1999 AAPM Annual Meeting

The New NCRP Report on Mammography
(Update of NCRP Report No. 85)

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Background

Committee reconstituted to revise:
NCRP Report No. 85:
Mammography--A User’s Guide

Published in 1986

NCRP Report No. 85

Significant Changes

- New Low Dose Screen-Film Systems
- Data from ACR-MAP, CRCPD
- End of Xeroradiography
- New Risk & Benefit Data
- Only Dedicated Mammography Units
- National Recommendations-MQSA & ACR
- Significant New Publications
- New Technology

Caveat

- Most of the material presented today is from a DRAFT Report of the Committee.
- Report has not yet been reviewed by either the full NCRP Council or Critical Reviewers
- NOTHING presented represents NCRP Policy
- Final Report MIGHT be Significantly Different
- Note: Effort to agree with ACR / CDC/MQSA Documents
ACR 1999 Mammography QC Manual

**Equipment**
- X-Ray Unit
- Screens
- Films
- Processing Systems

**X-Ray Unit**
- **Mechanical Assembly/General**
  - C-Arm
  - Locks
  - Compression
  - Image Receptor Support Device
  - Radiation Shield
  - Recording System

- **X-Ray Source Assembly**
  - Target
  - Window
  - Filter
  - Field Coverage
  - Focal Spot
  - Resolution

- **X-Ray Generator**
  - 3 to 10 kW
  - High Frequency generator
  - kVp Selection: 24 - 32 in 1 kV steps

- **X-Ray Beam Energy and Intensity**
  - kVp/100 to kVp/100+0.1 mm Al
  - 200 µC kg⁻¹ s⁻¹ at breast (28 kVp, 3 s)

- **Exposure Control**
  - AEC: OD ± 0.12 - 2 to 6 cm
  - Detector: 3 pos, indicator, right size
  - Density Adjustment: 9 steps (10 - 15 %)
  - Post-Exposure Display
  - Back Up Timer: indicator: 250 - 600 mAs
  - Manual: 2 to 600 mAs, display, 5% to AEC
X-Ray Unit
- Compression Device
- Grid
  - 4:1 to 5:1, thin septa, 32 l/cm, interlock,
    - moving, carbon fiber, rigid, two sizes
- Magnification Stand

Screen, Films, Processing
- Screens
  - Single, thin
- Films
  - Single emulsion, silver halide & gelatin
- Processing
  - Cycle Time: 90 to 150 s
  - Temperature: 33 to 39 C
  - Chemicals, Replenishment, Agitation, Drying

Darkroom Processor/Maintenance
- Correct electrical current
- Correct water flow
- Darkroom air, ventilation, temperature
- Eliminate dust and artifacts
- Humidity
- Safelight illumination
- Film Storage

Screen-Film Mammography
  - Complete Clinical Discussion
  - Anatomy
  - Viewing Mammograms - Arrangement
  - Film Identification - ACR
  - Breast Positioning (ACR Terminology Too)
    - Craniocaudal, Mediolateral Oblique, Others
  - Compression
  - Technical Decisions

Image Quality (1)
- Factors Which Affect Quality (Table)
  - Radiographic Sharpness
    - Radiographic Contrast
      - Subject, Scatter, Film
    - Radiographic Blurring
      - Motion, Geometry, Screen-Film
  - Radiographic Noise
    - Radiographic Mottle
      - Film Grain, Quantum, Structure
    - Artifacts
      - X-Ray Unit, Receptor, Processing, Handling

Image Quality (2)
- Viewing Conditions
  - Viewbox Brightness, Masking, Ambient Light
- Film Speed
  - Film, Screen
  - Processing Conditions
  - Ambient Conditions
  - Reciprocity Law Failure
  - Latent Image Fading
Dose Evaluation

- Risk Related Dose
- Dose Evaluation Procedures
- Published Data
  - Dose Recommendations
  - Dose Survey Results

Assumptions: Dose Calculation

- Firm Compression
- Uniform Cross Section
- 0.5 cm Adipose Layer - Top & Bottom
- Adipose / Gland Mix:
  - 100% / 0%
  - 50% / 50%
  - 0% / 100%

f - Factors

Adipose:
5.4 mGy/R

Glandular:
7.9 mGy/R

Dose and Exposure vs Thickness

Exposure to Dose Conversion (mGy/R)

<table>
<thead>
<tr>
<th>Mo Target</th>
<th>kVp</th>
<th>Mo Filter</th>
<th>4 cm</th>
<th>5 cm</th>
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<td>37</td>
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<td>1.59</td>
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<td>1.22</td>
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</tbody>
</table>

### Other D$_{eq}$ References
- **Mo/Rh and Rh/Rh:** Wu, Gingold, Barnes, Tucker. Radiology 1994, 193: 83-89
- **Magnification Mammography:** Liu, Goodsitt, Chan. Radiology 1995; 197:27-32.
- **Mo/Mo and W/Al:** NCRP Report No. 85

