Mammography Screening Guidelines: Challenges and Opportunities

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ACR SCREENING GUIDELINES

• Annual screening mammography beginning at age 40 for women of average risk.

• Untested Women with a first-degree relative with known BRCA mutation; yearly starting at 30, but not before age 25.

• Women with a 20% or greater lifetime risk for breast cancer based on cancer risk models; yearly starting at age 30, but not before age 25, or 10 years earlier than the age at which the youngest first-degree relative was diagnosed, whichever is later.
ACR Guidelines Continued

- Women with a history of mantle radiation between the ages of 10 and 30, yearly starting 8 years after radiation therapy, but not before the age of 25.
- Women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in-situ (DCIS), invasive breast cancer or ovarian cancer; yearly from the time of diagnosis, regardless of age.
Screening:
Not Just a 2-D Mammogram
The choices we make in breast imaging should result in excellent patient care, quality outcomes and reasonable cost.
Set Goals
Then
Make the Hard Choices
Goals of a Cost-Effective Screening Program

1. Detection of breast cancer at its earliest, most treatable stage.
2. Reduction in callbacks
3. Increase in cancer detection rate
4. Decrease in associated harms of screening, real and perceived
   - Anxiety
   - Inconvenience
   - Radiation exposure
   - Unnecessary image studies/biopsies
   - Overtreatment
5. Cost containment/reduction without a decrease in quality
The Breast Radiologist’s Screening Toolbox

- 2-D Digital mammography
- 3-D Tomosynthesis
- Whole Breast Ultrasound
  - Hand-held
  - Automated
- Breast MRI
Players in the toolbox end up being competitors in the sandbox.

Which supplemental modality receives top billing?
In an ideal world, with a 100% sensitivity and specificity, the most effective screening strategy would be to evaluate women with all four modalities, thus ensuring that no cancer would be missed. MRI alone would be the next best choice. However, the costs of such a program would be prohibitive.
The Hardest Choice:
Balancing Best Practice With Financial Constraints
We cannot make appropriate screening choices without the facts
The Facts We Like:

- Randomized Controlled Clinical Trials have shown screening mammography has decreased breast cancer mortality by 30%.
- Observational studies which consider women who have actually been screened, as opposed to those just “invited” to screen, have demonstrated an even greater benefit.
- Supplemental Screening tools – Tomosynthesis, Ultrasound, MRI – increase the cancer detection rate, and most likely decrease mortality.
The Facts We Like:

- The Affordable Care Act mandates coverage for breast cancer screening in women over 40
- Early detection leads to a decrease in stage and treatment cost
The Facts We Don’t Like:

• Not everyone, including many of our medical colleagues, are fans of mammography or other breast imaging modalities.

• Mammography has an unacceptably high false negative rate, particularly in women with dense breast tissue.

• Supplemental screening with other modalities, though shown to be more sensitive in detecting breast cancer, have not demonstrated a decrease in mortality.
The Facts We Don’t Like:

- Most supplemental screening tests significantly increase the cost of screening.
- Broad implication for Public Health Policies
- Screening tomosynthesis, ultrasound, and MRI are usually not covered by most insurance plans
- Out-of-pocket expenses unacceptable to many patients and providers
United States Preventative Services Task Force
The USPSTF examined the evidence on the efficacy of 5 screening modalities in reducing mortality from breast cancer.

- Film-Screen Mammography
- Clinical Breast Exam
- Self-Breast Exam
- Digital Mammography
- Magnetic Resonance Imaging
USPSTF CONCLUSIONS

- Recommends against routine screening in women ages 40 to 49
- Recommends Biennial screening in women ages 50 to 74
- Insufficient evidence to assess additional benefits and harms of screening in women 75 years or older
- Insufficient evidence to assess additional benefits and harms of clinical breast exam beyond screening in women 40 years or older
Conclusions Continued

- Recommends against teaching patients how to perform breast self-examination
- Insufficient evidence to assess additional benefits and harms of digital mammography or magnetic resonance imaging
HARMS OF MAMMOGRAPHY

