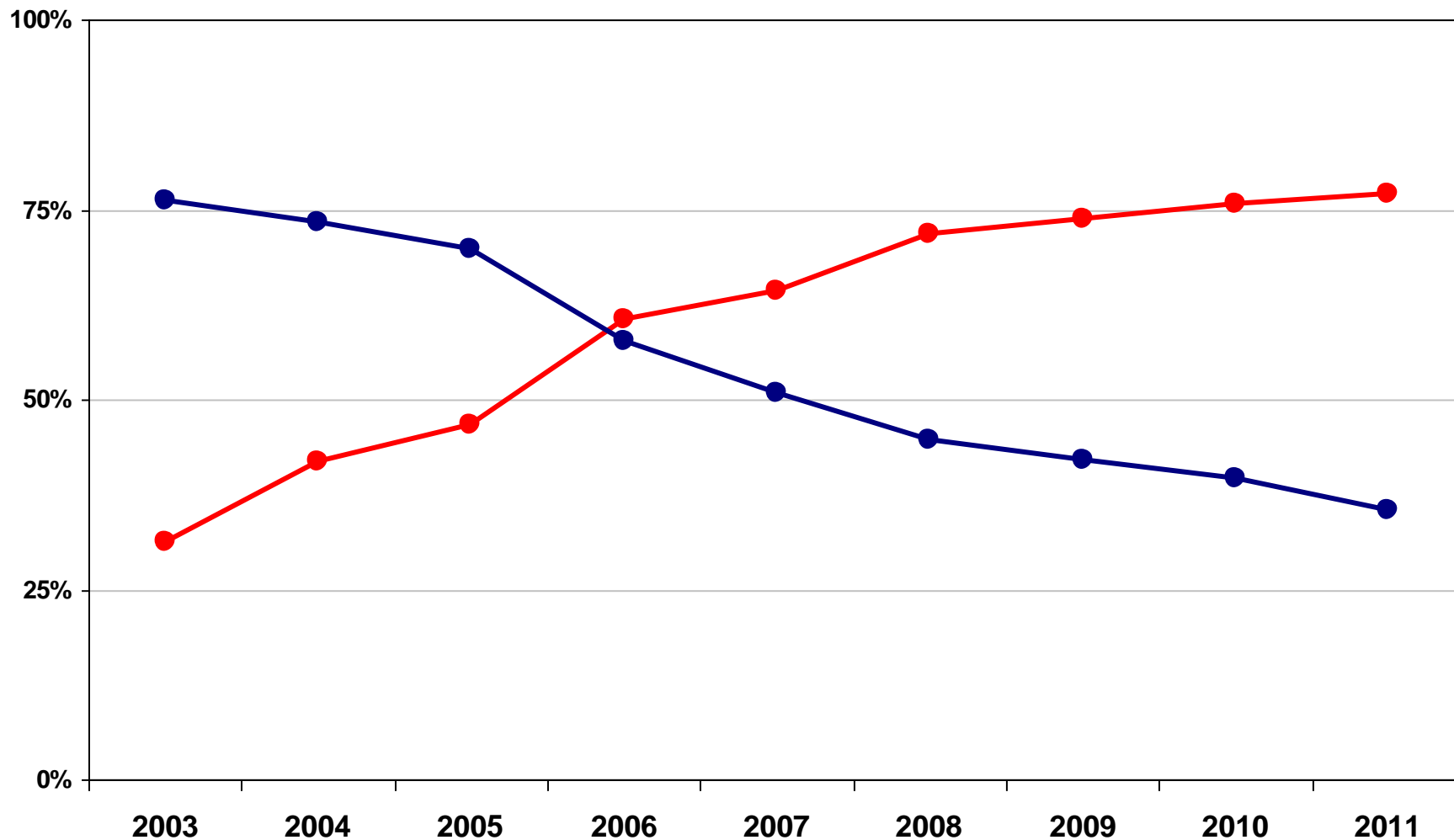
EUSOMA Network web data system

13 - SLN only in pN0



