President’s Column

Mammography screening has remained in the spotlight since the United States Preventative Services Task Force (USPFTF) produced their 2009 guidelines, which discouraged early breast cancer detection. In spite of clear evidence from countless well designed research studies that annual mammography screening beginning at age 40 years saves lives, proponents of the Task Force’s approach continue to attempt to discredit this valuable tool for early detection. The misinformation in that report has been amplified by those who prefer to politicize women’s lives rather than save them.

One of latest assaults was an attempt, lead by primary care physicians, to amend the American Medical Association’s (AMA) policy on screening mammography to exclude women younger than age 50 years. Previous to 2012, the AMA supported annual mammography beginning at age 40 years. The AMA policy (H-525-993) on screening mammography has been around since 1988; its most recent form (prior to 2012) strongly endorsed the positions of the American College of Radiology (ACR) as well as the American Cancer Society (ACS) and American College of Obstetrics and Gynecology (ACOG). It explicitly stated that the “AMA recommends annual screening mammography … in asymptomatic women 40 years and older.” Since the positions of the ACR, ACS and ACOG have not changed, it is difficult to see the need for the AMA to alter its policy. Certainly more is at play here than the science involved. If science prevailed, we would not have reports like the USPFTF 2009 guidelines, mammography or otherwise, in the first place.

Although the new AMA screening mammography policy may not be exactly what we would like, it is much better than the opponents of screening had hoped. This is in large part the work of radiologists involved in the AMA process, including direct representatives of the ACR such as Dr. Arl Van Moore, who played a critical role in ensuring that the voice of breast imagers and women nationwide was heard.

Several fellows of the SBI also played a role in shaping the message to the AMA delegates, including Barbara Monsees, MD, Society of Breast Imaging (SBI) Board member and Chair of the ACR Commission on Breast Imaging, Daniel Kopans, MD, Gold Medal recipient of the SBI, and Mark Helvie, MD, SBI Board member and Chair of the Scientific Advisory Committee of the SBI. Their measured approach to presenting the science behind our recommendations helped to shape the discussion. In the end, the new AMA policy on screening mammography stated that the AMA recognizes the mortality reduction benefit of screening mammography, supports its use as a tool to detect breast cancer, and believes that beginning at the age of 40 years, all women should be eligible for screening mammography. The AMA policy also voices support for insurance coverage for screening mammography, something rather than save them.

Current Design Considerations for a Proposed ACRIN Breast Tomosynthesis Multi-Center Screening Clinical Trial

Elodia B. Cole, MS and Etta D. Pisano, MD

Two-dimensional (2D) screening mammography has always been limited because of overlapping breast tissue. So-called “structural noise” makes it difficult to detect cancers that may be obscured by the low contrast differences between lesions and normal breast tissue. A newer technology, digital breast tomosynthesis (DBT), allows radiologists to assess breasts three dimensionally. This advancement could improve the detection of cancers in cases where overlapping breast tissue exists, potentially allowing for detection of breast cancers at earlier stages when they are most treatable. This tool might also decrease the number of women who are called back for diagnostic work-up and subsequent biopsy.

DBT acquires mammographic scans at multiple low-dose angles that, when integrated, provide a quasi-three-dimensional (3D) view of the breast. DBT systems are similar in size to DM systems, but have modified mechanics.

There is no consensus on how DBT should be performed based on the current literature, where various system-specific acquisition and interpretation methods have been described 2-5. As of this writing, there is only one commercially available DBT system in the United States 6. There are several companies with DBT systems under clinical investigation in manufacturer-specific clinical trials.

There are currently two European breast DBT single-vendor, single-site clinical trials underway for invited screening populations in

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Oslo, Norway (25,000 women, Hologic) and Malmö, Sweden (15,000 women, Siemens). These two studies are designed to assess a primary outcome of cancer detection rate.

Since there is no consensus on how DBT should be incorporated into clinical practice, issues like quality assurance, interpretation time, impact of DBT on downstream work-up, overall costs to the healthcare system and impact on patient screening behaviors have not been well studied. This is part of the rationale behind the proposal for a multi-vendor, multicenter DBT screening trial. In addition, such a trial in the United States and Canada would allow an assessment of the role of DBT in breast cancer screening for the North American population.

The proposed trial, to be run through the American College of Radiology Imaging Network (ACRIN), will investigate three key issues in DBT for breast cancer screening: diagnostic accuracy, cost and impact on patient health outcomes.

