What I'm Going to Talk About

- ACR Mammography Accreditation Program update
- ACR breast imaging accreditation programs update
- ACR breast imaging guideline and policy updates
- Breast imaging pay-for-performance measures
- New modalities

ACR Mammography Accreditation Program Update
What is ACR Accreditation?

- Peer review process developed and monitored by experts
  - Staff qualifications
  - Policies and protocols
  - Equipment specifications
  - Quality assurance and safety
  - Clinical image quality
  - Phantom image quality (most programs)
  - Therapeutic treatment quality

ACR Accredited Sites (2009)

<table>
<thead>
<tr>
<th>Modality</th>
<th>Accredited</th>
<th>Facilities</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mammography</strong></td>
<td>8481</td>
<td>12,765</td>
<td></td>
</tr>
<tr>
<td>MRI</td>
<td>6908</td>
<td>6458</td>
<td></td>
</tr>
<tr>
<td>Ultrasound</td>
<td>3257</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>3609</td>
<td>4545</td>
<td></td>
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<tr>
<td>Breast US</td>
<td>969</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>1489</td>
<td>2372</td>
<td></td>
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<tr>
<td>PET</td>
<td>802</td>
<td>853</td>
<td></td>
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<tr>
<td>Stereotactic Breast Biopsy</td>
<td>662</td>
<td>631</td>
<td></td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>180</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

MQSA - Who’s Who
(VHA has their own “who”)

The Law: Mammography Quality Standards Act (MQSA)

The Regulator: US Food and Drug Administration (FDA)

The Accreditation Bodies: (ACR, TX, IA, AR)

The Inspectors: States
As of 1/1/09
- 13,241 units at
- 8817 facilities
- # facilities have dropped by about 1000
- # units have increased by about 500
- ACR accredits over 95%

Look at the Growth of Full Field Digital Mammography (FFDM) in the US!
As of 1/1/09
- 6181 units at
- 4086 facilities
- 46% of all units in US are FFDM
- Significant increases since 2005 ACRIN results (5-6%/mo)
- Digital is the same as screen-film, but it’s different

MQSA Certification Requirements and Digital Mammography
- No different from screen-film mammography
- In order to legally start performing mammography in the US, facilities must
  - Meet all MQSA personnel, equipment, QC and reporting requirements
  - Have a medical physicist conduct an equipment evaluation
  - Apply for accreditation
  - Obtain a provisional MQSA certificate
- To continue performing mammography, facilities must
  - Continue to meet all MQSA requirements
  - Pass accreditation every 3 years
  - Obtain a full MQSA certificate every 3 years
  - Undergo inspection by an MQSA inspector every year
FDA Approved ACR to Accred

- GE
  - 2000D, DS, Essential
- Fischer
  - SenoScan
- Lorad
  - Selenia
- Siemens
  - Novation
- Fuji
  - FCRm (computed radiography)

ACR Accreditation for FFDM

The process is exactly the same as for screen-film

What You Must Do Before Examining Patients on a New Unit Depends On

- If you are a brand new facility
- If you installed a new unit at an already accredited facility
If You Are a Brand New Facility - Before You May Examine Patients

• Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass
• Facility must send ACR the Entry Application, fees and Equipment Evaluation Pass/Fail results
  – ACR staff reviews and approves complete application and Equipment Evaluation and notifies FDA (or state certifier)
• Facility must receive 6-month provisional MQSA certificate (or interim notice)
  – Not more than 4 days from the time facility submits required documentation to ACR
• Recommend scheduling Equipment Evaluation 1 week before examining patients (including “applications”)

See www.acr.org for New Facility Application

Currently, you must send in hardcopy application; in the future, you will be able to submit applications on-line (ACRedit)

If Your Facility Is Already Accredited - Before You May Examine Patients

• Call ACR for appropriate application materials
• Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass
• Facility must send ACR the application, fees and Equipment Evaluation Pass/Fail results
• Facility does not have to wait for a response from ACR to use the new unit for mammography
  – Facility already has a current MQSA certificate
• Beware if you have digital, CMS will not reimburse if they don’t have notification from FDA that you are approved for digital
  – Call ACR to be sure we have received your FFDM application and transmitted it to the FDA before using
ACR’s Current FFDM QC Requirements