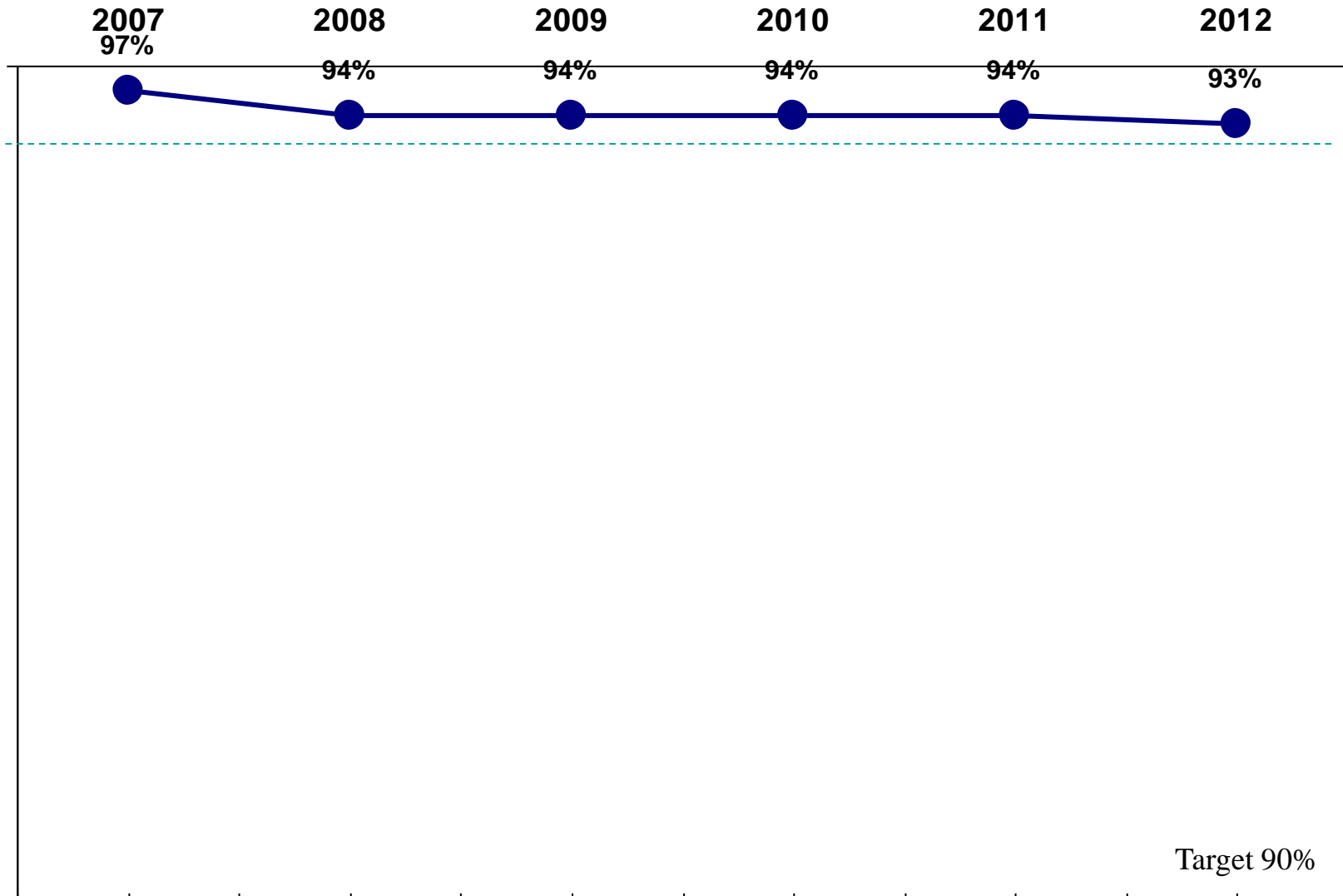
EUSOMA database – 48 units – 43256 invasive cancers

