

RINNA- JA EMAKAKAELAVÄHI KONVERENTS

Tallinna, 30. Aprill 2010

Eesti Vähiliit



Turun yliopisto  
University of Turku

# Optimization of Breast Cancer Screening

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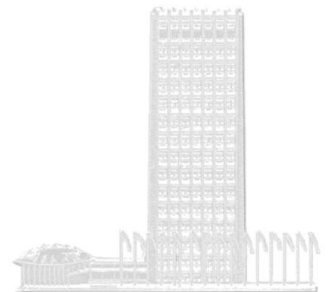


World Health Organization



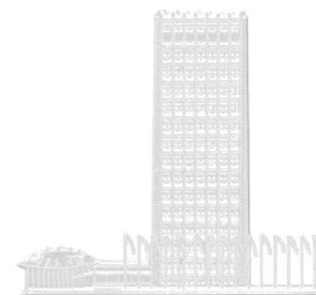
# A Fair Comparison of the Harms and Benefits of Screening

- Harms of screening vs.
- Harms of not screening
- Harms of mammography
- Harms of no mammography
- Benefits of screening vs.
- Benefits of not screening
- Benefits of mammography
- Benefits of no mammography



# A Fair Comparison of the Harms and Benefits of Screening

- Harms of screening vs.
  - Anxiety, operations
  - Harms of mammography
  - Radiation, extra procedures
  - Benefits of screening vs.
  - ~30% mortality decrease
  - Benefits of mammography
  - ~40-45% mortality decrease
- Harms of not screening
  - Anxiety, operations
  - Harms of no mammography
  - Higher breast cancer mortality
  - Benefits of not screening
  - Pension money “saved”
  - Benefits of no mammography

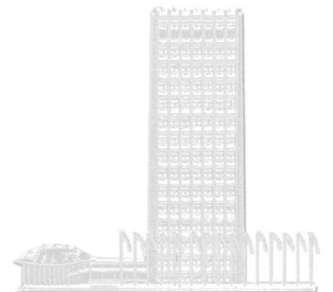


# Overdiagnosis versus Overtreatment

- So-called overdiagnosis is an integral part of the screening process
- The greatest harms of overdiagnosis are overtreatment



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# Prevention of an early death from breast cancer involves a chain of events

- A chain is no stronger than its weakest link
- The weakest links do the most damage to the process of early detection
- Optimization of the process needs to be concerned with each of the links

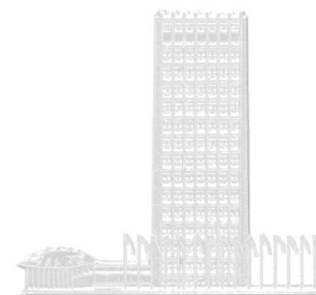


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[www.1800njdiver.com/MarineServSite/moorings.html](http://www.1800njdiver.com/MarineServSite/moorings.html)

## *Sequence of Steps in Quality-assured Screening Programme Implementation*

1. Comprehensive planning of screening process (professional performance, organisation and financing, quality assurance)
2. Preparation of all components of screening process to perform at requisite high level
3. Expert verification of adequacy of preparations
4. Pilot testing and modification, if necessary, of all screening systems and components, including QA
5. Expert verification of adequacy of pilot performance
6. Transition of pilot to service screening and geographically phased programme rollout in other regions of the country
7. Intensive monitoring of programme rollout for early detection and correction of quality problems



# IARC Handbook of Cancer Prevention Volume 7

- <http://www.iarc.fr/en/publications/pdfs-online/prev/index.php>

- 

2002; 229 pages  
ISBN 92 832 3007 8

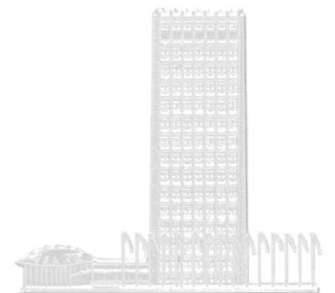
“There is sufficient evidence for the efficacy of screening women aged 50-69 years by mammography as the sole screening modality in reducing mortality from breast cancer.”