### Mean Glandular Dose Calculation
- Exposure in Air, $X_a$, at Entrance Surface (M)
- HVL - mm Al (M)
- Target Material (Mo, Rh, or W) (S)
- Filter Composition & Thickness (Mo, Rh, Al) (S)
- Peak Tube Potential - kVp (S)
- Adipose - Glandular Composition (E)
- Compressed Breast Thickness (M)
- M = Measured, S = Setting, E = Estimated

### Dose Recommendations / Surveys
- **Screen - Film with Grid**
  - 4.5 cm Compressed Breast (4.2 cm Equivalent)
  - 50% Adipose / 50% Glandular

### Assumptions: Dose Calculation
- Firm Compression
- Uniform Cross Section
- 0.5 cm Adipose Layer - Top & Bottom
- Adipose / Gland Mix:
  - 100% / 0%
  - 50% / 50%
  - 0% / 100%

### Is 50% Adipose/50% Glandular Average?
“A phantom composed of 30% glandular and 70% adipose tissue allows closer simulation of the phototimer response of the mammographic x-ray unit for the average breast. The phantom currently used contains 16% more glandular tissue than the average breast.”


### Dose Recommendations:
- **Screen-Film with Grid**
  - MQSA: 3 mGy
  - ACR-MAP: 3 mGy
  - NCRP SC -72: 3 mGy
  - NY State: 3 mGy
  - California: 3 mGy
  (Recently changed from 2 mGy)
<table>
<thead>
<tr>
<th>Year</th>
<th>MGD (mGy)</th>
<th>ESE (mR)</th>
<th>HVL (mm Al)</th>
<th>Optical Density</th>
<th>Phantom Score</th>
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<td>1988</td>
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<td>910</td>
<td>0.33</td>
<td>1.43</td>
<td>11.9</td>
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<td>1996</td>
<td>1.5</td>
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<td>0.33</td>
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<td>1997</td>
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<td>965</td>
<td>0.33</td>
<td>1.52</td>
<td>12.2</td>
</tr>
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</table>

From Suleman, Spolic, McCrohan Symonds Houn Radiology 1999;210:345-351

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**Quality Assurance**

- Quality Control - Technical Components
  - Equipment Selection
  - Equipment Performance Evaluation
  - Routine Equipment Monitoring
  - Technique Factor Selection
  - Evaluation of Positioning and Compression

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**Quality Assurance**

- Current Status of QA in US
- Essential Elements of Effective QA
- Quality Administration
  - Medical Audit
- Legislative Issues Relating to QA
  - OBRA: Passed 11/90, Effective 1/91
  - MQSA: Passed 10/92, Effective 10/94
  - States

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**Elements of a QA Program**

- Selection of Mammography Equipment
- Selections of Screens and Films
- Selection of Film Processing Conditions
- Quality Control Procedures
  - ACR QC Manuals
- Acceptance Testing Procedures

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**Quality Administration-Medical Audit**

- How to Conduct an Audit
- Audit Results from an Expert Practice
  - Radiologist Demographics
  - Disposition of Abnormal Interpretations
  - Biopsy Results
  - Characteristics of Breast Cancers
- How to Interpret Audit Results
- How to Use Audit Results Effectively
### Benefits / Risks - Mammography

- **Benefits**
- **Radiation Risk**
- **Benefit vs. Risk Analysis**

(MORE ABOUT THIS TOPIC LATER)

### Other Breast Imaging Modalities

- Ultrasonography
- Thermography
- Transillumination
- Computed Tomography
- Magnetic Resonance Imaging
- Magnetic Resonance Spectroscopy
- Digital X-Ray Mammography

### Ultrasonography

- Distinguishes Cystic from Solid masses
- Less accurate for Benign vs. Malignant
- Can not demonstrate cancers <1 cm
- Tomographic - many images needed
- High false positive for dense breasts
- Doppler does not distinguish malignant
- Not recommended for routine screening

### Computed Tomography

- Can detect early cancer, but only with iodine contrast - before/after scans
- Routine scanners require computer assistance for diagnosis
- High radiation dose - entire chest must be penetrated
- High cost of exam

### Magnetic Resonance Imaging

- No ionizing radiation
- Dense fibroglandular tissue imaged well
- Large and some small masses well imaged
- Spatial resolution well below screen-film
- Breast coils usually needed
- High cost of exam

### Magnetic Resonance Spectroscopy

- Biochemical Differences - specific metabolic processes measured
- $^{31}$P MR Spectral Profiles
- Large Voxel Size
Digital Mammography (1)
- Wide Dynamic Range
- Image Enhancement Capabilities
- Many Different Receptors