- Same as FDA’s
- Which are the same as the manufacturer’s
- ACR suggests using manufacturer’s data forms
- Dr. Finder will discuss these requirements in detail

Allow Time for QC

- QC may take longer with digital, especially in beginning
- Techs need adequate time for routine QC
  - Includes actual testing and documentation
  - More time needed for corrective action if problems
- Don’t be stingy
  - High-profile cases of fraudulent QC
  - MQSA certifications revoked
  - Fines levied
  - License and/or tech certificate revoked
  - Some cases went to court
  - Tech blamed insufficient time

Medical Physicist’s New Unit Equipment Evaluation & Annual Survey

- When submitting reports for accreditation
- Medical physicist must complete ACR’s summary forms
  - MQSA Requirements for Mammography Equipment (checklist)
  - Medical Physicist’s Mammography QC Test Summary (FFDM mfr-specific)
- Forms provides ACR with needed pass/fail information
  - If medical physicist passes test, ACR accepts it
  - If he/she fails test, ACR requests corrective action
  - If he/she writes “NA,” “see comments” (or anything other than pass or fail), ACR will follow-up; accreditation will be delayed
- Significantly different formats (even if they contain all the necessary information) will delay review
Have Your Medical Physicist Download
Summary Forms

- www.acr.org
- In Excel format
- Required for Equipment Evaluation report
- Addresses 900.12(b) of the FDA regulations
- Same for S-F and FFDM

MEDICAL PHYSICIST’S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – General Electric

Tips for Passing Accreditation

- Clinical image (fatty and dense breast)
- Phantom image
- Dose (<300 mrads)
- Processor QC or
- Laser QC for FFDM
  - Follow your mfr QC manual
- Criteria the same for digital as with screen-film
Clinical Image Quality Evaluation

- Positioning
  - Still major reason for failure
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID
  - Must be present
  - OK under HIPAA

Failure due to positioning and missing tissue

Phantom Image Quality Evaluation

- Follow ACR testing instructions
  - Expose at technique for 4.2 cm breast
  - Process image as done for clinical images
  - Window and level to best show test objects
- Scoring criteria
  - 4 largest fibers
  - 3 largest speck groups
  - 3 largest masses
  - Be sure to subtract for artifacts

For Digital, ACR Only Accepts Hardcopy for Accreditation

- Phantom
  - Do not zoom or rotate
  - Print as close to “true size” as possible (w/in +/- 25%)
- Clinical
  - Must be of “final interpretation quality”
  - Entire breast must fit on image; no “tiling”
  - Print as close to “true size” as possible
  - Must contain patient ID information
- Lead interpreting physician must review and approve all hardcopy images
Things You Should Know When Going Digital (from FDA guidance)

- Digitizing analog images
- Transferring digital images
- Transmitting digital images for interpretation
- Image labeling
- Archiving digital images
- MQSA certification requirements

May I Digitize Screen-Film Images?

- For comparison purposes
  - Yes, if interpreting physician deems it acceptable; FDA also suggest digitizers be cleared by FDA for mammography

- For retention purposes
  - No

- For final interpretation
  - No

How Must I Transfer Digital Images if Requested by Patient or MD?

- Must be able to provide hardcopy of final interpretation quality
  - Many complaints on poor hardcopies
- Softcopy original or lossless compressed images, if acceptable by receiving party
- Charging for hardcopies
  - May not charge for 1st hardcopy
  - May charge for additional copies (actual costs)
### May I Transmit Digital Images for Final Interpretation?