% **SLNB** & **ALND** trend across years



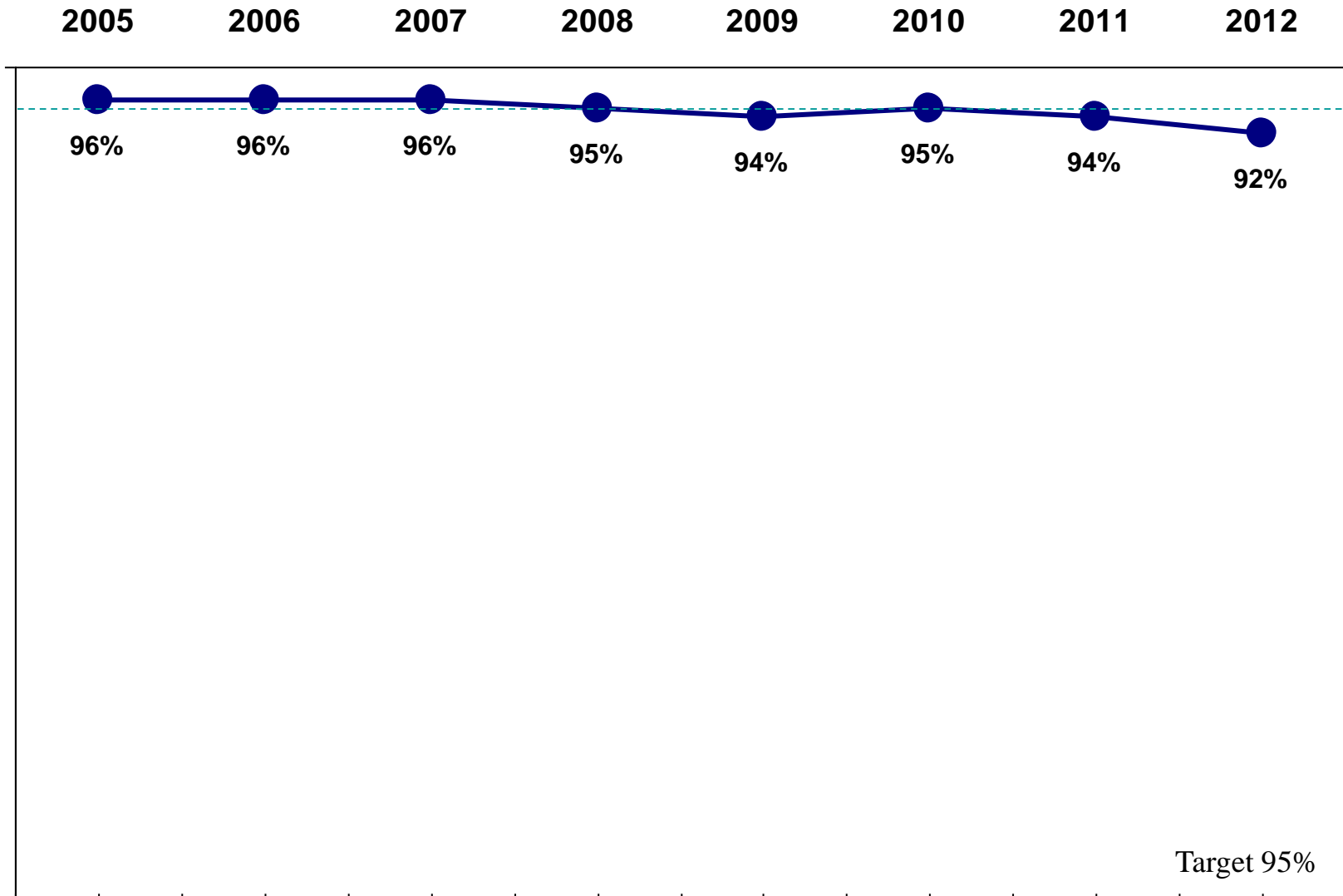
EUSOMA Network web data system

9 – Endocrine sensitive invasive ca. receiving HT



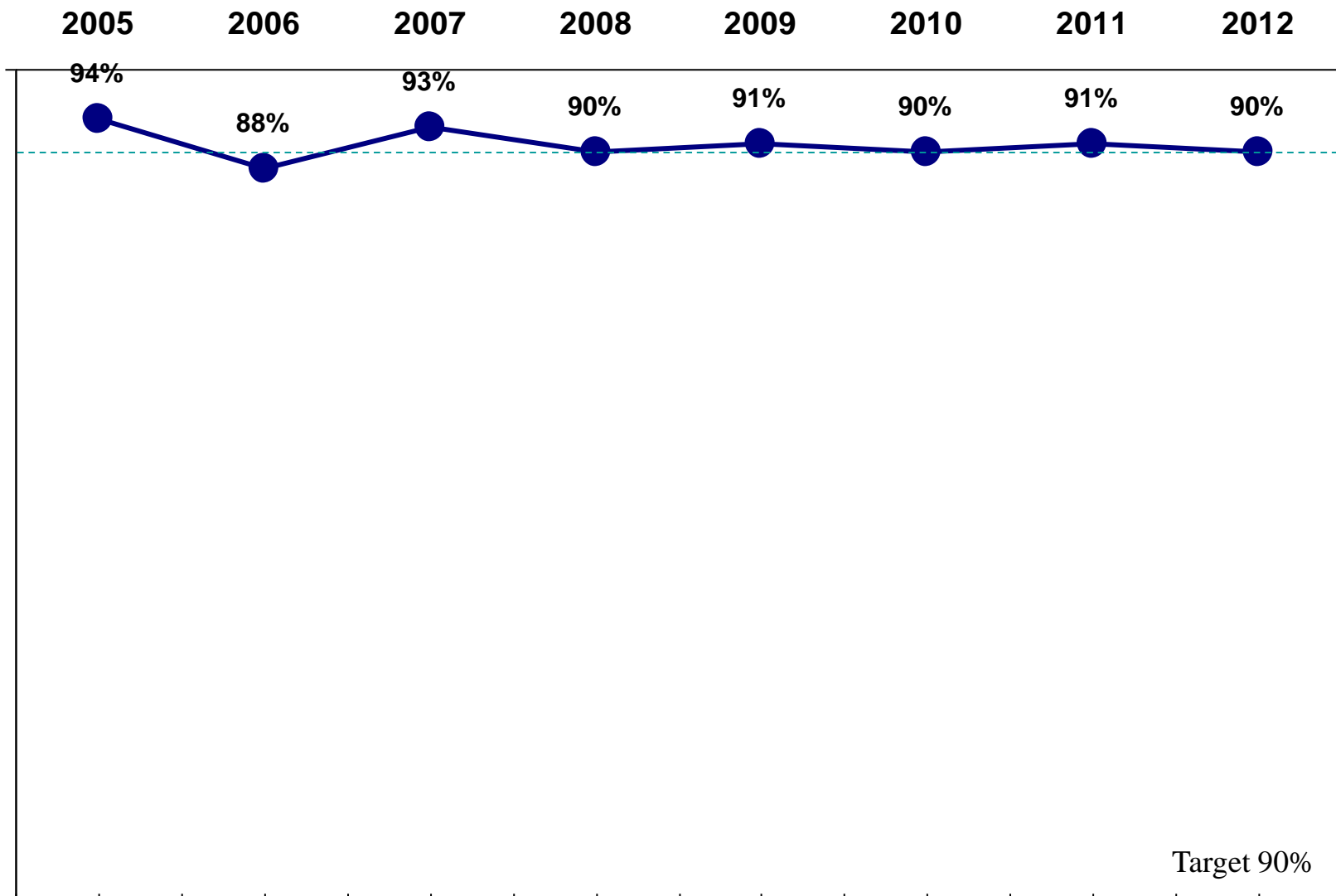
EUSOMA Network web data system