“There is limited evidence for the efficacy of screening women aged 40-49 years by mammography as the sole screening modality in reducing mortality from breast cancer.”

“There is inadequate evidence for the efficacy of screening women under 40 or over 69 years by mammography in reducing mortality from breast cancer.”



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**Participants and members of the secretariat:**

*First row from left: T. Kuroishi, M. Blettner, F. Bianchini, M. Hakama, P. Dean, B. Armstrong, P. Pisani, S. Robles, J. Thévenoux. Middle row: E. Suonio, K. Straif, C. Partensky, S. Taplin, E. Hesselting, C. Baines, J. Hall, I. Andersson, G. Welch, D. Thomas, N. Segnan, A. B. Miller, A. Kriker, H. Sancho-Garnier, S. Redman, L. Nyström. Back row: H. Vainio, S. Narod, H. de Koning, A. Ullrich, J. Tyczynski, E. Waidpass-Vainio, N. Day, L. Irwig. (Participants missing from photo: V. Beral, I. Ellis and R. Blanks)*



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**Table 27. Efficacy of screening for breast cancer by mammography alone in women aged 50–69**

Trial	Enrollment (years/age)	Intervention (invitations to screening)	Population x 1000 (screened/control)	Breast cancer mortality per 100 000 person-years (number) (screened/control)	RR (95% CI)
Malmö I, Sweden	1976–78/50–69	4 in 8 years	16.8/16.8	47 (134)/57 (162)	0.84 (0.68–1.04)
Kopparberg, Swedish Two-county	1976–78/50–69	3 in 6 years	23.3/10.7	20 (93)/39 (83)	0.52 (0.39–0.70)
Östergötland, Swedish Two-county	1978–81/50–69	4 in 8 years	23.6/22.4	33 (117)/40 (137)	0.81 (0.64–1.03)
Stockholm, Sweden	1981–83/50–64	2 in 4 years	24.8/13.0	14 (48)/21 (37)	0.68 (0.44–1.04)
Göteborg, Sweden	1982–84/50–59	3 in 5 years	10.1/16.0	31 (40)/33 (67)	0.94 (0.62–1.43)
Finland	1987–89/50–64	2 in 4 years	89.9/68.9	16 (64)/21 (63)	0.76 (0.53–1.09)
<b>All trials</b>			<b>188.5/147.8</b>	<b>25 (496)/36 (549)</b>	<b>0.75 (0.67–0.85)</b>

Tests for heterogeneity between trials  $\chi^2_5 = 8.83$ ;  $p > 0.1$ ; not significant

IARC Handbooks of Cancer Prevention, Volume 7: Breast Cancer Screening

**Table 26. Efficacy of screening for breast cancer by mammography alone in women aged 40–49**

Trial	Enrollment (years/age)	Intervention (invitation to screening)	Population x 1000 (screened/control)	Breast cancer mortality per 100 000 person-years (number) (screened/control)	RR (95% CI)
Malmö I, Sweden	1976–78/45–49	4 in 8 years	4.0/4.1	34 (24)/45 (33)	0.74 (0.44–1.25)
Malmö II, Sweden	1978–90/43–49	4 in 8 years	9.6/8.2	26 (29)/38 (33)	0.65 (0.39–1.08)
Kopparberg, Swedish Two-county	1976–78/40–49	3 in 6 years	9.5/5.1	14 (26)/16 (18)	0.76 (0.42–1.40)
Östergötland, Swedish Two-county	1978–81/40–49	4 in 8 years	10.3/10.5	18 (31)/17 (30)	1.05 (0.64–1.71)
Stockholm, Sweden	1981–83/40–49	2 in 4 years	14.3/8.0	17 (34)/11 (13)	1.52 (0.80–2.88)
Göteborg, Sweden	1982–84/40–49	3 in 5 years	10.9/13.2	16 (22)/28 (46)	0.58 (0.35–0.96)
<b>All trials</b>			<b>58.6/49.1</b>	<b>19 (166)/24 (173)</b>	<b>0.81 (0.65–1.01)</b>