The original proposed study design would enroll 31,200 asymptomatic women who would undergo both DBT and digital mammography (DM) at the time of their scheduled screening mammogram at one of 16 participating centers in the United States and Canada. The number of views would be standardized across all manufacturers of the DBT systems. Each woman would undergo both two-view DBT and two-view DM in randomized order during a single clinical visit. The same radiology technologist would perform both the DBT and the DM examinations. Radiologists at each site would interpret one of three arms independently (three readers per study participant) – (1) two-view DBT plus two-view DM, (2) DM; and (3) two-view DBT plus synthetic DM (if available).

A positive interpretation by any of the three readers would result in diagnostic imaging work-up. Ground truth would either be defined by biopsy results for appropriately actionable findings or, for non-biopsied subjects, 10-15 months of follow-up.

An alternative design that is also being considered would require at least double the number of subjects described in the aforementioned paired examination design. Each enrolled woman would be randomly assigned to undergo her scheduled screening mammogram with either DBT or DM. The number of DBT views would be standardized across all participating manufacturers of DBT systems and again would consist of two-view DBT plus two-view DM. Approximately twenty breast imaging centers across the US and Canada would enroll subjects. A single clinical interpretation would be performed for each subject. Each subject enrolled in the study would undergo two to three consecutive years of screening using the randomly assigned imaging modality. Ground truth for each screening round would be defined by biopsy for appropriately actionable findings or, for non-biopsied subjects, follow-up at the next screening round. Interval cancers would be studied and carefully compared. If the budget supports it, mortality endpoints might also be studied.

The primary aims of both trial designs are to compare the diagnostic accuracy using Receiver operating characteristic (ROC) analysis of DBT versus DM and to compare call-back and positive biopsy rates for both technologies, for women presenting for screening mammography. The secondary aims of the study are to assess the cost-effectiveness of the use of DBT for breast cancer screening; to study the impact of DBT in comparison to DM on patient-reported outcomes such as health related quality of life, anxiety, and satisfaction with care; to assess the impact of DBT in breast cancer screening via micro simulation modeling; and to assess and compare the characteristics (e.g., stage, grade, cell subtype) of cancers detected from screening by DBT and DM. The randomized design would also allow comparison of the rate of and subtypes of interval cancers for each technology and, possibly, mortality rates for each screening tool.

While there are definitely significant challenges in logistics and costs to bringing this trial to fruition, whichever design is ultimately selected, ACRIN’s leadership and we believe that it is very important to measure the performance of DBT versus DM across all vendors and in a North American cohort of women undergoing breast cancer screening.

References


Editor’s Note

S
s I write this, it is early August, and I am on vacation. Vacation has meant some time away from a busy clinical service and more family time. In the evenings, I have been having a lot of fun with one of our favorite family activities-working on puzzles. We have worked on all types of puzzles: puzzles of beautiful paintings, puzzles of wood carvings, puzzles of outdoor scenes, even puzzles of fire trucks.

In our day-to-day clinical lives, we work puzzles all the time. In "real" life, we often do not know how to recognize the pieces of the puzzle, and there is no puzzle box with a picture of the completed puzzle to serve as a reference. So how do we become good puzzle-workers? Well, we need to have focus. We must use our powers of observation to carefully look at the pieces. Also, we need to see what pieces fit together. On the other hand, we should not get so excited to force two pieces together when, in fact, they do not fit together.

A great puzzle-worker and problem-solver, Dr. Carol Lee, has completed her term on the SBI Newsletter board. Carol has put a lot of pieces together over the years as SBI president, as the editor of the SBI Newsletter, as chair of the ACR Commission on Breast Imaging, and in a number of other important roles. I thank Carol for her wisdom, her insights, and all her hard work.

