# False-positive results in mammographic screening in Europe

## A literature review and a survey

## of service screening programmes

Solveig Hofvind,

Bologna, January 30, 2014

ORIGINAL ARTICLE

# False-positive results in mammographic screening for breast cancer in Europe: a literature review and survey of service screening programmes

**Solveig Hofvind, Antonio Ponti, Julietta Patnick, Nieves Ascunce, Sisse Njor, Mireille Broeders, Livia Giordano, Alfonso Frigerio and Sven Törnberg The EUNICE Project and Euroscreen Working Groups (Members of the EUNICE Project and Euroscreen Working Groups listed at end of paper)**

*J Med Screen* 2012;**19 Suppl 1**:57–66
DOI: 10.1258/jms.2012.012083

# Definition
# False positive screening results

Findings on the screening mammograms →
recall for further assessment → negative / normal / benign

**Further assessment:**

Additional imaging and ultrasound

- no diagnosis of DCIS or breast cancer

Additional imaging, ultrasound and needle biopsy (FNAC, CNB, and/or SB/OB)

- no diagnosis of DCIS or breast cancer

Annals of Internal Medicine | Review

# Systematic Review: The Long-Term Effects of False-Positive Mammograms

Noel T. Brewer, PhD; Talya Salz, BS; and Sarah E. Lillie, MPH

**Background:** Although abnormal screening mammograms deleteriously affect the psychological well-being of women during the time immediately surrounding the tests, their long-term effects are poorly understood.

**Purpose:** To characterize the long-term effects of false-positive screening mammograms on the behavior and well-being of women 40 years of age or older.

**Data Sources:** English-language studies from the MEDLINE, Web of Science, EMBASE, CINAHL, PsycINFO, and ERIC databases through August 2006.

**Study Selection:** Studies were identified that examined the effects of false-positive results of routine screening mammography on women's behavior, well-being, or beliefs.

**Data Extraction:** Two investigators independently coded study characteristics, quality, and effect sizes.

**Data Synthesis:** 23 eligible studies ($n$ = 313 967) were identified. A random-effects meta-analysis showed that U.S. women who received false-positive results on screening mammography were more likely to return for routine screening than those who received normal results (risk ratio, 1.07 [95% CI, 1.02 to 1.12]). The effect was not statistically significant among European women (risk ratio, 0.97 [CI, 0.93 to 1.01]), and Canadian women were less likely to return for routine screening because of false-positive results (risk ratio, 0.63 [CI, 0.50 to 0.80]). Women who received false-positive results conducted more frequent breast self-examinations and had higher, but not apparently pathologically elevated, levels of distress and anxiety and thought more about breast cancer than did those with normal results.

**Limitations:** Correlational study designs, a small number of studies, a lack of clinical validation for many measures, and possible heterogeneity.

**Conclusions:** Some women with false-positive results on mammography may have differences in whether they return for mammography, occurrence of breast self-examinations, and levels of anxiety compared with women with normal results. Future research should examine how false-positive results on mammography affect other outcomes, such as trust and health care use.

*Ann Intern Med.* 2007;146:502-510. www.annals.org
For author affiliations, see end of text.

**Conclusions:** Some women with false-positive results on mammography may have differences in whether they return for mammography, occurrence of breast self-examinations, and levels of anxiety compared with women with normal results. Future research should examine how false-positive results on mammography affect other outcomes, such as trust and health care use.

European Journal of Cancer (2012) xxx, xxx–xxx

Available at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.ejconline.com

# Recall mammography and psychological distress

Inger Schou Bredal [a,*], Rolf Kåresen [a], Per Skaane [b], Kari Sletten Engelstad [c], Øivind Ekeberg [d]

**CONCLUDING STATEMENT:**

Recall after mammography was associated with transiently increased anxiety. Four weeks after screening, the level of anxiety was the same and depression was lower compared with the general female Norwegian population. The women were almost unanimously satisfied with their participation in the screening, would participate again and would recommend other women to participate.

# Risk of false positive screening results

Recall rate

- Age groups included
- Screening interval
- One or two views
- Interpretation procedure (single vs double reading, CAD etc)
- Use of short term follow-up
- Compliance in the program

# Risk of false positive screening results

Methodological issues

- The number of screening rounds with obervational data
- Independence in the screening results between the screening rounds?

# False positive screening results

## European studies

### Cumulative risk of a false positive screening result

Women aged 50-69 years
As of 2011 – four studies: three papers and one letter to editor

| | | |
|---|---|---|
| Hofvind et al. | 2004 | Norway |
| Njor et al. | 2007 | Fyn, Denmark, Cph, Denmark |
| Salas et al. | 2011 | Spain |
| Puliti et al.* | 2011 | Italy |

*letter to editor

# False positive screening results

## European studies

### Cumulative risk of a false positive screening result

| | | | Screening rounds | n |
|---|---|---|---|---|
| Hofvind et al. | 2004 | Norway | 3 | 83 416 |
| Njor et al. | 2007 | Fyn, Denmark, | 5 | 21 261 |
| | | Cph, Denmark | 9 | 9 039 |
| Salas et al. | 2011 | Spain | 6 | 251 275 |
| Puliti et al.* | 2011 | Italy | 7 | 28 500 |

