Quality and Safety in Mammography

Priscilla Butler, MS, FAAPM, FCR, FSBI
Retired
American College of Radiology

I have no conflicts…I’m retired!
Breast Cancer

- 2nd most common CA in US women (skin CA is higher)
  - 1 in 8 women will develop breast CA
- 2nd leading cause of CA death in women (only lung cancer kills more)
  - 1 in 38 women will die from breast CA
- But ACS reports death rates have gone down…Why?
  - Higher quality mammography
  - Earlier detection and better treatment
  - Role of physics in getting there

Breast Cancer Impacts Patients, Family and Friends

Libby was a survivor and a fighter for quality mammography
History of Mammography – 1930s

- 1st successful use of x-rays to diagnosis breast cancer
  (Dr. Warren, University of Rochester)
  - Screen-film with grid, 60 kVp and 2.5 sec
  - Quality was unreliable
  - Rarely used

History of Mammography – 1950s

- Dr. Gerson-Cohen (Philadelphia)
  - Direct exposure film
  - Compensation filters
- Dr. Leborgne (Uruguay)
  - Microcalcifications
  - Light compression
History of Mammography – 1960s

- Robert Egan, MD (Emory University)
  - Low kV
  - High mA
  - Industrial film
  - Easily reproducible
  - Widespread mammography
- He “wrote the book”
- US Public Health Service
  - Sponsored conference at MD Anderson
  - Usefulness and reproducibly of mammography

Egan Technique – 1960s to early 1970s

- Conventional x-ray unit
- Film processing by hand
History of Mammography – 1960s

1967 – Dr. Gros (physicist at U of Strasbourg) invented x-ray tube designed for mammography
   - Low voltage
   - Mo target instead of W
   - Compression cone
     - Reduce breast thickness
     - Spread out structures
   - Yes, it was invented by a man

1967 – 1st dedicated unit - CGR Senographe

History of Mammography – 1960s

Dr. Wendell Scott (Washington U)
   - Chairman of the ACR’s 1st mammography committee
   - Supported by USPHS and aid of Dr. Egan, developed training aids and teaching centers throughout the US for radiologists and techs
   - Asked Xerox to design a machine which could easily be operated, which remained clean and dry, and which could produce superb images
History of Mammography – 1970s

- Xeromammography (1971)
  - Championed by John Wolfe, MD
  - A photoelectric method of recording an x-ray image on a coated metal plate and dry chemical developers

- Screen-film mammography (1972)
  - Single emulsion film with high resolution intensifying screen
  - Vacuum cassette (DuPont)
History of Mammography – 1970s

- **US Breast Cancer Detection Demonstration Project (BCDDPs)**
  - Conducted between 1973 and 1980
  - Sponsored by the ACS and the NCI
  - 29 screening centers with 60 x-ray machines
  - 5 annual breast examinations to 283,222 women
  - **6 Centers for Radiological Physics to support**
    - Coordinated by AAPM
    - Radiation dose
    - Equipment/image receptor performance

Radiation dose at BCDDPs (1975)

- "Lo-dose" film, "non-screen" film and Xerox used
- Median surface exposure – 2.8 Roentgen (R)
- One center used “non-screen film” resulting in high exposures…8 R…practice ceased
- 6 R reported for a Xerox site…practice modified
- Concern about screening large #s of women with potentially high radiation doses
History of Mammography – 1970s

- Pennsylvania State inspector
  - Hank Bicehouse
  - 70 eastern PA facilities
  - Entrance exposures to breast ranged from 0.25 R to 47 R!!!!