5 - M0 invasive ca receiving postop. RT after BCT



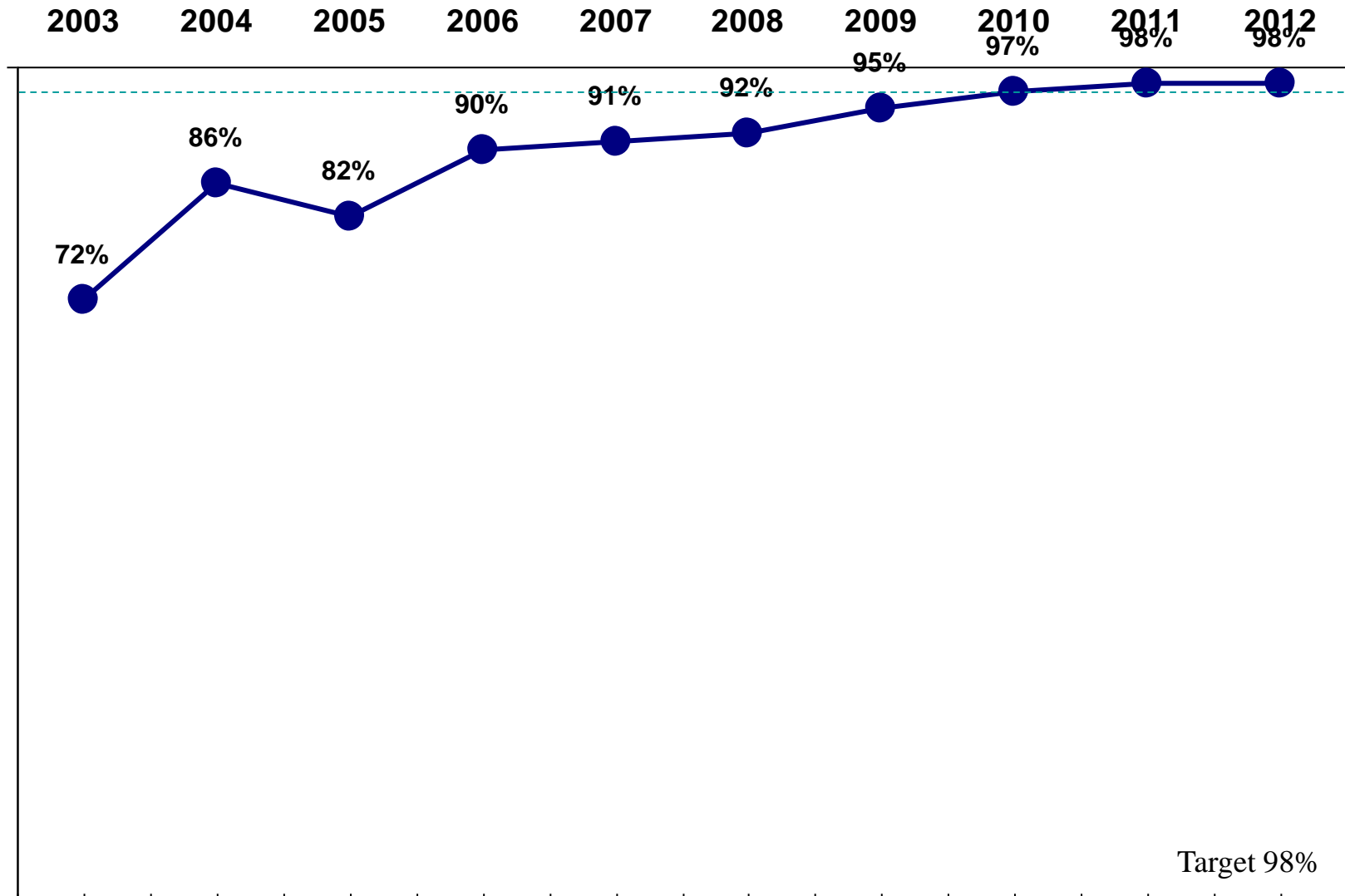
EUSOMA Network web data system

10 – ER- (T>1cm or N+) Invasive ca receiving adjuvant CT



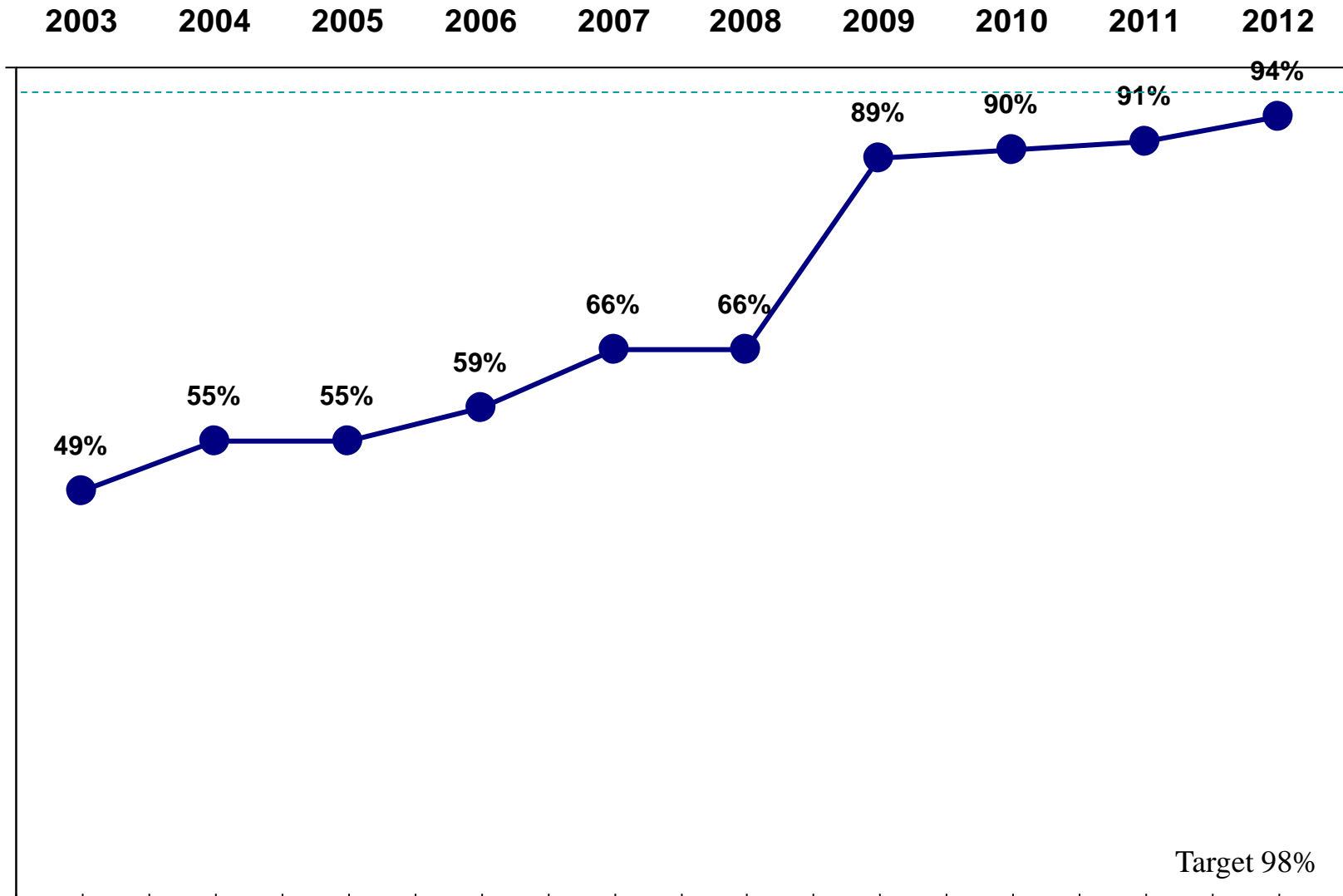
EUSOMA Network web data system