*letter to editor

# False positive screening results

## European studies

### Cumulative risk of a false positive screening result

| | | | Screening rounds | n |
|---|---|---|---|---|
| Hofvind et al. | 2004 | Norway | 3 | 83 416 |
| Njor et al. | 2007 | Fyn, Denmark, | 5 | 21 261 |
| | | Cph, Denmark | 9 | 9 039 |
| Salas et al. | 2011 | Spain | 6 | 251 275 |
| Puliti et al.* | 2011 | Italy | 7 | 28 500 |

*letter to editor

# False positive screening results

## European studies

### Cumulative risk of a false positive screening result

| | | | All recalls |
|---|---|---|---|
| Hofvind et al. | 2004 | Norway | 20.8% |
| Njor et al. | 2007 | Fyn, Denmark, | 9.9% |
| | | Cph, Denmark | 22.6% |
| Salas et al. | 2011 | Spain | 20.4% |
| Puliti et al.* | 2011 | Italy | 15.2% |
| | | | 19.7% |

*letter to editor, estimated on seven screening rounds

# False positive screening results

## European studies

### Cumulative risk of a false positive screening result

| | | | All recalls | Needle biopsy |
|---|---|---|---|---|
| Hofvind et al. | 2004 | Norway | 20.8% | 6.3% |
| Njor et al. | 2007 | Fyn, Denmark, | 9.9% | - |
| | | Cph, Denmark | 22.6% | - |
| Salas et al. | 2011 | Spain | 20.4% | 1.8% |
| Puliti et al.* | 2011 | Italy | 15.2% | 1.8% |
| | | | 19.7% | 2.9% |

*letter to editor, estimated on seven screening rounds

Roman et al, 2013; From Norway:
231,310 women, 50-51 at first mammography; 20.0% 4.1%

The New England
Journal of Medicine



VOLUME 338 APRIL 16, 1998 NUMBER 16

30%

## TEN-YEAR RISK OF FALSE POSITIVE SCREENING MAMMOGRAMS AND CLINICAL BREAST EXAMINATIONS

JOANN G. ELMORE, M.D., M.P.H., MARY B. BARTON, M.D., M.P.P., VICTORIA M. MOCERI, PH.C., SARAH POLK, B.A., PHILIP J. ARENA, M.D., AND SUZANNE W. FLETCHER, M.D.

**ABSTRACT**

***Background*** The cumulative risk of a false positive result of a breast-cancer screening test is unknown.

***Methods*** We performed a 10-year retrospective cohort study of breast-cancer screening and diagnostic evaluations among 2400 wome
years old at study entry. Man
breast examinations that were i
minate, aroused a suspicion of
recommendations for additiona
whom breast cancer was not
next year were considered to b

MAMMOGRAPHY and clinical breast examination are the two principal means of screening for breast cancer.[1] The effectiveness of breast-cancer screening has been well documented in eight randomized

> 50%

Annals of Internal Medicine | ORIGINAL RESEARCH

# Cumulative Probability of False-Positive Recall or Biopsy Recommendation After 10 Years of Screening Mammography

## A Cohort Study

Rebecca A. Hubbard, PhD; Karla Kerlikowske, MD; Chris I. Flowers, MD; Bonnie C. Yankaskas, PhD; Weiwei Zhu, MS; and Diana L. Miglioretti, PhD

**Background:** False-positive mammography results are common. Biennial screening may decrease the cumulative probability of false-positive results across many years of repeated screening but could also delay cancer diagnosis.

**Objective:** To compare the cumulative probability of false-positive results and the stage distribution of incident breast cancer after 10 years of annual or biennial screening mammography.

**Design:** Prospective cohort study.

and 41.6% (CI, 40.6% to 42.5%) with biennial screening. Cumulative probability of false-positive biopsy recommendation was 7.0% (CI, 6.1% to 7.8%) with annual and 4.8% (CI, 4.4% to 5.2%) with biennial screening. Estimates were similar when screening began at age 50 years. A non–statistically significant increase in the proportion of late-stage cancers was observed with biennial compared with annual screening (absolute increases, 3.3 percentage points [CI, −1.1 to 7.8 percentage points] for women age 40 to 49 years and 2.3 percentage points [CI, −1.0 to 5.7 percentage

# Recall rates

## U.S. – U.K

Crude 50-69 years, subsequent exams, 1996-1999:
8.0% in the U.S.
3.6% in the UK

## Vermont – Norway

Age-adjusted 50-69 years, subsequent exams, 1997-2003:
9.8% in Vermont, U.S.
2.7% in Norway