In the meantime, Dr. Peter Eby, an established puzzle-worker, has joined the SBI Newsletter board. Peter, who is a radiologist at Virginia Mason Medical Center in Seattle, is a SBI fellow with a strong publication record, especially in breast MRI. I look forward to working with Peter on the SBI Newsletter.
ACR Breast Imaging Accreditation Program Updates

Priscilla Butler, M.S.
Medical Physicist and Senior Director, ACR Department of Quality and Safety

The American College of Radiology’s (ACR) Mammography Accreditation Program has been helping facilities improve the quality of mammography through peer review and professional feedback since 1987. Initially conceived as a voluntary program, accreditation became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all United States mammography facilities to become accredited and certified. Since that time, the ACR has launched three additional voluntary accreditation programs: Stereotactic Breast Biopsy, Breast Ultrasound (with Ultrasound-Guided Breast Biopsy) and Breast MRI. In 2007, the ACR offered the Breast Imaging Center of Excellence (BICOE) designation to centers achieving accreditation in Mammography, Stereotactic Breast Biopsy, and Breast Ultrasound and Ultrasound-Guided Breast Biopsy. Breast imaging facilities have embraced this award, finding it useful in marketing their centers to both patients and payors. As a result, applicants to the voluntary accreditation programs have increased significantly. The current tally of accredited facilities and units is tabulated below. Note that most programs accredited the facility and the unit; the breast ultrasound program only accredited the facility.

<table>
<thead>
<tr>
<th>ACR Accreditation Program</th>
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<tr>
<td>Mammography</td>
<td>8117</td>
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<tr>
<td>Stereotactic Breast Biopsy</td>
<td>1043</td>
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<tr>
<td>Breast Ultrasound</td>
<td>1612</td>
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<tr>
<td>Breast MRI</td>
<td>1230</td>
</tr>
<tr>
<td>Breast Imaging Center of Excellence (centers)</td>
<td>846</td>
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ACR accreditation programs try to keep pace with evolving clinical practice, technology, and federal regulations. In addition, the ACR continuously explores new ways to reduce the administrative burden on applicants and make the process more efficient. As a result, there have been significant improvements to these programs over the past year and more improvements are planned for 2012 - 2013. The following is a brief summary of these changes:

**All ACR Accreditation Programs**

An increasing number of hospitals and outpatient imaging centers are applying for multiple accreditation programs. The ACR’s Commission on Quality and Safety recognizes that the majority of radiologists interpret examinations from multiple modalities. Many have difficulty keeping up with the many program-specific qualifications for their accredited modalities. In an effort to streamline these requirements, the committees for the accreditation programs have generalized many of the personnel requirements. The committees also looked at other aspects of their requirements that could be made identical across all programs. Because the Mammography Accreditation Program is subject to the United States Food and Drug Administration (FDA) MQSA regulations, these changes do not apply to mammography.

In the fall of 2011, the continuing medical education (CME) qualifications for the interpreting physicians were revised to allow more options. The following requirements are for all ACR accreditation programs:

- Currently meets the maintenance of certification (MOC) requirements for the American Board of Radiology (ABR), OR
- Completes 150 hours (that includes 75 hours of Category 1 CME) in the prior 36 months pertinent to the physician’s practice patterns, OR
- Completes 15 hours CME in the prior 36 months specific to the imaging modality or organ system

References
Effective January 1, 2012, all providers that bill for CT, MRI (including breast MRI), nuclear medicine and the Positron Emission Tomography (PET) under part B of the Medicare Physician Fee Schedule must be accredited in order to receive technical component reimbursement from Medicare. The ACR has had to implement new accreditation requirements to comply with the Centers for Medicare & Medicaid Services (CMS) rules. Among these is the requirement for Primary Source Verification:

- The Medicare Improvements for Patients and Providers Act (MIPPA)/CMS final rule requires verification of personnel qualifications with primary source verification. It is no longer enough to simply obtain a copy of your physicians’ and staff’s credentials. You must now have a process in place to directly contact the credentialing sources (e.g., American Board of Radiology (ABR), American Osteopathic Board of Radiology (AOBR), American Board of Nuclear Medicine (ABNM), American Registry of Radiologic Technologists (ARRT)) to confirm that your personnel are properly credentialed.

Other general changes include:

- Allowing applicants to go back six months to obtain images for submission.
- Allowing facilities that appeal negative accreditation decisions to resubmit required images or series that they inadvertently neglected to include in the original submission (as long as they were acquired at the same time as the information in the original submission).

Mammography Accreditation
Mammography accreditation is the ACR’s oldest accreditation program and consequently operates via the ACR’s oldest accreditation database system (PASS). A new, web-based database system (ACRedit) has been designed over the past few years to accommodate ACR’s newer accreditation programs. ACRedit allows facilities to apply and submit all accreditation materials (with the exception of images) online. Specifications are currently being developed to include mammography in ACRedit. The mammography component should be launched 2013.