- Psychological harms
- Unnecessary imaging tests
- Unnecessary biopsies in women without cancer
- Inconvenience due to false-positive screening results
More Harms

- Harms associated with treatment of cancer that would not become clinically apparent during a woman’s lifetime (overdiagnosis)
- Harms of unnecessary earlier treatment of breast cancer that would have become apparent, but would not shorten a woman’s life
- Radiation exposure
BENEFITS OF SCREENING MAMMOGRAPHY

- Decreases the mortality of breast cancer in women over 40
- Decrease in morbidity from treatment: Earlier detection often obviates the need for mastectomy, radiation therapy and chemotherapy
MAMMOGRAPHY DETECTS MOST, BUT NOT ALL BREAST CANCERS

- 80-85% in women with fatty or average breasts
- 30-55% in women with dense or extremely dense breasts
- Digital mammography, not considered in the USPSTF, report detects up to 70% in dense tissue (50% of women under 50)
The results of multiple trials for screening mammography have shown a reduction in breast cancer mortality for all groups of at least 30%, and up to 60% in some recent studies.
The gold standard for assessing the efficacy of a screening program, using mortality as an endpoint, is the randomized control trial (RCT). It compares mortality of study group with control group.
Study design for randomized control trial for screening mammography

- Population randomized into two groups of roughly equal size
- Study group: Invited to receive screening mammography and standard care
- Control group: Standard care only
- End point: Mortality
- Once randomization complete, whatever occurs to women remains as data for that particular group
RCTs underestimate benefit of screening through bias

- Contamination bias: A woman in control group has a mammogram with a beneficial effect
- Compliance bias: A woman in the intervention group (mammography) fails to comply, resulting in adverse outcome.
In 2002 the USPSTF, relying on an analysis of data from several RCTs, recommended that women begin screening mammography at age 40.
In November 2009, the USPSTF reached a different conclusion than in 2002: Routine screening not recommended in the 40 to 49 year-old age group. In addition to analyzing new data, the task force also considered the harms of screening.
THE SCIENCE BEHIND 2009 GUIDELINES

- An updated meta-analysis of the trials analyzed in 2002
- Inclusion of one new trial and updated data from an earlier study
- Significant service screening studies from Canada and Sweden, that analyzed women who actually underwent screening, not included
- Harms of mammography weighed against benefits
Once efficacy of a screening test established, observational studies offer better study design to measure effectiveness among women who actually undergo screening. Such results, particularly from service screening in Sweden and British Columbia, were not included in USPSTF analysis.
The number of women needed to invite to screening (NNI) to save one life in the USPSTF analysis

- 1904 for women age 40 to 49
- 1339 for women age 50 to 59
Since the USPSTF derived their estimates for lives saved from RCTs that only considered women invited to screening, the NNI is an overestimation for those who actually participated in screening.
If just the number of women who actually undergo screening is considered, only 600-900 women need to be screened to save one life in the 40 to 50 year-old age group.
If the only test shown in Randomized Clinical Trials to decrease mortality is not accepted by our colleagues, we should be very critical and selective when assessing other screening modalities.
Difficult Choices

Informed choice requires careful analysis of the medical literature. Not all screening studies are created equal.

Must carefully evaluate: Study design, potential conflict of interests, number of subjects, inclusion criteria, selection bias and supporting literature.
Reasonable Assumptions

- Supplemental screening probably saves lives, if we consider tumor size, grade, stage, as an acceptable surrogate endpoint for mortality.
- Most women would choose early detection, even if it meant that the possibility of some cancers might be over treated.
The Case For Supplemental Screening
Supplemental Screening Tools

- 3-D Tomosynthesis
- Ultrasound
  - Hand-held
  - Automated
- MRI
A three dimensional imaging technology that involves acquiring images of a stationary compressed breast at multiple angles. Images reconstructed into a series of thin high-resolution slices that can be displayed individually or in a dynamic cine mode.