- The original or lossless compressed FFDM data
- Yes, if acceptable by receiving party
- Lossy compressed FFDM data
- No

### Image Labeling

- FDA-required image annotation (view & laterality, pt name and ID, etc)
  - All must be visible on each displayed image in the standard or default display (view & laterality MUST be near axilla)
  - May be switched off
  - Applies to BOTH hardcopy and softcopy images

### May I Retain Digital Mammograms as:

- Original or lossess compressed FFDM data?
  - Yes
- Lossy compressed FFDM data?
  - No
- Hardcopy film of final interpretation quality?
  - Yes
Healthcare Site with Complex Problematic Process involving heterogeneous information system

Vendor expertise

Integration Profile

Proposed solution Using existing standards

IHE Technical Framework details solution

Vendor implements solution into REAL product

Vendor tests solution at Connect-a-thon

Professional Societies Demonstrate/Educate That solution exists

Healthcare Site Includes IHE in RFP

IHE

Manufacturer’s FFDM QC Requirements

• Tests vary for each manufacturer and model
  – Some tests same but names different
  – Some tests not required by some manufacturers

• Frequencies vary for each manufacturer and model

• Procedures vary for each manufacturer and model

• Pass/fail criteria vary for each manufacturer and model

• All of the above may vary with QC manual revisions of same manufacturer/model

ACR FFDM QC Manual Project

• Eric Berns, Ph.D., chair, Subcommittee on QA

• Standardize QC tests, performance criteria and frequencies across all systems
  – Will apply to all manufacturers and models
  – Fewer tests and written to be “tech friendly”
  – New phantom to be more applicable to digital (but usable with screen-film)
  – When ready, draft will be sent to manufacturers for their input before it is final

• When final, ACR will apply for FDA alternative standard

• Hope to have draft completed by end of 2008
Where to Go for Help on Digital QC, MQSA Certification and ACR Accreditation

Your Medical Physicist Is Your Friend

• Talk with her before the annual survey
  – Let her know if you have equipment or QC problems/questions
• Talk with her after you receive the report
  – Make sure you understand all results, recommendations and timeframes
• Talk with her during the year any time you have questions or concerns about equipment performance
  – Show clinical images illustrating the problem (physicists like pictures too)

Contact FFDM Manufacturer for QC Assistance

<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td><a href="http://www.gehealthcare.com">www.gehealthcare.com</a></td>
</tr>
<tr>
<td>Fuji</td>
<td><a href="http://www.fujimed.com">www.fujimed.com</a></td>
</tr>
<tr>
<td>Lorad</td>
<td><a href="http://www.hologic.com">www.hologic.com</a></td>
</tr>
<tr>
<td>Siemens</td>
<td><a href="http://www.medical.siemens.com">www.medical.siemens.com</a></td>
</tr>
</tbody>
</table>
Question 1: What are the essential quality control tests for new mammography equipment?

Mammography systems with image quality that meets the requirements may undergo periodic quality control procedures that are recommended by national organizations in the field. These tests assess the system’s performance in terms of image quality, exposure, and other key parameters. The results of these tests must be documented and reviewed by qualified personnel.

Question 2: Can a facility use prior and retroactive approval of test results as part of the MAMC?

Yes, a facility may use prior and retroactive approval of test results if its MAMC unit is not operative. However, if a facility uses this approach, it must ensure that all tests and documents submitted for the facility’s MAMC unit are completed with a quality assurance program that is sustained.

Table: Accreditation Results

<table>
<thead>
<tr>
<th># Units*</th>
<th>Overall</th>
<th>Pass</th>
<th>Deficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen-Film</td>
<td>19,854</td>
<td>89.0%</td>
<td>11.0%</td>
</tr>
<tr>
<td>FFDM</td>
<td>5085</td>
<td>93.3%</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

*1st attempt for both initials and renewals; 2/15/03 – 4/24/08
**Reasons Facilities Do Not Pass Accreditation**

<table>
<thead>
<tr>
<th>1st Attempt Screen-Film Deficiencies (2/15/03 - 4/24/08)</th>
<th>1st Attempt FFDM Deficiencies (2/15/03 - 4/24/08)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical: 72.6%</td>
<td>Clinical: 81.2%</td>
</tr>
<tr>
<td>Phantom: 27.4%</td>
<td>Phantom: 18.8%</td>
</tr>
</tbody>
</table>

**Clinical Images: Fatty vs. Dense Deficiencies**

<table>
<thead>
<tr>
<th>Screen-Film Clinical Deficiencies</th>
<th>FFDM Clinical Deficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dense: 56.3%</td>
<td>Dense: 47.3%</td>
</tr>
<tr>
<td>Fatty: 43.7%</td>
<td>Fatty: 52.7%</td>
</tr>
</tbody>
</table>