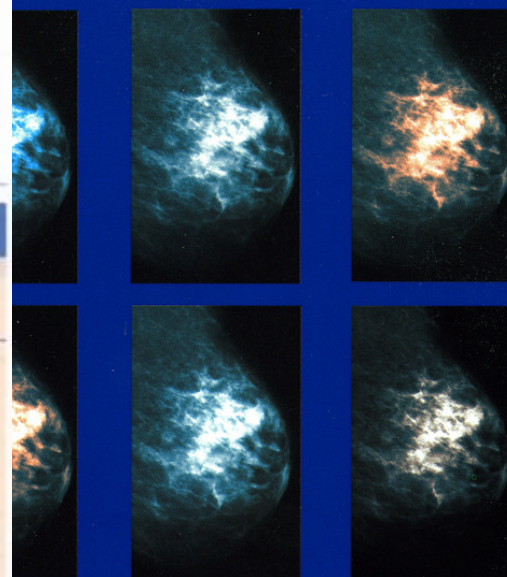
Tests for heterogeneity between trials  $\chi^2_5 = 7.34$ ;  $p > 0.1$ ; not significant

## Handbooks of Cancer Prevention



International Agency for Research on Cancer  
World Health Organization

## Breast Cancer Screening



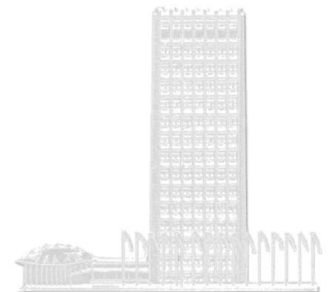
IARC Press  
2002

# The Chain of Events in Breast Cancer Screening

- Population registry
- Screening invitation, and re-invitation
- Positioning and exposing the image
- Image post-processing, archiving, ?CAD
- Image interpretation: double reading with consensus
- Normal/Recall with full diagnostic workup
- Preoperative multidisciplinary conference
- Preoperative localization, sentinel node injection, surgery, specimen radiography, pathology
- Postoperative multidisciplinary conference
- Adjuvant therapy when necessary
- Cancer registry

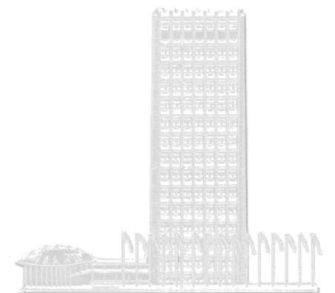


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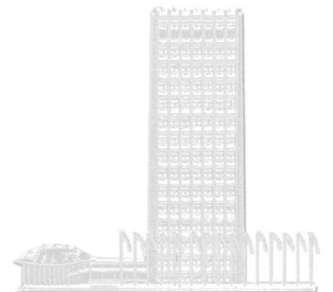
# Population registry

- Accurate and up-to-date
  - Birth date, address and telephone number
  - E-mail?
- 
- Change of address between screens
  - Foreigners
  - Individuals outside the registry or with no health insurance coverage



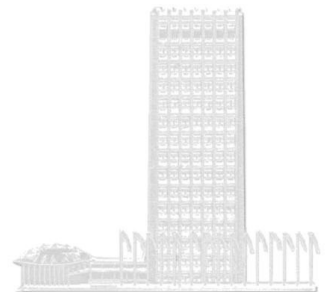
# Screening invitation, and re-invitation

- Computer-driven, by mail
- Telephone contact for a change in the appointment
- Re-invitation, preferably by telephone, if the woman does not attend
- Second re-invitation
- Invitation after two years – many change their minds and attend
- Appropriate age ranges for invitation



# Positioning and exposing the image

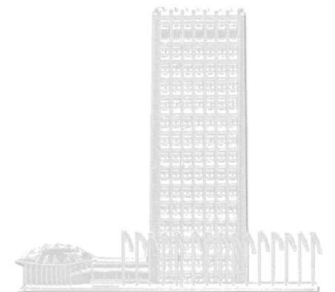
- Well-trained and responsible radiographers
- Need further training and supervision to produce consistently high quality images
- Not all are suited to this demanding task
- A good teacher and supervisor is crucial
- This is one of the strongest links in the chain
- Digital mammography is highly dependent on the quality of the image receptor
- CR vs. DR