The greatest advantage of 3-D over 2-D is the elimination of tissue overlap, particularly in dense breasts.
12,631 Women screened (26,652 invited to participate as part of the Norwegian Screening Program)

- 37 – 40% Reduction in callbacks (False Positives)
- 75% Increase in detection of invasive cancer (False Negatives)

Breast Ultrasound

Hand-held

• Berg
  • Elevated Risk Population (2,662 patients)
  • Mammography alone: 7.6 cancers/ 1,000 screened
  • Mammography plus ultrasound: 11.8 cancers/ 1,000 screened
  • Additional 4.2 cancers detected/ 1,000 screened with mammography and ultrasound

Breast Ultrasound

Hand-Held

- Weigert
  - Multi-institutional retrospective analysis
  - 41% of population had dense breast tissue
  - 72,030 Screening mammograms; 8,647 screening U/S
  - Only 12% underwent follow-up U/S
  - Additional 3.2 cancers /1,000 screened with mammography and ultrasound

Breast Ultrasound

Automated Whole Breast Ultrasound (AWBS)

- Kelly
  - 4,419 study subjects (dense tissue, personal/family history CA, implants)
  - Non-randomized, multi-institutional prospective study
  - Mammography alone: 3.6 cancers /1,000 screened
  - Mammography plus AWBS 7.2/cancers/ 1,000 screened
  - Additional 3.6 cancers/1,000 screened with mammography and AWBS

Assembling Additional Facts in Determining the Right Choices

- Professional Society Recommendations and Guidelines
- Financial Considerations
- Workflow Issues
- Patient Demographics
American College of Radiology/Society of Breast Imaging

- Except MRI in high-risk women (greater than 20-25% lifetime risk), supplemental screening not routinely recommended.

“Screening breast ultrasound may have a role as a supplemental screening tool for high-risk women who have contraindications to MRI or in those whose levels of risk do not reach the level recommended for breast MRI screening by the ACS.”

Breast cancer screening with imaging: Recommendations from the society of breast imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. 2010 American College of Radiology.
Financial Considerations

- **Insurance Coverage**
  - Varies by state
  - Inconsistent reimbursement by company

- **Out-of-Pocket Charges to Patients**
  - Two-tier health care coverage

- **Pushback by Radiologists**
  - Incremental interpretation time not commensurate with remuneration

- **Institutional Resistance**
  - Equipment Cost
  - Additional FTEs

- **The Costs of “Free” Care**
Workflow Issues

• **Interpretation Time**
  - Tomosynthesis: At least doubles read time
  - Ultrasound:
    - Variable: Hand-held vs AWBS

• **Triage**
  - Patient Selection: Age, breast density, risk
  - Public Relations Fallout
Patient Demographics

- Risk
  - Age
  - Ethnicity
  - Personal/Family history
- Socioeconomic Status
Intermountain Healthcare Experience

Urban Central Region
(Metropolitan Salt Lake City)

One Central Diagnostic Center
Four Screening Centers
Breast Center Statistics

- 40,000 Screening Mammograms
- 9,000 Diagnostic Mammograms
- 6,000 Ultrasounds
- 450 Stereotactic Biopsies
- 1,000 Ultrasound-Guided Biopsies
- 500 Cancers Diagnosed
Supplemental Screening Program

- **Screening Tomosynthesis since 2014**
  - Beginning 2\textsuperscript{nd} Quarter 2014, insurance coverage by local carrier (1/3 Intermountain patients)
  - Non-insured will be charged out-of-pocket

- **Screening Ultrasound**
  - Hand-held upon request

- **Screening MRI**
  - Available to high-risk patients, in accordance with ACS guidelines
Opportunities

Once mature screening and diagnostic programs are established, valuable data can be collected and analyzed for outcomes research.
Improving Patient Outcomes through Quality Improvement Projects
“As part of controlling health spending, we will have to move to a system whereby hospitals and doctors are reimbursed for proven quality and cost-effective services, rather than for procedures alone. This will require a uniform system of healthcare information whereby consumers will be able to access a hospital’s or individual doctors performance records.”