8 – DCIS with no axillary clearance



EUSOMA Network web data system

3 – DCIS with main histopathology parameters recorded



WHY IS ACCREDITATION NEEDED?

- Large variations in practice even when good evidence is available
- These variations are confusing for patients and likely lead to poor outcomes for some patients
- Variations in treatment not based on evidence are not cost efficient and increase patient complications

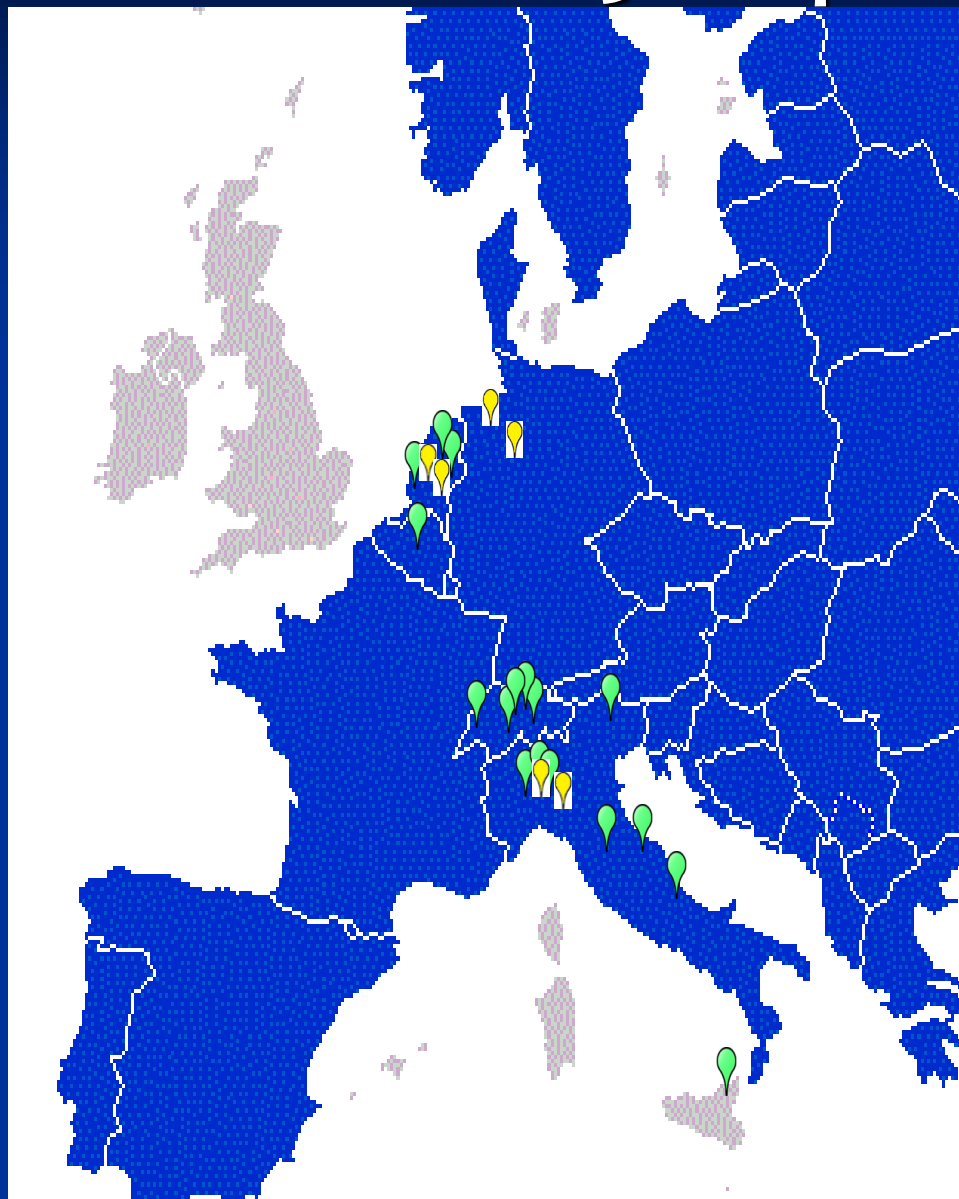
« European State of Art » 13th April 2015