**Phantom Images and Dose**

<table>
<thead>
<tr>
<th></th>
<th>Average Scores</th>
<th>Ave Dose* (mrads)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># Units</td>
<td>Fibers</td>
</tr>
<tr>
<td>Screen-Film</td>
<td>19,854</td>
<td>4.71</td>
</tr>
<tr>
<td>(SD)</td>
<td>(0.47)</td>
<td>(0.39)</td>
</tr>
<tr>
<td>FFDM</td>
<td>5085</td>
<td>5.01</td>
</tr>
<tr>
<td>(SD)</td>
<td>(0.55)</td>
<td>(0.31)</td>
</tr>
</tbody>
</table>

*as measured by TLD
ACR Breast Imaging Accreditation Programs Update

• Assesses entire facility performance
  – Personnel qualifications (professional guidelines developed by ACR/ACS Joint Task Force in 1997)
  – Equipment
  – Quality control
  – Quality assurance and outcome data
  – Exam identification and labeling
  – Clinical performance
  – Phantom image quality
  – Radiation dose
• Report provides detailed recommendations for improvement

Stereotactic Breast Biopsy Accreditation Program (SBBAP)

• Assesses entire facility performance
  – Personnel qualifications (professional guidelines developed by ACR/ACS Joint Task Force in 1997)
  – Equipment
  – Quality control
  – Quality assurance and outcome data
  – Exam identification and labeling
  – Clinical performance
  – Phantom image quality
  – Radiation dose
• Report provides detailed recommendations for improvement

Professional Guidelines

• In 1997 ACR and the American College of Surgeons agreed on and published guidelines for physician training, qualifications, and continuing experience*
  – Collaborative setting: radiologists and surgeons work together
  – Independent settings: radiologists or surgeons work independently

SBBAP - Clinical Performance

Goal: Determine ability to accurately perform the procedure
- Case material
- Devices
  - Gun-needle
  - Vacuum suction
  - Other FDA-approved core biopsy devices
- Submit examples of best work
- Criteria
  - Accurate needle positioning of biopsy probe in relation to the target at specified stage of procedure for the probe being used

SBBAP - Equipment, Phantom Images and Dose Criteria

Goal: Equipment functioning optimally; dose does not exceed level set for mammography
- QC evaluation
- Phantom image quality assessment
- Dose criteria - must be less than 300 mrad

<table>
<thead>
<tr>
<th>MAP Phantom</th>
<th>Mini Phantom</th>
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</thead>
<tbody>
<tr>
<td>Fibers</td>
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</tr>
<tr>
<td>4.0</td>
<td>5.0</td>
</tr>
<tr>
<td>2.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Speck Groups</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>4.0</td>
</tr>
<tr>
<td>2.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Masses</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>3.5</td>
</tr>
<tr>
<td>2.0</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Quality Problems Exist

- Only highly motivated facilities voluntarily accredit
- But more than 20% of all stereotactic breast biopsy applicants did NOT pass on their first attempt between 2005-2008
- Failures are primarily clinical, targeting issues
- Phantom failures also show image quality problems
- After corrective action, less than 2% of the total applicants did not pass after a 2nd try
Excessive Radiation Dose

- 6% failures due to excessive radiation dose
  - They exceed 300 mrad
  - Mostly due to inappropriate techniques
- For comparison, there are no failures for dose in the ACR Mammography Accreditation since MQSA

Facilities are Not Voluntarily Accrediting

- Estimated 2300 x-ray units in United States used for stereotactic breast biopsy (FDA 2005; IMV 2005)
- As of January 2009, accredited (or in process)
  - ACR: only 631 units at 602 facilities
  - ACoS: only 4 units at 4 facilities
- Only 27% after 12 years
- Mammography had the same problems before MQSA
  - Less than 50% accredited voluntarily
  - 30% of units failing dropped out of accreditation
  - They continued mammography - poor quality mammography

National Mammography QA Advisory Committee (Nov 2007)

- ACR and Society of Breast Imaging statement
  - In order to improve the quality of these procedures at ALL facilities in the US (not just those that voluntarily accredit), for ALL women, the exemption for stereotactic breast biopsy should be lifted
  - The American College of Radiology supports inclusion of stereotactic biopsy under MQSA to improve care for all women by all physicians
- NMQAAC
  - 9 out of 14 members voted in favor of advising the FDA to regulate stereotactic breast biopsy facilities under MQSA
Breast Ultrasound Accreditation Program (BUAP)