CURRENTLY
- Limited Spatial Resolution
- Small Imaging Area

Digital Mammography (2)
- Full Field Gives Either Very Large Matrix or Reduced Resolution
- Multiple Images Can Not Be Viewed
- Resolution Limited by Display Monitors

Digital Mammography (3)
- Currently Most Images From Digitized Film
- Image Archive and Retrieval
- Teleradiology
- Dual Energy Subtraction
- Computer - Aided Image Analysis
- Computer - Aided Instruction

Benefits: Considerations
- Mammography vs. Physical Exam
- Biases:
  - Lead Time Bias
  - Length Bias
  - Selection Bias

Benefits
- Women Over 50
  - General Agreement on Benefit
  - Annual Screening Recommended
- Women 40 - 49
  - Benefits Have Been Controversial
  - Varying Recommendations from Professional Organizations and Advisory Bodies

Benefits
- Case-Control Studies
- Dutch
- Italian
- United Kingdom Correlation Trial
 Follow-Up Studies
- BCDDP
Benefits - RCT Data Including Women 40 - 49

- HIP, NY
- Malmo Sweden
- Kopparberg, Sweden
- Ostergotland, Sweden
- Edinburg, Scotland
- Stockholm, Sweden
- Gothenburg, Sweden
- Canadian National Breast Screening Study

Variations - RCT's

- Number of Views: 1 or 2
- Screening Frequency: 12 to 28 Months
- Years of Follow Up: 10 to 18 Years - Increasing
- Relative Risk: 0.56 to 1.14
- Mortality Reduction: -14% to +44%

RCT Including Women 40-49

<table>
<thead>
<tr>
<th>Study</th>
<th>Views</th>
<th>Freq</th>
<th>Follow Up</th>
<th>Rel Risk</th>
<th>95% Conf</th>
<th>Mort Reduc</th>
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<tbody>
<tr>
<td>HIP-NY</td>
<td>2</td>
<td>12 mo</td>
<td>18 y</td>
<td>0.77</td>
<td>0.53-1.11</td>
<td>23%</td>
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<tr>
<td>Malmo</td>
<td>1 or 2</td>
<td>18-24</td>
<td>12.7 y</td>
<td>0.64</td>
<td>0.45-0.99</td>
<td>36%</td>
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<tr>
<td>2Cty-K</td>
<td>1</td>
<td>24 mo</td>
<td>15.2 y</td>
<td>0.67</td>
<td>0.37-1.22</td>
<td>33%</td>
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<tr>
<td>2Cty-O</td>
<td>1</td>
<td>24 mo</td>
<td>14.2 y</td>
<td>1.02</td>
<td>0.59-1.77</td>
<td>-2%</td>
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<tr>
<td>Edin</td>
<td>1 or 2</td>
<td>24 mo</td>
<td>12.6 y</td>
<td>0.81</td>
<td>0.54-1.20</td>
<td>19%</td>
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<tr>
<td>Stock</td>
<td>1</td>
<td>28 mo</td>
<td>11.4 y</td>
<td>1.01</td>
<td>0.51-2.02</td>
<td>-1%</td>
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<tr>
<td>Goth</td>
<td>2</td>
<td>18 mo</td>
<td>12 y</td>
<td>0.56</td>
<td>0.32-0.98</td>
<td>44%</td>
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<td>CNBSS</td>
<td>2</td>
<td>12 mo</td>
<td>10.5 y</td>
<td>1.14</td>
<td>0.83-1.56</td>
<td>-14%</td>
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Meta-Analyses: Mammo RCT

<table>
<thead>
<tr>
<th>Studies</th>
<th>Relative Risk</th>
<th>95% Conf</th>
<th>Mortality Reduction</th>
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<tr>
<td>All 8 RCT</td>
<td>0.82</td>
<td>0.71-0.95</td>
<td>18%</td>
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<tr>
<td>All 7 Pop Base RCT</td>
<td>0.74</td>
<td>0.63-0.88</td>
<td>26%</td>
</tr>
<tr>
<td>All 5 Swedish RCT</td>
<td>0.71</td>
<td>0.57-0.89</td>
<td>29%</td>
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</table>

Benefits - Meta-Analysis of RCT's

- Relative Risk: 0.71 to 0.82
- Mortality Reduction: 18 to 29%

Risk Data: Radiation Exposures

- Japan A-Bomb Survivors
- Massachusetts TB Patients - Chest Fluoro
- Nova Scotia TB Patients - Chest Fluoro
- Swedish Benign Breast Disease Radiation
- Rochester Postpartum Mastitis Radiation
Risk Data - Key Results (1)
- Increased Incidence following Irradiation
- Linear Function Generally Fits Data
- Age of Exposure - Higher Risk for Younger
- Latent Period of at Least Five Years
- No Major Effect from
  - Dose Fractionation
  - Reduced Dose Rate

