

# **Image-Guided Breast Procedures: Who Should Do Them?**

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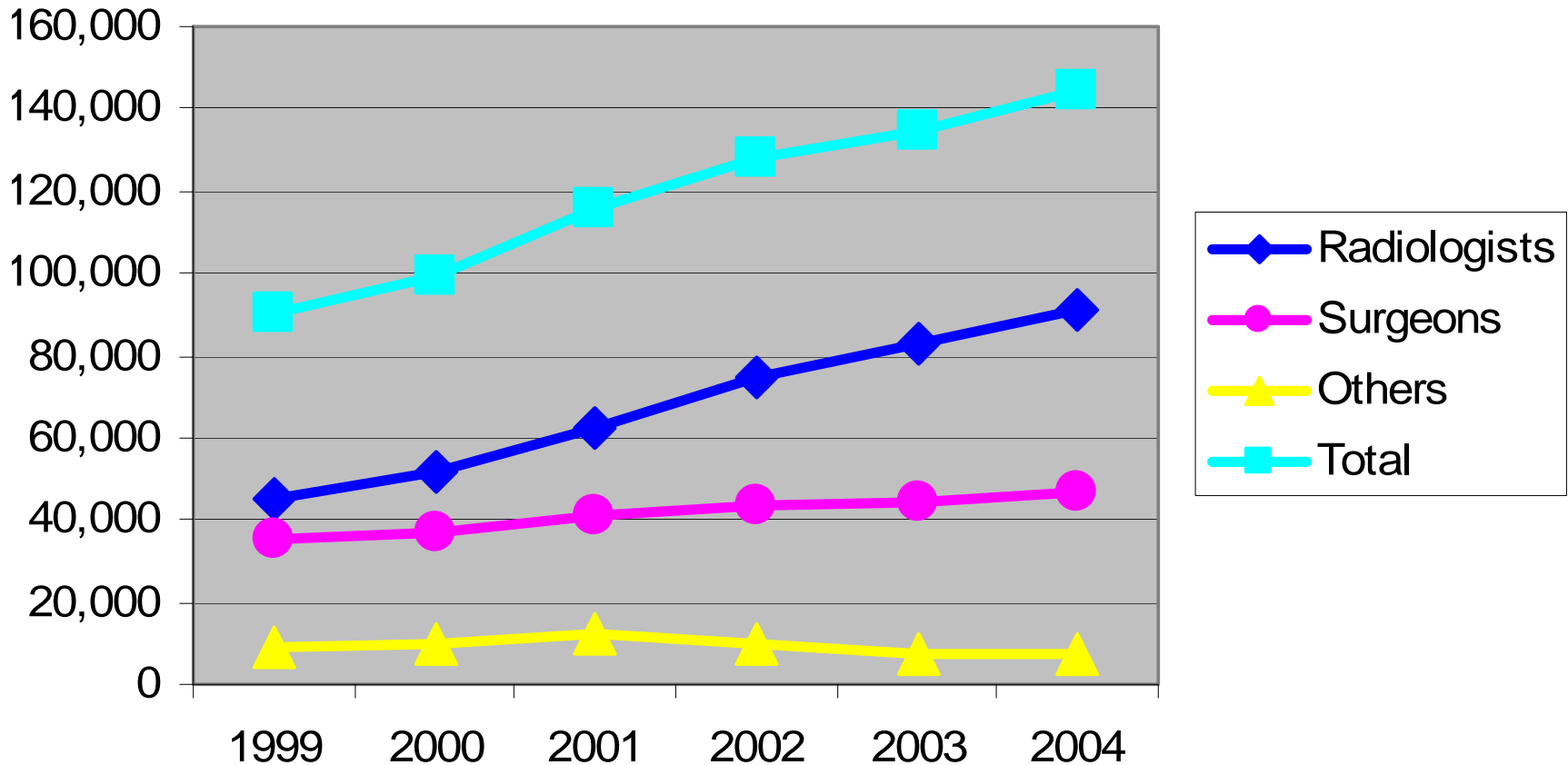
*Chair, American College of Radiology Board of Chancellors*

*The American Society of Breast Surgeons*

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# Current Practice Patterns and Trends in Breast Biopsy Among Radiologists and Surgeons *(Levin et al JACR 2006;3:707A)\**



***CMS data for 2004 - Actual number including private and other payors much higher - 50,000 Stereotactic Bx***

- **Why the Growth?**
  - **Compared to open surgical biopsy**
    - **Less morbidity**
    - **Faster**
    - **Lower cost**
    - **Comparable accuracy when properly performed in an appropriate setting**

**But.....**

**But..... There are Pitfalls**

# Pitfalls

- Insufficient Sample
  - No matter what modality is being used, highly accurate *targeting* of the lesion is crucial to the outcome