# Image post-processing, archiving, ?CAD

- Post-processing done by the radiographers, but often on a low-resolution monitor
- This is a weak and poorly understood link in the imaging chain which deserves more attention
- Archiving – image transfer is often slow, expensive, sometimes unreliable
- CAD has yet to live up to its promises



# Image interpretation: double reading with consensus

- Need a minimum of two radiologists per center, available daily
- Training in clinical mammography is not sufficient – training in screening should be mandatory
- Independent double reading – if both radiologists call the case normal, a letter is automatically sent to the participant
- Either can request a consensus conference
- A decision can be delayed until previous images are available
- When there is a disagreement, the woman should be recalled and evaluated by the concerned radiologist



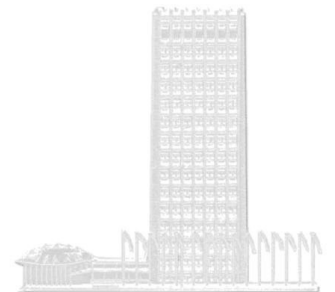
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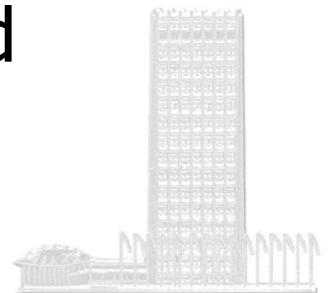
# Problems with double reading

- The second radiologist is not available
- The second radiologist does not participate in the evaluation of call-backs
- The second radiologist is too inexperienced or unskillful to be useful
- Either or both radiologists fail to learn from their mistakes
- Failure to monitor performance



## Normal/Recall with full diagnostic workup

- The normal diagnosis should be received within one week of the examination
- Recall invitations may take a few days longer, but the date of the recall examination should be very soon after the woman has been notified
- To develop and maintain competence as screeners, all screening radiologists must perform recall examinations, preferably on women they have recalled themselves
- This is a stressful situation for all concerned



# Normal/Recall with full diagnostic workup

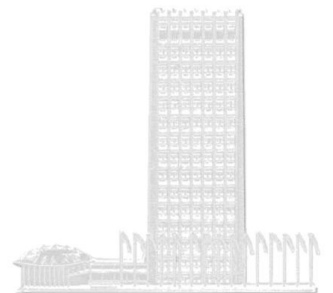
- Normally a direct lateral projection mammogram, microfocus magnification in CC and lateral views, breast ultrasound in most cases, and percutaneous core needle biopsy whenever indicated
- Cysts can usually be positively identified with ultrasound; some should be drained by fine needle aspiration, and pneumocystography is sometimes needed
- The majority of women recalled do not need biopsy – cysts and superposition of normal structures cause many callbacks
- Biopsied women are informed of the results within one week, and referred to the multidisciplinary center





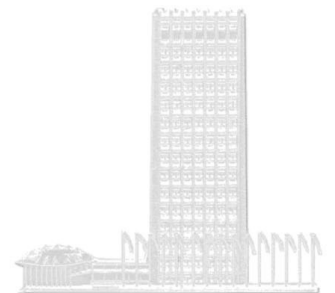
# Preoperative multidisciplinary conference

- To determine if further diagnostic procedures are necessary prior to surgery – such as repeat percutaneous biopsy, stereotactic biopsy, breast MRI, re-evaluation of the core needle biopsy samples, etc.
- To determine if multifocality is present so that repeat operation will not be necessary – for this purpose MRI has become increasingly important



# Preoperative localization, sentinel node injection

- Nonpalpable, screen-detected lesions are usually best localized by percutaneous injection of a radioactive isotope under ultrasound guidance
- Palpable lesions can also be better identified with ultrasound-guided isotope injection
- This also serves to identify the sentinel node
- Injecting the isotope using only palpation for guidance may cause the lesion to be missed by the surgeon, partially removed, or removed with insufficient margins