FDA’s Bureau of Rad Health – 1975

- Breast Exposures: Nationwide Trends (BENT)
  - Administered by FDA (with support from NCI)
  - Conducted by state radiation control agencies
  - Cooperation of state radiological societies

- Objectives
  - Determine ranges of patient exposures
  - Determine causes of unnecessarily high and low exposures
  - Reduce unnecessary exposures through practice improvements
FDA’s BENT – 1970s

- States mailed dosimetry card to all mammography facilities in state

ACR Mammography Accreditation Program - 1987

- Developed by the radiologists and physicists of the ACR’s Breast Task Force
  - Seed money provided by ACS
  - Voluntary
  - Purpose was to address documented concerns for inadequate and varying mammography quality
ACR Mammography Accreditation Program - 1987

- Chairs
  - Gerald Dodd, MD – Breast Task Force
  - Robert McClelland, MD – Committee on Mammography Accreditation
  - Dr. Hendrick – Subcommittee on Mammography Physics

- ACR staff
  - Marie Zinninger
  - Pam Wilcox

ACR Mammography Accreditation Program - 1987

- First site applied for accreditation in Aug 1987

- By 1991, 4717 sites with 5745 mammography units applied (over half of all in the US)
ACR Quality Control Manuals

- A critical part of quality – the “Bible”

ACR Cooperative Agreement w/CDC

- 1990 - Bob Smith, PhD developed concept for the National Breast and Cervical Cancer Detection Program - passed by Congress
- Created the opportunity for a new grant for Mammography Quality Improvement Activities
- Co-chaired by Larry Bassett, MD and Ed Hendrick, PhD
Cooperative Agreement – 1990 to 1994

- CDC provided $4M over 4 years
- Committees
  - Radiologist Education
  - Radiologic Technologist Education
  - Medical Physicist Education
  - State Inspectors Education
  - Mammography Skills Assessment
  - Clinical & Phantom Image Correlation

CMS Regulation – 1992

- Congress passed Medicare coverage of screening mammography
  - Facilities seeking coverage had to register with Health Care Financing Administration (HCFA) and meet quality standards similar to ACR’s Mammography Accreditation Program
  - Federal inspections of Medicare-registered screening facilities began in 1992
- Some people still believe that regulation and accreditation only apply to screening
Patchwork of State Regulations

- Only 9 states had Quality Assurance provisions in regulations
  - They were all different
  - Michigan was the most rigorous
- There was no quality requirement for all women at all mammography facilities in US

Mammography Quality Standards Act – early 1990s

- MQSA - originally introduced in 1990 by Brock Adams of WA
  - Didn’t pass
- Reintroduced by John Dingell of MI
  - Shepherded by Barbara Mikulski of MD 1992
  - Passed with implementation date of 1994
  - Signed by George HW Bush August 22, 1992
- Assigned to the FDA
- Required establishment of National Mammography Quality Assurance Advisory Committee (NMQAAC)
NMQAAC - 1994

- 13–19 members…radiologists, radiologic technologists, medical physicists, referring physicians, nurses, state radiation control reps and breast CA consumer health organization reps
- Advise FDA on
  - Developing regs for mammography facilities and sanctions
  - Developing regs for accrediting bodies
  - Developing procedures for monitoring compliance
  - Establishing a consumer complaint mechanism
  - Determining if shortage of facilities in rural and health professional shortage areas exists
  - Determining if sufficient # of medical physicists exist

FDA MQSA Regulations

- Interim rules – 1994
- Final rules – 1997
  - Most rules effective April 28, 1999
  - Some rules effective October 28, 2002
Regulation - MQSA

- In order to legally perform mammography in the US, facilities must
  - Meet all quality rules
  - Be accredited every 3 years
  - Be inspected every year
  - Have an MQSA certificate

Certification
- FDA
- States (Iowa, Illinois, South Carolina, Texas)

Digital Mammographic Imaging Screening Trial (DMIST)

- 2005 NEJM paper
  - Over 42K women at 33 facilities
  - Digital mammography more accurate for women over 50 and those with dense breast
- Physics acceptance and QC integral to trial
ACR Digital Mammography QC Manual

- 2016: FDA approved ACR DM QC Manual as alternative standard
- 2018: FDA approved supplemental DBT material to be integrated into ACR DM QC Manual
- November 2018: New manual published and made available at no charge to all ACR accredited facilities and ACR medical physicist members
- Adoption is a choice

Phantom for Digital and DBT

- New ACR phantom must be used with new ACR Digital QC manual
  - Old, small phantom may not be used
New Manual Provides Standardization Across Manufacturers and Models