“That Used To Be Us” Friedman & Mandelbaum
Traditional Paradigm

The more you spend, the better the outcome

In practice, however...

High quality healthcare costs less
Changing Clinical Practice

Measure practice variation
  - Variation among individual units of care
  - Variation within process

Provide feedback on variation to a peer group
  - Why are they different? What is best care?
  - Pull in literature, experts, special analyses

Act
  - Change clinical practice
  - Fix the measurement system
Breast Imaging Data
Intermountain Healthcare
Time to Biopsy
Percutaneous Biopsy Rate

Percent Percutaneous Biopsy

Efficiency and Cost Containment in Breast Imaging

Identification of opportunities to control costs and maintain quality.

- Reducing number of unnecessary short term follow mammographic evaluations
- Reducing costs for imaging-guided diagnosis of breast cancer
- Eliminating unnecessary imaging examinations at the front end
Perception among breast radiologists of wide variation in use of BI-RADS 3 for screening patients called back for additional imaging.

Complaints from referring clinicians that short-term imaging recommendation caused patient anxiety.

Concern about unnecessary radiation exposure.

Cost to the system.
System Variation

BI-RADS 3 Rates by Facility (2011)
Goal

Reduce the percent of screening mammography patients called back for additional imaging procedures who, upon diagnostic evaluation, are classified as requiring “short-term follow-up” (BI-RADS 3) by 20% from baseline rates; or attain an overall rate of 15%.
Overview Of Project Implementation

Analysis of current data
Review of appropriateness criteria for BI-RADS 3 lesions
Request list of BI-RADS 3 cases
Review previous cases individually or as a group
Determine appropriate categorization of cases
Adjust or maintain practice patterns as appropriate
Implementation

Physician involvement/participation

- Outreach to include physicians around the system in project
- Notification
- Data sharing
- Physician education
- Data tracking and followup
- Longitudinal data collection
- Regular data feedback
Implementation

Notification

• E-mail and personal telephone call to lead radiologist at each facility
• Explanation of goal, benefits of standardization, evidence summary, data sharing
• Individual physician report cards sent to each radiologist showing how they compare to their colleagues and the system
• Individual physician data is blinded in order to protect confidentiality
• Keeps focus on the process rather than judging individuals
Implementation

Physician education

- Individual data report cards sent to each radiologist
- Face to face meetings with individual radiology groups
- Ongoing case review at individual sites
  - Each facility provided with case list of BI-RADS 3 patients
  - Allows radiologists to review their own cases individually and as a group
- Provide ongoing education and support
2012 Board Goal Final Results

Rate of Short-Term Imaging Recommendation in Mammography

Percent of callback patients recommended for short-term follow-up imaging

Date Range: 01-Apr-2012 To 30-Sep-2012

<table>
<thead>
<tr>
<th>Facility</th>
<th>Cases</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Rural</td>
<td>264</td>
<td>22.7</td>
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<tr>
<td>SWR</td>
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<tr>
<td>UCR</td>
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<tr>
<td>System</td>
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<td>14.1</td>
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Source: Mammography Reporting System

Goal Period is from April to September 2012

Goal is to reduce rate

Updated: 14-Nov-2012

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BI-RADS 3 Goal Rates

Rate of Short-Term Imaging Recommendation in Mammography
Percent of callback patients recommended for short-term follow-up imaging

Source: Mammography Reporting System

2013 Average:

System

<table>
<thead>
<tr>
<th>Q3 2012</th>
<th>Q4 2012</th>
<th>Q1 2013</th>
<th>Q2 2013</th>
<th>Q3 2013</th>
<th>Q4 2013</th>
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<tr>
<td>Eligible (n)</td>
<td>768</td>
<td>842</td>
<td>779</td>
<td>890</td>
<td>864</td>
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<tr>
<td>Rate (%)</td>
<td>23</td>
<td>21.4</td>
<td>22.5</td>
<td>20.2</td>
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</tbody>
</table>

Updated: 03-Feb-2013

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New Quality Improvement Projects