# Surgery

- Diagnosis should be preoperative – surgery should be therapeutic and definitive
- Earlier diagnosis through imaging has placed much of the responsibility for diagnosis in the hands and eyes of the radiologist
- Preoperative mapping of the full extent of the disease allows the surgeon to remove all malignant tissue in one definitive operation
- Insufficient margins or incomplete tumor removal are a sign of failure in the chain of events for which both the radiologist and surgeon are responsible



# Continuous monitoring of results

- Surgeons, radiologists and pathologists need to monitor their results to learn from their mistakes
- Errors can be forgiven only if one learns not to repeat the same error
- Errors need to be reviewed by all, so that all can learn to avoid them
- This is a painful process and opposed by many
- Whenever an error is noted, it should be discussed, the cause determined (if possible) and steps taken to prevent the same error from being repeated



# Specimen radiography and pathology

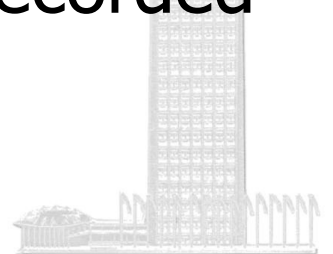
- Specimen radiography requires an enclosed microfocus X-ray device for magnified digital images at very high resolution
- Slicing the specimen into 4-5 mm thick slices and taking specimen radiographs of each slice further improves image resolution and assists the pathologist in mapping the full extent of the lesion
- Large size glass pathology slides of the specimen enable the pathologist to accurately determine disease extent and evaluate the full surgical margin
- Radiological-pathological correlation – a necessity!





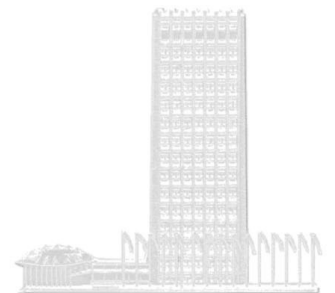
# Postoperative multidisciplinary conference

- Essential for good patient management
- Essential for monitoring of performance
- Essential for continuing education
- Time-consuming, may require many hours of preparation each week
- Participation should be obligatory for all screening radiologists, pathologists, surgeons and oncologists
- A coordinating nurse is essential
- The decisions reached for each patient are recorded



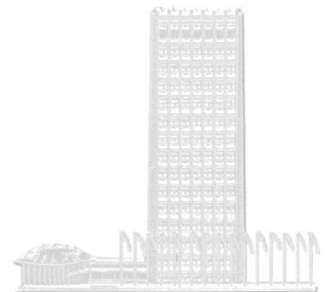
# Adjuvant therapy when necessary

- Adjuvant therapeutic regimens have been established for patients with larger cancers, but not directly for patients with smaller breast cancers
- Small screen-detected cancers have less need of adjuvant therapy
- Most cancers smaller than 1 cm have survival rates approaching 100% without adjuvant therapy
- Newer minimum size guidelines are needed to curtail overtreatment
- This should not be “cookbook medicine”



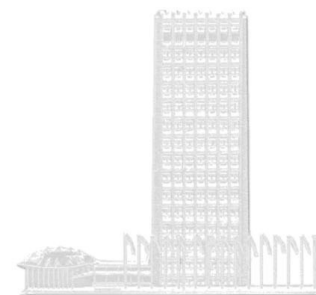
# Cancer registry

- Information collection can have many weak points, beginning with the individual(s) who fill out the forms
- Errors in size, date, etc. occur and the data are seldom verified
- The effect of screening appears only gradually, but if the prescreening data are unreliable, we will not be able to determine the full impact of screening
- We have now come the full circle from the population registry



## *Sequence of Steps in Quality-assured Screening Programme Implementation*

1. Comprehensive planning of screening process (professional performance, organisation and financing, quality assurance)
2. Preparation of all components of screening process to perform at requisite high level
3. Expert verification of adequacy of preparations
4. Pilot testing and modification, if necessary, of all screening systems and components, including QA
5. Expert verification of adequacy of pilot performance
6. Transition of pilot to service screening and geographically phased programme rollout in other regions of the country
7. Intensive monitoring of programme rollout for early detection and correction of quality problems



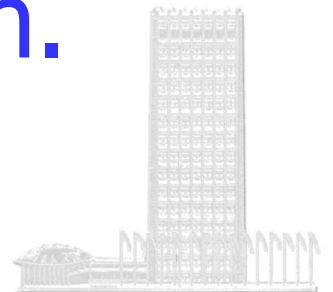
Breast cancer screening is not for  
amateurs or dilettantes

Screening can be learned, either from  
experienced teachers, or at the  
expense of inexperienced patients

Thank you for your attention.



