ACR Stereotactic Breast Biopsy Accreditation Program - Update

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Society of Breast Imaging

NMQAAC
September 28-29, 2006
I have no conflict of interest to declare.

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The American College of Radiology and the Society of Breast Imaging endorse regulation of stereotactic breast biopsy under MQSA.

The ACR program for accreditation of stereotactic breast biopsies, which uses the same format as that used by the FDA for mammography accreditation, could be used for this process.
ACR Stereotactic Breast Biopsy Accreditation Program

• First offered in 1996
• Modeled after ACR Mammography Accreditation Program with assessment of:
  – Personnel
  – Equipment
  – Clinical performance
• ACR reviews applications under contract for the American College of Surgeons Stereotactic Breast Biopsy Accreditation Program
ACR Stereotactic Breast Biopsy Accreditation Program evaluates:

- Personnel qualifications
  - Physicians
  - Technologists
  - Physicists
- Clinical image quality
  - Only assesses stereotactic breast biopsy procedures (no needle localization, ductography)
- Phantom image quality/dose
- Quality control program
Personnel

Goal: Ascertain minimum level of training and experience whatever combination of personnel are performing biopsies

• Physicians
  – Qualifications worked out with ACR and the American College of Surgeons
  – Collaborative setting: radiologists and surgeons work together in same setting
  – Independent settings: radiologists or surgeons work independently

• Medical physicists

• Technologists
Personnel Qualifications

- Initial qualifications including education and hands-on experience
- Continuing education
- Continuing experience
Clinical Image Evaluation

Goal: determine ability to accurately perform the procedure

- Case material
- Devices
  - Gun-needle
  - Vacuum suction
  - Other FDA-approved core biopsy devices
- Criteria
  - Accurate needle positioning of biopsy probe in relation to the target at specified stage of procedure for the probe being used
Phantom Images and Dose Criteria
Goal: Exposure does not exceed level set for mammography; equipment functioning optimally

- Dose criteria - must be less than 300 mrads
- Phantom image quality criteria

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Quality Control

- Published in 1999
- Applicants must follow QC outlined in ACR QC Manual
SBBAP Reviewer Qualifications

- Reviewers must be:
  - ABR certified
  - ACR members
- Must participate in formal training program
- Minimum 5 years experience
- In clinical or physics practice across the U.S.
- To address potential conflicts, the reviewer may not review images from own state
- Reviewer QC is performed by ACR
499 Units/450 Facilities Accredited
(as of 9/1/06)
1ST Attempt Deficiencies
2002 - 2005

- CLINICAL+PHANTOM: 63%
- CLINICAL (no Phantom): 21%
- PHANTOM (no Clinical): 10%
- ONLY DOSE: 6%
- ONLY PROCESSOR: 0%

ACR
American College of Radiology
Breast Biopsy* Trends from CMS Data
(Levin et al. JACR 2006; 3:707)

*includes image-guided and non-image-guided procedures
Trends in Performance of Breast Biopsy based on 2004 CMS Data (Levin et al. JACR 2006; 3:707)

• Of image-guided breast biopsies:
  – 72% done by radiologists
  – 24% done by surgeons

• From 1999-2004 rate of increase in performance of biopsies:
  – Radiologists: 79%
  – Surgeons: 16%
Trends in Performance of Breast Biopsy based on 2004 CMS Data (continued)

- # breast biopsies total in 2004: 144,697
- # image-guided breast biopsies in 2004: 124,423
  - 86% of all biopsies are image-guided
- # stereotactic breast biopsies in 2004: 49,770
  - Estimate 40% of all image-guided biopsies are stereotactic
- Data does NOT include procedures covered by private insurance
Thank you.

Questions?