Centres
in process



Certified
Centres



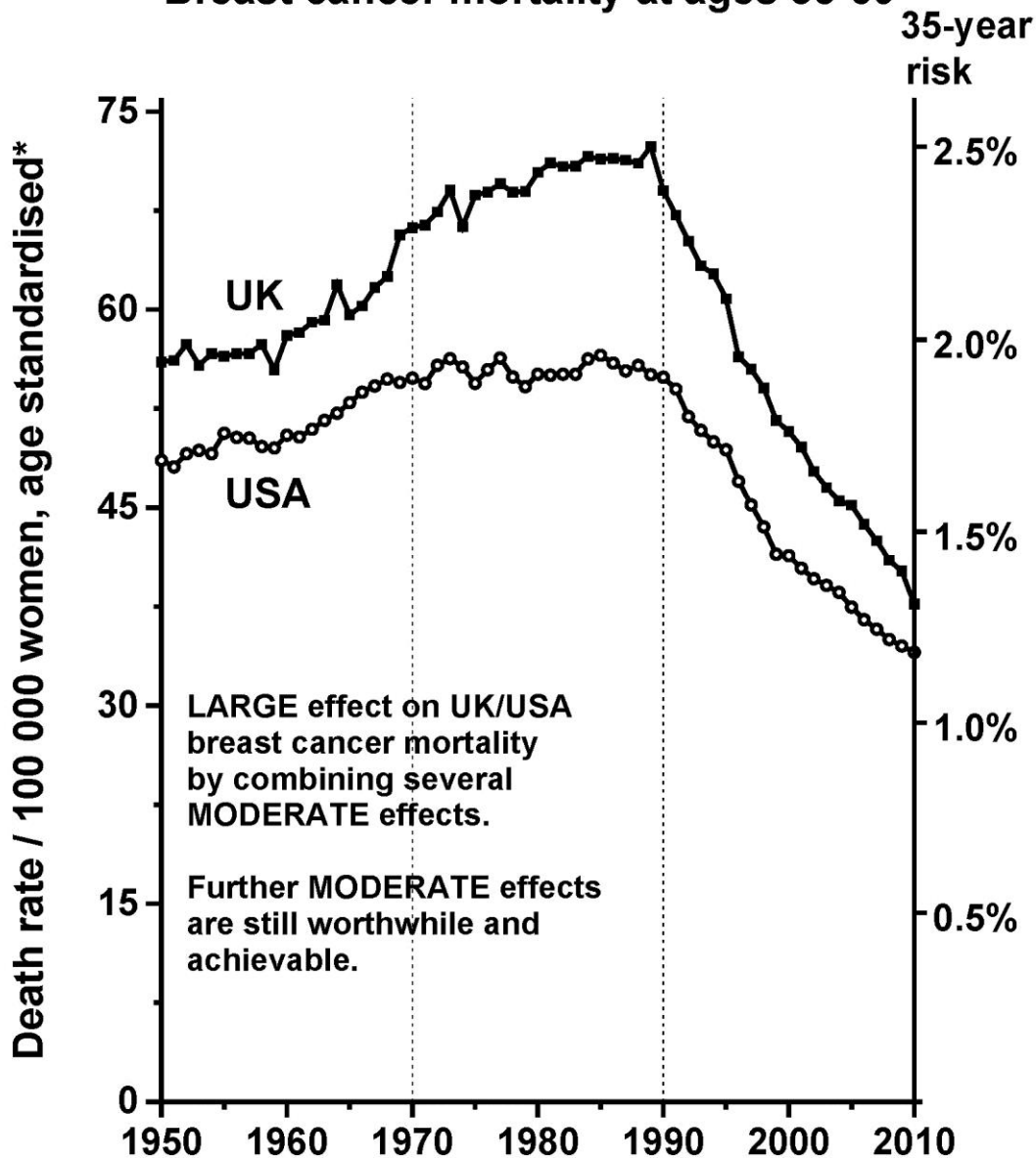
THE FUTURE

- European Commission via JRC (joint research centre based in Ispra, Italy) will manage a 3yr programme to update European Breast Guidelines and produce an accreditation plan to be used across all European Breast Centres according to European Parliament resolutions