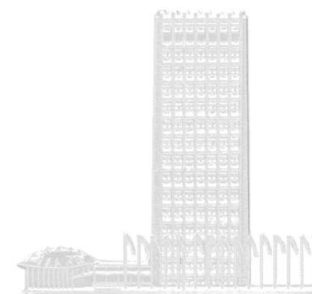
International Agency for Research on Cancer  
Centre International de Recherche sur le Cancer







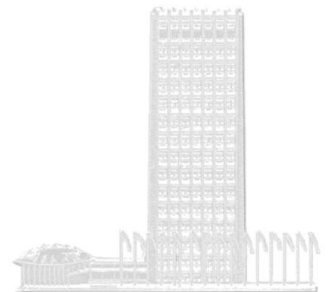
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# EU Screening Guidelines

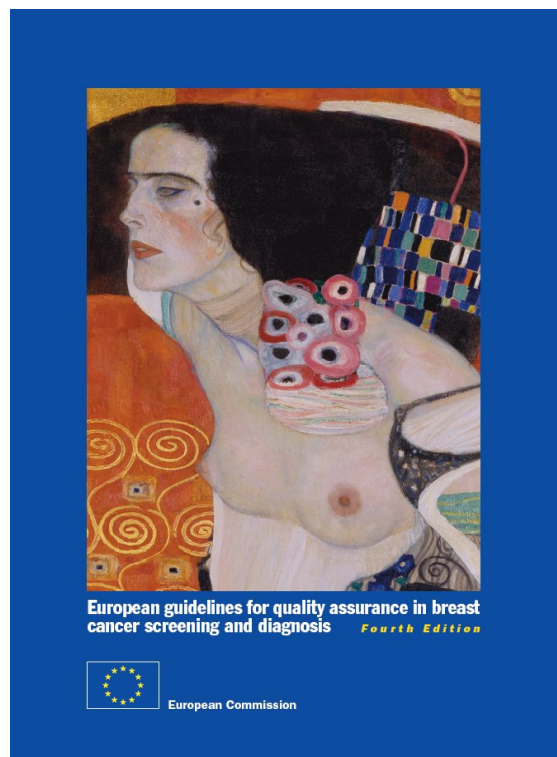
## Underlying Concepts

- Screening as a public health endeavour
- Overriding aim of minimising harm and maximising benefit
- Comprehensive, multidisciplinary process of screening
- Standards of performance and procedures of best practice
- Continuous quality improvement
- Need for population-based organisation, monitoring and evaluation

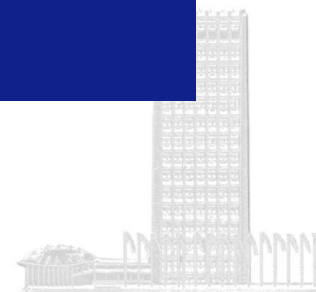


# EU Guidelines for *BREAST* and *CERVICAL* cancer screening

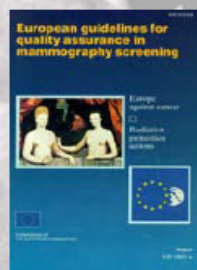
*COLORECTAL* is coming soon



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**1993**  
**First edition:**  
**67 pages**



### Main issues

- Screening process
- Organisational aspects
- Medical aspects
- European protocol for physico-technical quality control

**1996**  
**Second edition:**  
**176 pages**



### New chapters:

- Epidemiology quality assurance
- Cytopathology quality assurance
- Pathology quality assurance
- Revised physico-technical protocol