The ACR realizes that most mammographic images are now acquired digitally in the United States. The ACR is working on the many technological challenges that will enable applicants to submit soft copy digital images for review (rather than films, as is required now). In the system under development, facilities will download the required images to a secure ACR website. This new system should be available at the same time that the mammography accreditation component is launched in ACRedit.

In May 2012:

- The ACR started using Landauer’s state-of-the-art dosimeters (optically stimulated luminescence – OSLs) instead of thermoluminescent dosimeters (TLDs) for improved accuracy and consistency of dose assessments for the Mammography Accreditation Program.
- All of the digital manufacturer-specific and screen-film accreditation instructions and forms were combined into one set of “universal” documents. The only exceptions are the medical physicist survey and quality control (QC) forms which must remain manufacturer-specific to comply with FDA QC regulations.
- The ACR no longer requests laser printer or film processor QC charts for accreditation review. However, facilities must still check that they perform the required QC on the appropriate documents.

Stereotactic Breast Biopsy Accreditation
The program requirements and accreditation documents were recently revised to make the accreditation program more accessible and less onerous while maintaining the ACR’s focus on quality. Some of the major changes are:

- The continuing experience qualifications for radiologists were changed to require upon renewal, “36 image-guided breast biopsies in the prior 36 months, and at least 9 of these must be stereotactic breast biopsies.”
- The image identification requirements have been changed to be consistent with current ACR guidelines:
  - Patient’s first and last names (required)
  - Identification number and/or date of birth (required)
  - Examination date (required)
  - Facility name (required)
  - Facility location (city, state and zip)
  - Designation of left or right breast (required)
  - Annotation of mammographic view (e.g., CC, MLO/ML/LM)
  - Technologist’s identification number or initials
- The testing instructions have been edited for clarity and now outline the following:
  - The applicants may only submit BI-RADS® Category 4 or 5 calcification biopsy cases.
  - The two-view mammogram must be printed in “true size” (or have a scale), must include the entire breast, and the calcifications must be circled.
  - The calcifications must be visible on both stereotactic views.
  - The images must be submitted on 10 x 12 inch film or smaller; facilities may trim the film to meet this requirement.
  - New procedures for the phantom image reduce the number of exposures necessary for a larger field of view (FOV) system.
  - New illustrations to explain required labeling.
- In addition, the ACR also integrated the new OSL into the Stereotactic Breast Biopsy Accreditation Program.

Breast Ultrasound Accreditation
The Committee on Breast Ultrasound Accreditation also made major revisions to its program in 2011; some of the major changes are:

- The continuing experience qualifications for interpreting physicians were changed to recommend upon renewal, “200 breast ultrasound exams in the prior 36 months.”
- The biopsy continuing experience qualifications for interpreting physicians were changed to require upon renewal, “36 image-guided breast biopsies in the prior 36 months.”
- The continuing education requirements for interpreting physicians were eliminated for ultrasound-guided breast biopsy.
- The testing instructions have been edited for clarity and now outline the following:
  - The two-view mammogram must be printed in “true size” (or have a scale).
  - Facilities must circle only the cyst/mass being evaluated on each mammogram and not use radiopaque markers. (This is because of the confusion caused by facilities using various markers to indicate which mass/cyst was examined.)
  - Applicants may only submit cases that meet the BI-RADS® criteria for a simple cyst: a) anechoic, b) circumscribed margin, and c) posterior enhancement.
  - Applicants may only submit BI-RADS® Category 4 or 5 biopsy cases.
- Device terminology was changed to accommodate devices that may be used in multiple modes.
“Non-vacuum devices” are now called “devices used in fire mode”
“Vacuum suction devices” are now called “devices used in non-fire mode (i.e., manually advanced)”

- For all biopsy cases, the position of the needle relative to the solid mass must be easily appreciated on the pre-biopsy sonograms and on the images obtained during the biopsy.
- For core needle biopsy devices used in the fire mode (i.e., fired into tissue sampling position), the pre-fire sonogram must demonstrate that the needle is aimed towards the mass just prior to insertion. The position of the needle should be in the long axis and approximately parallel to the chest wall.
- For core needle biopsy devices used in non-fire mode (i.e., manually advanced into biopsy position), the post-biopsy sonogram must demonstrate the long axis of the needle in the tissue acquiring position, either under or through the mass.
- Needle aspirations of cysts or axillary lymph nodes for fine needle aspiration cytology (FNAC) are not acceptable.
- For FNAC, the biopsy sonogram must demonstrate the needle position clearly within the mass in the long axis.
- Illustrations have been added to the testing instructions to help clarify expectations for proper needle positions.