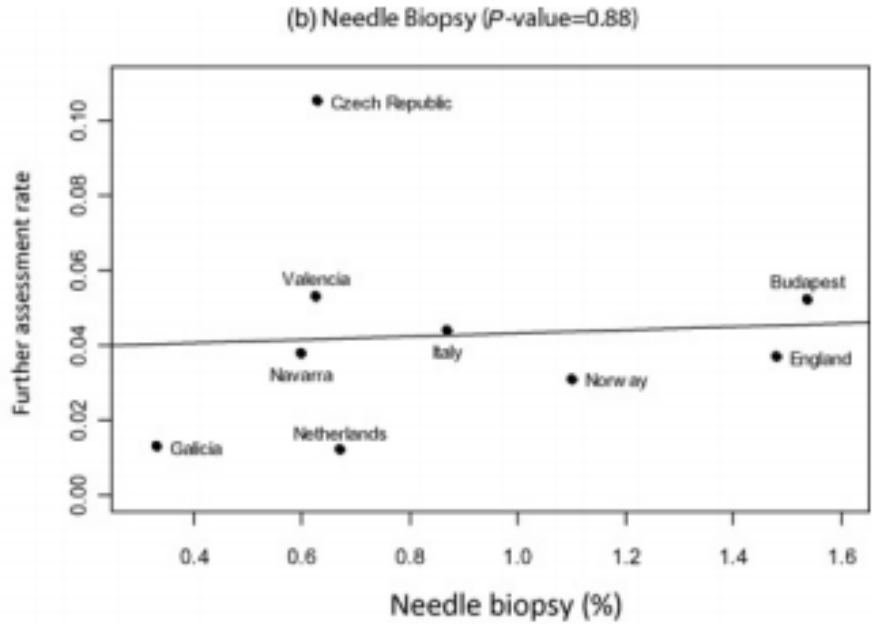
Smith-Bindman et al, JAMA 2003
Hofvind et al, J Natl Cancer Inst 2007

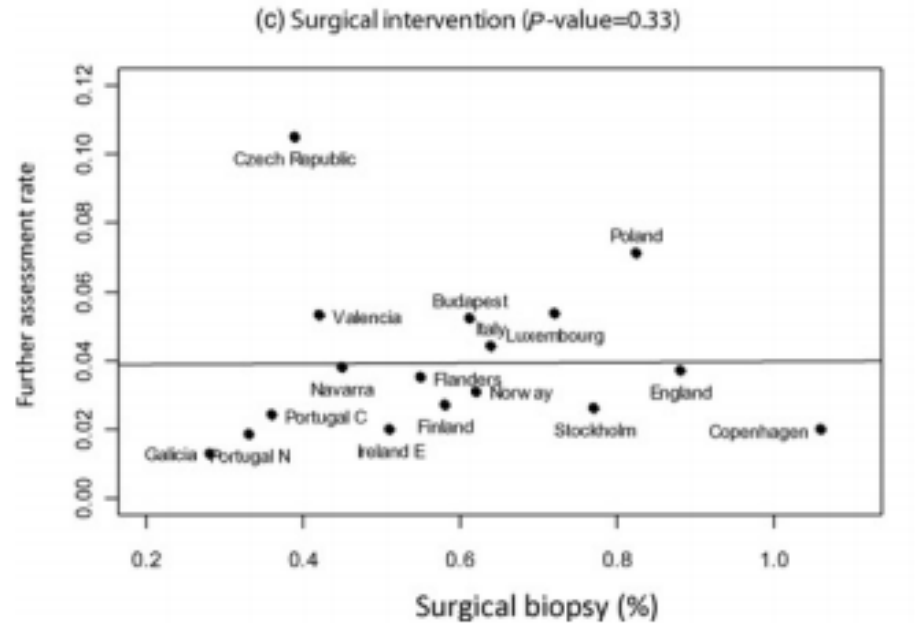
# From the EUNICE project

Subsequent screens

| | Period | FA (%) | Needle biopsy (%) |
|---|---|---|---|
| Belgium Flanders | 2005 | 3.5 | – |
| Denmark | 2005 | 2.0 | – |
| Copenhagen | | | |
| Estonia† | 2005–2006 | – | – |
| Finland | 2005 | 2.7 | – |
| Hungary | 2005 | 5.2 | 1.5 |
| Budapest§ | | | |
| Italy | 2005 | 4.4 | 0.9 |
| Luxembourg | 2004–2005 | 5.3 | – |
| Norway | 2005–2006 | 3.1 | 1.1 |
| Poland | 2007 | 7.1 | – |
| Portugal centre | 2005 | 2.4 | – |
| Portugal north | 2005 | 1.9 | – |
| Republic of Ireland** | 2005–2006 | 2.0 | – |
| Spain Galicia†† | 2005–2006 | 1.3 | 0.3 |
| Spain Navarra | 2005–2006 | 3.8 | 0.6 |
| Spain Valencia | 2005–2006 | 5.3 | 0.6 |
| Sweden Stockholm | 2005 | 2.6 | – |
| Switzerland Fribourg | 2005 | – | – |
| UK England‡‡ | 2005–2007 | 3.7 | 1.5 |

From the EUNICE project



A recall for further assessment with negative/benign outcome

≠

an unnesessary assessment

# Summing up

About 20 in 100 women will experience a false positive screneing result during their screening period (10 exams every two years, from age 50)

- 17 additional imaging/ultrasound
- 3 a FNAC/biopsy

Negative consequenses of a false positive screening result

- Waiting time from assessment to diagnosis associated with anxiety
- Scar tissue after open surgical biopsies