Risk Data - Key Results (2)
- No Evidence that Risk Returns to Bkgd
- Interaction with Other Risks
  - Relative Risk Model Chosen
- Radiation Cancers Same as Other Cancers
- Substantial Contribution to Risk Estimates for Doses below 1 Gy

Risk Negligible for Diagnostic Exam of a Given Woman
Benefits and Risks Must Be Known for Screening of Large Populations of Asymptomatic Women

Risk-Benefit: Assumptions (1)
- Natural Incidence Taken from SEER Data
- Lifetime Refers to Age 99
- Average Dose/Two Views = 3 mGy
- Incidence and Mortality from BEIR V Models Starting Five Years after Exam
- Baseline Incidence Multiplied by RR

Risk-Benefit: Assumptions (2)
- Benefit Modelled as % Reduction Mortality starting 2 yr after first screen and ending 15 years after last screen
- Benefit Calculated for Both Decrease in Deaths and Years of Life Saved

Risk-Benefit: Decrease in Deaths

<table>
<thead>
<tr>
<th>Starting Age</th>
<th>Total Cases</th>
<th>Excess Cases</th>
<th>Total Deaths</th>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
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</thead>
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<td>40</td>
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<td>11</td>
<td>3,453</td>
<td>-3</td>
<td>283</td>
<td>569</td>
<td>856</td>
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<td>45</td>
<td>12,469</td>
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<td>3,369</td>
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<td>272</td>
<td>547</td>
<td>823</td>
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<td>50</td>
<td>11,517</td>
<td>2</td>
<td>3,233</td>
<td>0</td>
<td>256</td>
<td>514</td>
<td>773</td>
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<td>2,800</td>
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<td>412</td>
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<td>2,522</td>
<td>0</td>
<td>172</td>
<td>345</td>
<td>518</td>
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100,000 Women Have Annual Screenings with Dose of 3 mGy until Age 69
Excess Cases Assumes Radiation Risk Only, No Benefit from Screening
Total Cases and Total Deaths Are Natural Incidence at Given Age
### Risk-Benefit: Decrease in Deaths

<table>
<thead>
<tr>
<th>Starting Age</th>
<th>Total Cases</th>
<th>Excess Cases</th>
<th>Total Deaths</th>
<th>0%</th>
<th>1%</th>
<th>20%</th>
<th>40%</th>
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<tr>
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<td>2,522</td>
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<td>17</td>
<td>345</td>
<td>692</td>
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</table>

100,000 Women Have Annual Screenings with Dose of 3 mGy until Age 69
Excess Cases Assumes Radiation Risk Only, No Benefit from Screening
Total Cases and Total Deaths Are Natural Incidence at Given Age

### Risk - Benefit: Years Gained

<table>
<thead>
<tr>
<th>Starting Age</th>
<th>Increase in Years of Life with Benefit of:</th>
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<tr>
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<td>40</td>
<td>-43</td>
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100,000 Women Have Annual Screenings with Dose of 3 mGy until Age 69

### Summary and Conclusions

**Summary**

- Mammography, in conjunction with physical examination, is the method of choice for early detection of breast cancer. Other methods should not be substituted for mammography in diagnosis or screening, but may be useful adjuncts in specific diagnostic situations.

**Conclusions**

1. Mammography, in conjunction with physical examination, is the method of choice for early detection of breast cancer. Other methods should not be substituted for mammography in diagnosis or screening, but may be useful adjuncts in specific diagnostic situations.

2. Diagnostic mammography of symptomatic women should always be performed when indicated, utilizing recommended equipment and techniques and well-trained, knowledgeable personnel.
3. Screen-film mammography requires dedicated x-ray units, taut compression, and an x-ray spectrum produced by an appropriate combination of x-ray tube target, tube window, filtration, peak generating potential, screen-film combination, film processors, technique, and viewing conditions. Craniocaudal and mediolateral oblique views are recommended as the standard views for all types of mammography.

4. Mammographic equipment should be chosen to provide acceptable image quality at a typical average glandular dose [for a two-view examination] of 6 mGy or less for screen-film with grid for a patient having 4.5 cm thick compressed breasts of 50% adipose / 50% glandular tissue composition.

5. Image quality and appropriate dose level should be maintained by a quality assurance program conducted by a quality assurance technologist and medical physicist involving specified periodic measurements and readjustment of all aspects of the imaging / viewing system.

6. Average glandular dose should be determined at each installation for the techniques used at representative breast thicknesses. This dose can be calculated from data supplied in this report by measuring beam quality and in-air exposure at the entrance surface of the breast.

7. Annual mammographic examinations appear to provide favorable benefit-risk ratios in terms of breast cancer mortality in women age 50 or above, if acceptable image quality and dose are maintained.

8. Given the present state of knowledge, randomized trials of screening mammography suggest a real benefit in terms of breast cancer mortality reduction for women from the age of 40 years.