Breast MRI Accreditation
The Committee on Breast MRI Accreditation also made major revisions to its program in 2011; some of the major changes are:
- The continuing experience qualifications for interpreting physicians were changed to require upon renewal, “75 breast MRI examinations in the prior 36 months” (instead of the prior 24 months).
- The ACR now “strongly recommends” that the cooperating facility be accredited by the ACR in breast MRI (instead of requiring it).
- The negative case is no longer required for accreditation; only a cancer case is required.
- The testing instructions were revised to accommodate the unique protocols of the Aurora dedicated systems.
- Facilities may not submit cases from mastectomy patients.
- Facilities are reminded that the case will fail if, on the T2-weighted/bright fluid series, bright fluid is absent or indistinguishable from the background tissues, such that the deficit could lead to misdiagnosis or is inadequate to reliably distinguish cysts from solid masses. If the bright fluid contrast is present, but is faint or highly variable, the case could fail if other image problems exist.

Summary
The ACR accreditation programs were developed by radiologist and medical physicist members, dedicated to the improvement of early breast cancer detection, accurate diagnosis, and quality patient care. These programs not only contribute to these goals but also prepared the imaging community for today's attention towards quality from the federal government, payors, and patients.
Breast Density Legislation From A Legal Perspective

Nick Oweyssi, Attorney at Law

In September 2011, following a burgeoning trend started by Connecticut, Texas passed its first piece of breast density legislation (House Bill No. 2102, now codified as Texas Health and Safety Code §86.013). Henda’s Law, named after the Dallas-area woman who championed its adoption, mandates the inclusion of breast density risk language in reports sent to women after their mammogram. Compulsory compliance became effective on January 1, 2012.

Unlike its counterpart law in Connecticut, which requires insurance companies to provide coverage for comprehensive ultrasound screening of an entire breast or breasts if a mammogram demonstrates dense breast tissue, Henda’s Law does not require insurers to pay for supplemental screenings. The legislative history suggests that insurance lobbyists may have had a hand in shaping the Texas bill, as there was a radical shift in the language concerning insurance coverage from the initial drafts to the final adopted version.

As expected, the Connecticut law has led to a “flood” of patient callbacks requesting supplemental screenings. The same is being experienced in Texas currently. However, as much as insurance providers are not required to cover ultrasounds and MRIs under Henda’s Law, Texas physicians may find themselves exposed to greater liability.

The scope of the liability created under Henda’s Law remains to be seen. Given that compulsory compliance has been in effect for only about six months and most malpractice claims are resolved through confidential settlements, the appellate courts have not had an opportunity to provide any guidance on the issue. Nonetheless, from the perspective of an attorney, it is easy to identify deficiencies in the legislation.

A New Standard Of Care?

It appears that Henda’s Law does not create a standard of care, but that is not necessarily the case. Compliance requires that the mammography facility send a notice to patients advising them if dense breast tissue has been detected on their mammograms, then they might benefit from supplemental screenings. The language from the statute must be directly cut and pasted into the notice letter. Compliance for facilities seems relatively simple, if not costly.

It is the ordering physician, however, who must discuss additional risk factors with the patient and suggest “supplemental screening tests.” It is important to note that the statute uses the plural term “tests.” This leaves open the possibility that a physician, who has ordered an ultrasound that came back negative, may have not fully complied with the statute because an MRI may have detected an abnormality. The statute places no constraint on how much the ordering physician must do.

Ordering physicians might take refuge in the fact that Henda’s Law expressly states: “Notwithstanding any other law, this section does not create a cause of action or create a standard of care, obligation, or duty that provides a basis for a cause of action.” It further states that violations of Henda’s Law cannot be mentioned in litigation or professional disciplinary proceedings: “The information required by this section or evidence that a person violated this section is not admissible in a civil, judicial, or administrative proceeding.” This language only creates a false sense of security for physicians.

In the context of litigation, a standard of care is not necessarily established by reference to any laws. It is frequently established through testimony of an expert witness, who describes the prevailing standard of care in the community. Compulsory compliance has in essence made Henda’s Law the new standard of care. Therefore, it is perfectly acceptable and expected that in a deposition or trial, an expert may identify the requirements under Henda’s Law as the prevailing standard of care without directly citing the law itself.