- Its good
- QC program structured for modern facilities
  - Multiple units… multiple RWS… multiple facilities
- What’s standardized?
  - Tests themselves
  - Test frequencies
  - Performance criteria
  - Clinical relevance
  - Operator-friendliness

Standardization Benefits

- Improved efficiency
  - Fewer QC tests than mfr
  - Less total time spent on QC tests
  - More efficient artifact detection
  - 2D and DBT both included, streamlined
- Overall benefits
  - Expect cleaner MQSA inspections
  - Reduces errors
  - No more chasing down mfr manual versions
  - Current and future revisions will always be available
  - Current and future Excel forms will always be free
- Team approach for mammography professionals
## Facility QC Review

### Image Quality

<table>
<thead>
<tr>
<th>Room 1</th>
<th>Room 2</th>
<th>Room 3</th>
<th>Room 4</th>
<th>Room 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>Score</td>
<td>Score</td>
<td>Score</td>
<td>Score</td>
</tr>
</tbody>
</table>

### Radiation Dose

<table>
<thead>
<tr>
<th>Room 1</th>
<th>Room 2</th>
<th>Room 3</th>
<th>Room 4</th>
<th>Room 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>Dose</td>
<td>Dose</td>
<td>Dose</td>
<td>Dose</td>
</tr>
</tbody>
</table>

### Other QC Notes

- Lead Interpreting Radiologist: [Name]
- Facility Manager/Dept. manager: [Name]
- QC Technologist: [Name]

### Medical Physicist QC Letter for the Radiologist

**January 15, 2019**

**To:** Medical Physicist

**From:** Lead Physicist

Subject: Review of Medical Physicist Survey

The above mammography unit at your facility recently underwent an annual Medical Physicist Survey. Below is the relevant summary information as a result of this survey. Please review the results and follow-up on the action items below to ensure consistent and compliant documentation from the service engineer.

**Image Quality**

- ACR Digital Mammography Phantom score: 10/12
- 9 of 9 views pass criteria
- No disqualifying factors

**Radiation Dose**

- ACR Digital Mammography Phantom radiation dose: 0.5 mGy

**Recommended Action Items**

- Ensure all mandatory documentation is completed and reviewed.
- Follow-up on any non-passing views.

**Comments on Monitoring, Monitor QC & Viewing Conditions**

- Description

**Comments on Tech QC**

- Description

If you have any questions, please do not hesitate to call.

Sincerely,

**[Name]**

**Phone:** 111-222-3333
**Email:** myemail@email.com
**Resources**

- Up-to-date FAQs
- Phantom scoring key (good for teaching!)
- Excel forms for QC tests (tech and med phys!)
- Webinars by Eric (tech and med phys!)
- Approved phantom vendors

**Mammography Quality Standards Act: FDA’s 2019 Proposed Rule**

- First changes since 1997 Final Rule
- Published March 2019
- Comments were due 6/26/2019
2019 Proposed Rule

Possible major changes

- Breast CT excluded from MQSA
- Accrediting bodies cannot accept applications from facility with 3 failures for at least 1 year
- Facilities must provide copies of their personnel records to current or former personnel
- Digital accessory components (eg, monitors) must have been cleared/approved by FDA for mammography
- Unit converted from one modality to another (eg, film-screen to digital) is a “new unit” and needs equipment evaluation

Possible major changes (continued)

- Interpretation must be done on modality originally produced (eg, not copies or digitized from analog)
- Several new final assessment categories for reports
- Lay summaries for “Suspicious” or “Highly suggestive of malignancy” communication
  - Referrer - 7 days from interpretation; 14 days from exam date
  - Patient - 7 days from interpretation; 21 days from exam date
- **Breast density notification to patients –language specified**
- If MQSA certificate revoked, owners/operators may not own or operate again for 2 years
In Summary, Has Mammography Quality Improved?

YES

Thank You

Acknowledgements

- Eric Berns, PhD, FACR
  - Chair, ACR Subcommittee on Breast Imaging X-ray Physics
  - Chair, ACR Subcommittee on QA in Mammography

- Dustin Gress, MS, DABR, DABSNM
  - ACR Senior Advisor for Medical Physics
  - dgress@acr.org