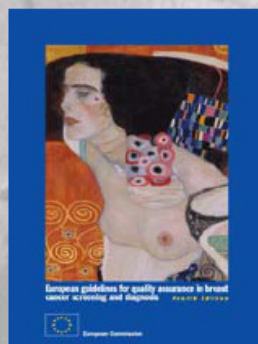
**2001**  
**Third edition:**  
**366 pages**



### New chapters:

- Data collection
- Radiographical quality issues
- Radiological quality assurance
- Surgical management guidelines
- Training recommendations

**2005**  
**Fourth edition:**  
**416 pages**



### New chapters:

- Certification protocol
- Communication
- Digital mammography
- Multidisciplinary diagnosis
- Specialist breast units

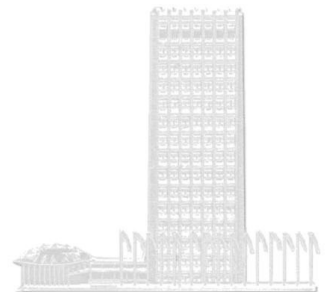


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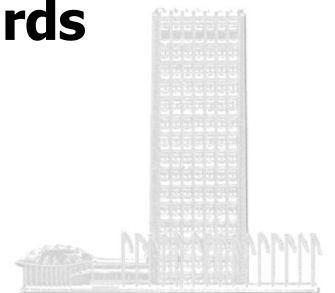
*EU Breast Screening Guidelines*  
*Key general elements of QA and best practice - 1*

- **Population-based invitation to screening**
- **Training of all staff, particularly: radiographers, radiologists, pathologists and surgeons**
- **Dedicated equipment and specialisation of personnel**
- **Observance of volume levels**
- **Multidisciplinary team working, including above staff as well as breast care nurses and medical oncologist/radiotherapist**



*EU Breast Screening Guidelines*  
*Key general elements of QA and best practice – 2*

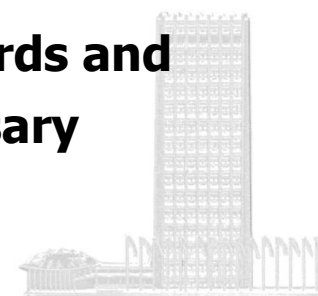
- **Targets, performance indicators and regular audit**
- **Organization of preoperative and post-operative multidisciplinary conferences**
- **Avoidance of mixing of screening and symptomatic women (?)**
- **Complete and accurate recording of all relevant data for evaluation**
- **Accreditation of units meeting quality standards**





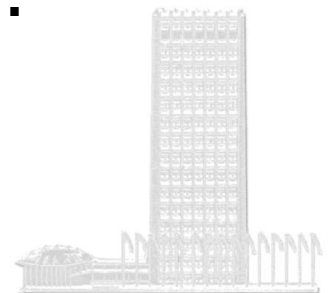
## *More specific requirements for quality assurance of breast cancer screening*

- **Adequate, *unbiased* information to allow informed choice as to whether to attend**
- **Extensive QA protocols for equipment and technical performance in conventional and digital mammography**
- **Interpretation of screening mammograms by two independent readers**
- **Standardization of pathology procedures and reporting**
- **Standardization of data collection and monitoring**
- **Comprehensive protocols for professional QA**
- **Nomination of a given professional responsible for overall unit performance and with the authority to maintain standards and outcomes by suspending inadequate elements if necessary**



## *Some key quality requirements for specialist breast units*

- **Breast surgery by *specially trained surgeons* in *specialist units* providing a minimum of 150 primary breast cancer operations annually.**
- **Each breast surgeon should perform a minimum of 50 primary breast cancer operations per year.**
- **Clinical, imaging and pathology findings of all women requiring breast surgery should be discussed and documented in regular pre-operative and post-operative meetings of the full multi-disciplinary team (radiologist, radiographer, pathologist, surgeon, nurse counsellor and medical oncologist/radiotherapist).**
- **Patient support by specialist breast care nurses or psychologically professionally trained staff with expertise in breast cancer.**
- **Continuous monitoring of outcomes and regular audit**