It should not be ignored that these cases are prime candidates for trial because breast cancer patients are very sympathetic plaintiffs in front of juries. It is only a matter of time before we see the effect of Henda’s Law unfold in the courtrooms.

Conclusion

While the motivation behind Henda’s Law was a noble one, legislators did not sufficiently appreciate the practical and legal challenges of its implementation. At this early stage, we can only speculate as to the extent of malpractice liability it has created. But we can be fairly certain that it has given plaintiff’s attorneys another arrow in their quiver.

Upcoming Events & Activities

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<tr>
<td>Sept. 1</td>
<td>Deadline for submission of 2012 SBI Fellows Applications</td>
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<tr>
<td>Sept. 6 – Conference Call</td>
<td>SBI Board of Directors</td>
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<tr>
<td>Sept. 22-23 – Las Vegas, NV</td>
<td>SBI Weekend MRI Education Course</td>
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<tr>
<td>October 2012</td>
<td>Breast Cancer Awareness Month</td>
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<td>Oct. 4 – Conference Call</td>
<td>SBI Board of Directors</td>
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<td>Nov. 1 – Conference Call</td>
<td>SBI Board of Directors</td>
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<tr>
<td>Nov. 25 – Chicago (RSNA) 3:00 – 6:00 p.m.</td>
<td>SBI Board of Directors Meeting</td>
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<td>Nov. 26 – Chicago (RSNA) 4:00 – 5:00 p.m.</td>
<td>SBI Newsletter Committee Meeting</td>
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<td>Nov. 26 – Chicago (RSNA) 6:00 – 8:30 p.m.</td>
<td>SBI Fellows Meeting</td>
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<td>Jan. 26-27 – Orlando, FL</td>
<td>SBI Weekend MRI Education Course</td>
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<tr>
<td>April 6 - 9 - Los Angeles, CA</td>
<td>SBI 11th Postgraduate Course</td>
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<tr>
<td>May 4 - 8 – Washington, DC</td>
<td>ACR Annual Meeting &amp; Chapter Leadership Conference</td>
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<tr>
<td>Sept. 28-29 – Las Vegas, NV</td>
<td>SBI Weekend MRI Education Course</td>
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<tr>
<th>2014</th>
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<tbody>
<tr>
<td>April 26-30 – Washington, DC</td>
<td>ACR Annual Meeting &amp; Chapter Leadership Conference</td>
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When we consider any examinations or cluster of exams we must think of their efficacy in terms of detecting disease and the “cost of achieving that detection. Intuitively, the more exams we bundle together the more disease we will find. What we must consider is the expenditure for these exams, the stage of disease detected and if this disease detection produces a significant impact on the population tested. An examination or group of exams that correctly identifies breast cancer is termed a true positive exam. However, since there is no "free lunch" and a down side exists (1). The exam or group of exams may indicate no breast cancer when this is untrue (false negative-FN) or that breast cancer is present when it is not (false positive-FP). ROC analysis teaches us that these two variables tend to be directly related. As TPs increase FPs increase as well.

X-ray (XRM) mammography is currently the only imaging modality that is marketed and labeled for breast cancer screening in the United States. However the exam has limitations. Perhaps its greatest limitation is detection of breast cancer in the dense breast (Breast Imaging Reporting and Data System (BI-RADS) heterogeneously dense and extremely dense). Presently we have two additional exams, whole breast ultrasound (WBU) and breast magnetic resonance imaging (MRI), to add to screening XRM in an effort to increase the accurate detection of malignancy (more TPs with less FPs). While XRM and MRI are completely free of direct physician interaction ultrasound is not. Additionally ultrasound is the only modality other than fluoroscopy, that has real-time imaging capability. WBU may be performed with minimal technologist or physician interaction.