# Pitfalls

- Insufficient Sample
- There are high risk lesions that require excision
  - Atypical ductal hyperplasia
  - Columnar cell change or flat epithelial atypia.
    - Less common
  - A thorough knowledge of what constitutes a high-risk lesion is crucial for making proper management recommendations

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  - Findings on the pre-biopsy mammogram are not explained by the pathology results

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- There are high risk lesions that require excision
- Mammographic-histologic discordance
- Variable false-negative rate
  - From 0.3% (3 in 1000)
  - To 4.3% (nearly 1 in 20)

- **FDA's 1997 Quality Mammography Standards Regulations**
  - Temporarily exempted interventional mammography (such as stereotactic breast biopsy)
  - Due to “agency’s belief that science had not advanced to the point where effective national quality standards could be developed”
- **Things have changed since 1997**

- 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
- Currently there is no formal agreement between ACR and the ACoS / ASBS on the physician qualifications for performing breast ultrasound guided biopsies.....

**Whoever is qualified, appropriately trained, appropriately experienced and uses equipment and techniques that maximizes procedure accuracy, and optimizes both patient outcome and patient safety.**

- **Assess entire facility performance**
  - Personnel qualifications
  - Clinical performance
  - Quality assurance/outcome data
  - Equipment
  - Quality control
  - Radiation dose (as applicable)
- **Provides educational feedback for quality improvement**

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    - **Personnel qualifications (professional guidelines developed by ACR/ACoS Joint Task Force in 1997)**
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    - **Equipment**                      **Phantom Image Quality and Quality Control of Equipment and Facility**

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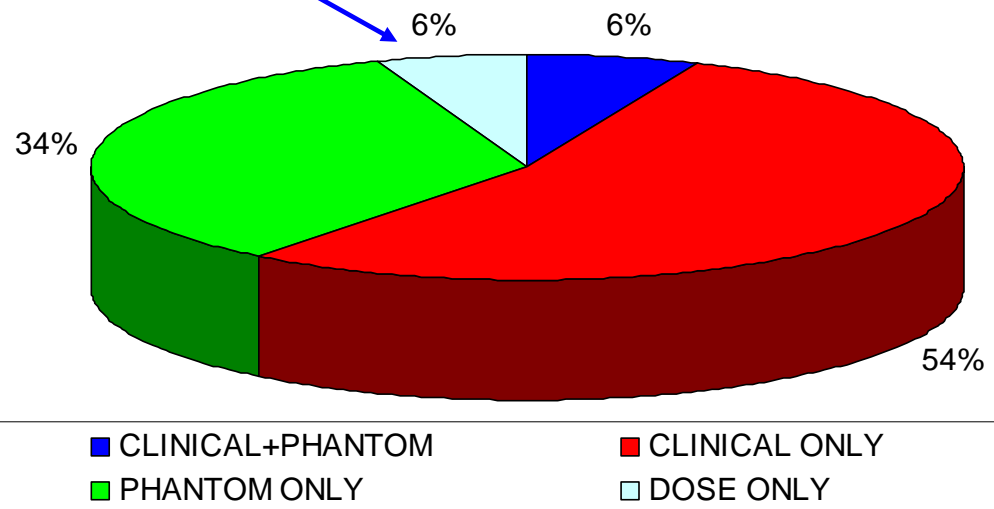
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    - **Equipment**
    - **Radiation dose < 300 mrad**
  - **Report provides detailed recommendations for improvement**
- **American College of Surgeons Stereotactic Breast Biopsy Accreditation Program**
  - **Separate program entrance through the American College of Surgeons**

## ACR ACCREDITATION PROGRAM FAILURES

- **25% of all applicants failed on first attempt (2004-06)**
- **54% due to clinical images (targeting)**
- **34% due to phantom (poor quality images)**
- **6% both clinical images and phantom**
- **6% due to excessive radiation dose**

- **6% failures due to excessive radiation dose**
  - The radiation dose exceeded 300 mrad
  - Majority failures due to inappropriate techniques
- For comparison, there are no failures for excessive dose in the ACR

**Mammography  
Accreditation since  
MQSA**



- **Estimated 2300 x-ray units in United States used for stereotactic breast biopsy (*FDA 2005; IMV 2005*)**
- **As of November 2007**
  - **ACR: only 471 units at 459 facilities accredited**
  - **ACoS: only 4 units at 4 facilities accredited**
- **Only 20% accredited **after 10 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**

- **Mammographic image quality improvements that have occurred since the implementation of MQSA have resulted in earlier breast cancer detection leading to an improvement in the 5 year survival rates of these women**

- **The number of breast biopsies is increasing in the United States**
- **The accuracy of these procedures requires expertise and great care in many aspects of the procedure**
- **Quality, safety, and accuracy are variable**
- **Voluntary accreditation programs have not witnessed widespread participation**
- **The American College of Radiology supports inclusion of stereotactic biopsy under MQSA to ensure high quality in the performance of this procedure for **all** women by all physicians**