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 Unit

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

X-Ray Unit

- 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)

X-Ray Unit

- 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

Screens, 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

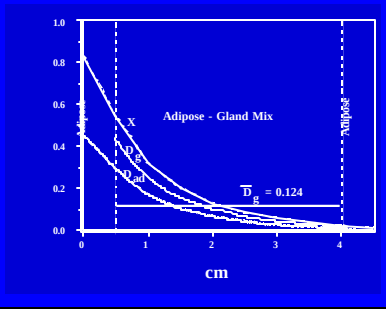
- Firm Compression
- Uniform Cross Section
- 0.5 cm Adipose Layer - Top & Bottom
- Adipose / Gland Mix:
  - 100% / 0%
  - 50% / 50%
  - 0% / 100%

f - Factors

Adipose:
5.4 mGy/R

Glandular:
7.9 mGy/R

Dose and Exposure vs Thickness



$$(D_g)_{av} = (D_{gN})_{av} * X_a$$

Exposure to Dose Conversion (mGy/R)

	kVp	HVL	4 cm	5 cm	6 cm
Mo Target Mo Filter	29	0.30	1.61	1.32	1.09
		0.32	1.73	1.39	1.15
		0.34	1.82	1.46	1.21
		0.36	1.91	1.54	1.27
50%Adipose 50%Glandular	31	0.31	1.71	1.37	1.14
		0.33	1.80	1.45	1.20
		0.35	1.89	1.52	1.26
		0.37	1.97	1.59	1.22

From: Wu, Barnes and Tucker.
Radiology 1991; 179:143-148.

Other D_{gN} 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, Xa, 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."

Geise RA, Palchevsky A.

Radiology 1996; 198: 347-350

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)

Mammography in U.S. 1988 - 1997

	1988	1992	1995	1996	1997
MGD (mGy)	1.3	1.9	1.5	1.5	1.6
ESE (mR)	683	NA	910	943	965
HVL (mm Al)	0.8	0.3	0.3	0.3	0.3
Optical Density	0.6	1.8	1.4	1.4	1.5
Phantom Score	10.3	11.2	11.9	12.0	12.2

From Suleiman, Spelic, McCrohan, Symonds, Houn
Radiology 1999;210:345-351

Quality Assurance

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

Quality Assurance

Quality Administration: Monitoring Interactions

- Mammography Provider and Patient
- Interpreting Physician and Referring Physician
- Skills of Interpreting Physician
  - Screening or Diagnostic Results
  - Outcomes Analysis
- Other Administrative Monitors of Quality

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

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

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
- Edinburgh, Scotland
- Stockholm, Sweden
- Gothenburg, Sweden
- Canadian National Breast Screening Study

RCT Including Women 40-49

Study	Views	Freq	Follow Up	Rel Risk	95% Conf	Mort Reduc
HIP-NY	2	12 mo	18 y	0.77	0.53-1.11	23%
Malmo	1 or 2	18-24	12.7 y	0.64	0.45-0.89	36%
2Cty-K	1	24 mo	15.2 y	0.67	0.37-1.22	33%
2Cty-O	1	24 mo	14.2 y	*1.02*	0.59-1.77	*-2%*
Edin	1 or 2	24 mo	12.6 y	0.81	0.54-1.20	19%
Stock	1	28 mo	11.4 y	*1.01*	0.51-2.02	*-1%*
Goth	2	18 mo	12 y	0.56	0.32-0.98	44%
CNBSS	2	12 mo	10.5 y	*1.14*	0.83-1.56	*-14%*

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%

Meta-Analyses: Mammo RCT

Studies	Relative Risk	95% Conf	Mortality Reductior
All 8 RCT	**0.82**	**0.71-0.95**	**18%**
All 7 Pop Base RCT	**0.74**	**0.63-0.88**	**26%**
All 5 Swedish RCT	**0.71**	**0.57-0.89**	**29%**

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

Starting Age	Total Cases	Excess Cases	Total Deaths	Decrease in Deaths with Benefit of: 0%	10%	20%	30%
40	12,855	11	3,453	-3	282	569	856
45	12,349	5	3,369	-1	272	547	823
50	11,517	2	3,233	0	256	514	773
55	10,580	1	3,039	0	233	468	704
60	9,534	0	2,800	0	205	412	619
65	8,316	0	2,522	0	172	345	518

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

Starting Age	Total Cases	Excess Cases	Total Deaths	Decrease in Deaths with Benefit of: 0%	1%	20%	40%
40	12,855	11	3,453	-3	25	569	1,145
45	12,349	5	3,369	-1	25	547	1,100
50	11,517	2	3,233	0	24	514	1,032
55	10,580	1	3,039	0	23	468	940
60	9,534	0	2,800	0	20	412	826
65	8,316	0	2,522	0	17	345	692

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

Starting Age	Increase in Years of Life with Benefit of: 0	10%	20%	30%
40	-43	5,046	10,146	15,263
45	-19	4,615	9,258	13,914
50	-9	4,025	8,067	12,119
55	-3	3,333	6,682	10,037
60	0	2,619	5,242	7,872
65	1	1,918	3,837	5,757

100,000 Women Have Annual Screenings with Dose of 3 mGy until Age 69

Risk - Benefit: Years Gained

Starting Age	Increase in Years of Life with Benefit of: 0	1%	20%	40%
40	-43	469	10,146	20,386
45	-19	444	9,258	18,577
50	-9	392	8,067	16,178
55	-3	329	6,682	13,402
60	0	258	5,242	10,507
65	1	191	3,837	7,684

100,000 Women Have Annual Screenings with Dose of 3 mGy until Age 69

Summary and Conclusions

- Summary
- ***DRAFT*** Conclusions

NCRP SC-72 *DRAFT* 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.

NCRP SC-72 *DRAFT* Conclusions

2. Diagnostic mammography of symptomatic women should always be performed when indicated, utilizing recommended equipment and techniques and well-trained, knowledgeable personnel.

NCRP SC-72 *DRAFT* Conclusions

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

NCRP SC-72 *DRAFT* Conclusions

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.

NCRP SC-72 *DRAFT* Conclusions

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.

NCRP SC-72 *DRAFT* Conclusions

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.

NCRP SC-72 *DRAFT* Conclusions

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.

NCRP SC-72 *DRAFT* Conclusions

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.