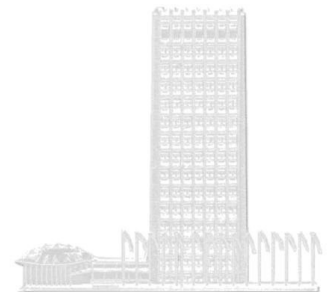


## To Order Breast Guideline Book and Obtain Free Executive Summary and Summary Table of Key Performance Parameters

1. go to:  
<http://bookshop.europa.eu/eubookshop/publicationDetails.action?pubuid=235525&offset=1>
2. download free PDF: European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis
3. The Easy Way: by Google – EU Bookshop Breast Cancer



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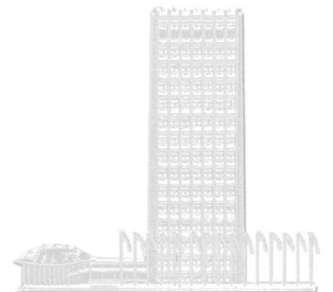
# EU Breast Screening Guidelines

## Future Updates

- **Digital Mammography**
- **Pathology**
- **Breast Care Nursing**
- **Certification of Specialist Breast Centers**
- **Implementation of Screening Programmes**
- **Regional and National Status Reporting**

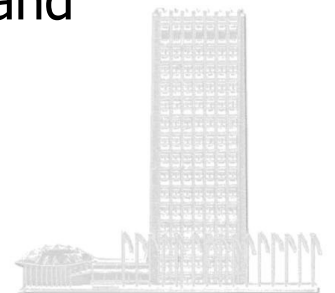


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# Nationwide implementation of population-based screening improves the entire range of cancer care

- The population-based approach is essential to monitoring and maintaining high quality at every step in the screening process.
- Nationwide implementation of population-based programmes makes services performing to the high multidisciplinary standards accessible to the entire eligible target population.
- Large numbers of professionals undertake further specialisation in order to meet the screening standards.
- Consequently, these nationwide efforts also lead to widespread improvement in multidisciplinary diagnosis and management of cancers which are detected outside of screening programmes.





# THE COUNCIL OF THE EUROPEAN UNION

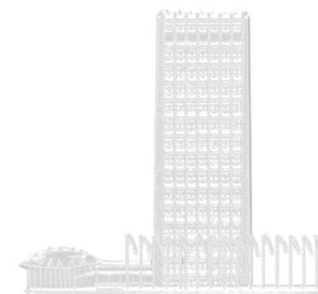
Council Conclusions on reducing the burden of cancer  
2876th EPSCO Meeting, Luxembourg, 10 June 2008



- 4. WELCOMES the European Parliament Resolutions on combating cancer and on breast cancer, which underline the new challenges in this field for the enlarged EU...
- 20. INVITES the Commission to:
  - ...
  - explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the European guidelines for quality assurance in breast cancer screening and diagnosis;



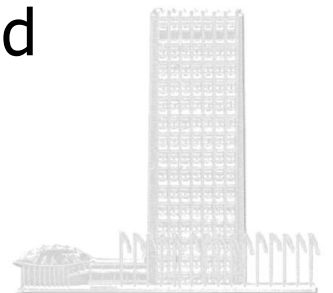
International Agency for Research on Cancer  
Centre International de Recherche sur le Cancer





# Major challenges in development of an accreditation/certification scheme for breast units

- The major challenge in the project will be to specifically adapt the rules and procedures developed in the EU for **accreditation and certification**, and currently applied to a number of economical and social activities, to the special professional activities **in multidisciplinary diagnosis and management of breast cancer**
- These activities should not be performed in isolation. They should be integrated into overall efforts to improve the quality, effectiveness and cost effectiveness of cancer services in the EU



## Key elements in piloting an EU-wide accreditation/certification scheme for breast units

- Piloting and training incentives for proactive quality improvement
- Voluntary EU-wide quality competition to stimulate innovation
- Robust monitoring of professional performance in certified units
- Professional evaluation of the accrediting and certifying bodies (expert review of certified units)
- Network of expert centres and programmes to develop resources for quality improvement and quality control