Info at JRC Science hub

<https://ec.europa.eu/jrc/en/research-topic/healthcare-quality>

UK and USA 1950–2010: Breast cancer mortality at ages 35-69



*Mean of annual rates in the seven component 5-year age groups

WHO (& 2009–10 US NCHS) mortality and UN population estimates

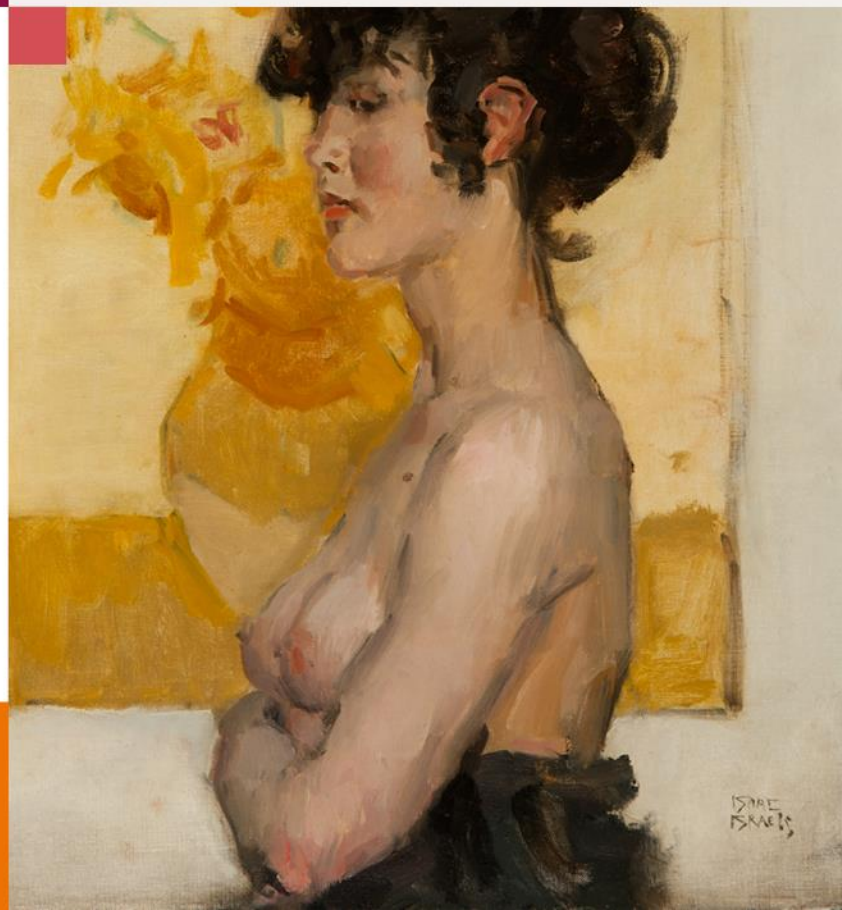
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