Ultrasound-Guided Biopsy: Vacuum-Assisted vs Spring-Loaded
Breast Ultrasound Evaluation for Pain in Women Under 30
The cost of ultrasound-guided vacuum-assisted biopsy is more than double that of spring-loaded needle biopsy. An analysis of practice patterns across the Intermountain system revealed wide variation among radiologists.
While most Intermountain facilities had a vacuum-assisted rate of 25% or less, one facility was as low as 1.25% and another nearly 85%. Other outcomes measures—callback rate, cancer detection rate and PPV2—were fairly similar across the system. The ultrasound biopsy data indicated that this was an area of obvious practice variation.
Assuming accurate targeting and sampling, spring-loaded needle systems provide samples adequate for diagnosis of most lesions amenable to ultrasound-guided biopsy. For spring-loaded devices, most data support the use of 14-gauge and larger needles. Vacuum-assisted core needle biopsy and other biopsy systems are also available for use in ultrasound-guided procedures [2014].
Percent Vacuum Assisted Biopsy

- Hospital A: 23.7%
- Hospital B: 8.2%
- Hospital C: 63.8%
- Hospital D: 4.3%
- Hospital E: 1.2%
- Hospital F: 84.8%
- Hospital G: 55.2%
- System: 23.8%
STRATEGY

Notify lead radiologists, both by e-mail and telephone, of system variation.

Request radiologists complete survey regarding ultrasound biopsy patterns, indicating reasons behind biopsy equipment preference.

Survey results e-mailed to radiologists, detailing system, facility and personal data.

Radiologists invited to participate in system-wide conference call to discuss survey results and share ideas.
Survey Questions

Equipment choice for ultrasound breast biopsy
% cases performed with vacuum-assistance
Needle preference for axillary lesions
% cases FNA axillary lesions
Criteria for choosing vacuum over spring-loaded
% cases with clip placement after core biopsy
Selection criteria for clip placement
Q 1: Equipment preference for ultrasound guided-biopsy.

- Spring-loaded 17
- Vacuum-assisted 6
- No response 2
- Total Respondents 25
Q 2: % cases using vacuum-assistances

- 0-25%: 16
- 26-50%: 1
- About 50%: 1
- 51-75%: 0
- 76-100%: 6
- Unsure: 1
- Total Respondents: 25
Q1: In general, what is your equipment preference in the performance of percutaneous, ultrasound-guided breast biopsy?
Q2: What percentage of the time do you use a vacuum-assisted biopsy device in the breast?
Follow-up Conference Call with Intermountain Radiologists

September 28, 2014
Breast Biopsy Form

Date of Procedure (____/____/______)

Patient Identification Number: ______________________

Breast Biopsy Device:

☐ Spring-loaded, Tru-Cut
☐ Vacuum Assisted

All Cases:

Post-biopsy Clip  Yes ☐  Post-Procedure Mx  Yes ☐

No ☐  No ☐

Vacuum Assisted Biopsy:

Reasons (one or more)

☐ Lesion Size
  ☐ Small
  ☐ Large

☐ Lesion Morphology/Imaging Characteristics

☐ Lesion Removal

☐ Radiologist Preference

☐ Ease of Handling

☐ Other ________________________________
Ultrasound Biopsy Data Collection

- Radiologists’ Consensus
- Staff Cooperation
- Mechanism to Collect and Analyze Results
- Feedback to Radiologists
- Long-term monitoring
There is a perception among Intermountain radiologists that the efficacy of breast ultrasound in the evaluation of pain in women under 30 is negligible, and should be evaluated.
To evaluate the effectiveness of ultrasound in women under 30 with breast pain, outcomes will be tracked for one year, beginning March 2014.

- Women with lumps or other symptoms excluded from analysis
- High-risk women excluded
Data To Be Tracked

Age
Type of Pain
- Focal
- Diffuse
- Acute
- Chronic
- Cyclical
- Migratory
Duration of Symptoms
Family History
Prior Imaging: Yes/No