- Assesses entire facility performance
  - Personnel qualifications
  - Equipment
  - Quality control
  - Quality assurance and outcome data
  - Exam identification and labeling
  - Clinical performance
- Biopsy Accreditation via separate module
- Report provides detailed recommendations for improvement

BUAP - Clinical Performance

Goal: Image Quality and ability to accurately perform the procedure

- Breast ultrasound
  - Simple cyst, and
  - Solid mass
- Ultrasound-guided breast biopsy
  - Core needle biopsy
    - Gun-needle or
    - Vacuum suction
  - Fine needle aspiration cytology
  - Accurate needle positioning of biopsy probe in relation to the target at specified stage of procedure for the probe being used
- Submit examples of best work

Quality Problems Exist

- Only highly motivated facilities voluntarily accredit
  - 969 facilities currently accredited (Jan 2009)
- But 23% of all breast ultrasound applicants did NOT pass on their first attempt between 2005-2009
- Failures are primarily due to biopsy
- After corrective action, only 2.5% of the total applicants did not pass after a 2nd try
Breast Imaging Centers of Excellence

- A center must be fully accredited in:
  - Mammography by the ACR (or an FDA-approved state accrediting body)
  - Stereotactic Breast Biopsy by the ACR
  - Breast Ultrasound by the ACR (including the Ultrasound-Guided Breast Biopsy module)
- 305 centers of excellence (Jan 2009)
- For more information, go to www.acr.org/accreditation/bicoe.aspx

Breast MRI Accreditation Program

- Committee on Breast MRI Accreditation
  - Connie Lehman, M.D. and Elizabeth Morris, M.D., co-chairs
- Program under development
- Expect to go live in 2009

ACR Breast Imaging Guideline
and Policy Updates
Breast Imaging Guideline and Policy Updates

- Guidelines to be approved by Council
  - Screening and diagnostic mammography (2008)
  - Breast MRI (2008)
  - Ultrasound guided breast biopsy (2009)
  - Stereotactic breast biopsy (2009)
- Breast screening statement
  - Under development
- BI-RADS®
  - New FAQs on multimodality and audit benchmarks*
  - Committee will begin updating 2003 Atlas in 2009


ACR Statement on NEJM Study Regarding CAD*

- CAD is not a substitute for human interpretation, and those using this tool must use it properly, as an adjunct to, rather than a replacement for, careful mammographic evaluation.
- Vendors also should strive to continue to improve the performance of CAD systems.
- There is a fair amount of evidence outside the current study to suggest that, when properly used, CAD may indeed be worthwhile and it seems unwarranted to consider abandoning this potentially valuable tool at this time.


ACR Position Statement on the Benefits and Limitations of Mammography

The American College of Radiology reaffirms its position, consistent with such other organizations as the American Cancer Society and the National Cancer Institute, that all women over 40 undergo annual screening mammography. The American College of Radiology will undertake an educational program that discusses and reviews with ACR membership and the American public the indications, efficacy, benefits, and limitations of mammography; 2002 (Res. 41).
It is unclear at what age, if any, women cease to benefit from screening mammography. Because this age is likely to vary depending on the individual's overall health, the decision as to when to stop routine mammography screening should be made on an individual basis by each woman and her physician.

Breast Imaging Pay-for-Performance Measures

Physician Performance Measures

- Developed by the AMA’s Physician Consortium for Performance Improvement in collaboration with the National Committee for Quality Assurance (NCQA) and the ACR
- Radiology Work Group
  - David Seidenwurm, MD, and William Golden, MD, (Internal medicine), co-chairs
- Contact Judy Burleson (jburleson@acr.org) for more info
New Modalities

- Breast tomosynthesis
  - Screening vs. diagnosis
  - Scientific research on efficacy relative to existing techniques
  - Volume of images per case
  - Quality control
  - Accreditation
  - Certification
- Breast CT
  - Ditto

Mammography HAS Improved, Thanks to Your Efforts