What is the data concerning WBU and breast cancer detection? Dr. Wendie Berg led a multicenter trial (ACRIN) to determine the impact of WBU adjunctively added to screening mammography (2). The cohort of women consisted of those with a high risk for breast cancer and dense breasts. Thus, the results, strictly speaking, can not be applied to the general population. There were a total of 111 breast cancers over a three-year study period. A unique facet of the study was an MRI at the termination of the study, in a subpopulation of the study participants, in an effort to determine what malignancies were not identified by WBU and XRM. The results are interesting. XRM alone as a screening exam had a sensitivity of 31.3% and a specificity of 92.1%. XRM and WBU had a sensitivity of 43.8% and a specificity of 84.4%. When all three exams were considered (XRM, WBU, and MRI) sensitivity was 100% and specificity was 65.4%. As FPs increase our specificity decreases and as FNs decrease our sensitivity increases (sensitivity = TP/TP + FN; specificity = TN/TN + FN). The ACRIN 6666 data clearly demonstrated this trade-off with sensitivity increasing from 31.3% to 100% while specificity decreased from 92.1% to 65.4% going from XRM alone to XRM and WBU to XRM, WBU and MRI, respectively. The “currency” we use to detect more cancers are the FPs. The FNs can be thought of as a budget item. Do we spend as much “currency” (FPs) as needed to be perfect and go “over budget” (FNs) or do we stay within the budget and not achieve perfection? This is the “good” and the “bad”.

What about the “ugly”? Most of the data is clear but the management is not. From the paper by Berg et al, we can see that MRI and XRM may be perfect as far as breast cancer detection, but we spend more FPs than on XRM alone (2). MRI also requires the need for contrast and is very expensive. Who will pay for this? Are there enough MRI units to satisfy this need? Is there enough general expertise to interpret these MRI exams? The combination of XRM and WBU is a compromise. While this combination is not as sensitive as XRM and MRI there may be fewer FPs. The same consideration of the additional cost of ultrasound is also operative although it is much less so. There is one unique and very important factor to consider with the XRM/WBU combination. Since ultrasound allows for direct real time imaging, who will perform these additional exams? Obviously physician time is expensive and, in many cases, limited. Although sonographer or technologist time is less expensive than physician time, this too involves a greater time input than the directed ultrasound exams currently done. A possible solution is the introduction of Automated Breast Ultrasound (ABUS) that does not require direct physician involvement and less technologist or sonographer involvement than a hand held approach. For any of the data presented (US and MRI alone or with XRM) we do not have the data screening XRM alone possesses: is there a significant decrease in mortality from breast cancer with this test or a combination of tests? We will probably never be able to answer this question directly with randomized trials, mostly due to their expense. We must therefore rely on surrogate endpoints in an effort to predict mortality (tumor size, nodal status and stage). External funding sources have to realize that they either fund randomized trials or accept surrogate endpoints. This seems to be occurring although slowly.

References
New Endeavors in Breast Imaging Education

Sally Herschorn, MD

Having completed residency in the 1980s, I can say that today’s breast imaging residency curriculum is far different from my own experience and even from the experience of those who graduated five or ten years ago. While we read books, today’s resident uses on-line material and is increasingly moving to mobile devices over textbooks. A primarily screen film mammography curriculum with a few needle localizations, back in the day, has been supplanted by digital mammography, breast ultrasound, and breast MRI. Residents also require a thorough knowledge and understanding of the Breast Imaging-Reporting and Data System (BI-RADS) and computer-aided detection, physics, and skills in practice audit, risk assessment, patient advocacy and journal interpretation. Talking with patients and being compassionate while delivering bad news are equally important. Graduating residents must be able to generate concise standardized reports and biopsy and localization procedures using ultrasound, stereotactic and MRI guidance. A revised breast imaging curriculum incorporating these and other objectives will be released soon.

To add to the mix of changing requirements, the American Board of Radiology (ABR) examinations are changing; oral board exams will be no more as of 2013. A computerized test in the third year will be given to all. Since the final exam, to be taken 15 months after the first test, will include only four areas of radiology; some residents will be tested on breast imaging only during their first exam.

All of these factors mandate a change in how we teach and evaluate residents in breast imaging. Let us take procedures, for example. During my residency, any procedure to be learned could be summed up by “see one, do one, teach one.” Ultrasound-guided biopsy procedures, in particular, require advanced hand-eye coordination skills. Nowadays, most academic medical centers have simulation centers to help candidates acquire necessary procedural skills (e.g., inserting central lines). While our residents currently practice needle skills on a combination of commercial and homemade Jell-O mold breast phantoms before attempting their first live patient biopsy; I believe that in the future, this type of skill be practiced in a simulation center. Simulation phantoms will even be able to grade competency and determine when skills are good enough to graduate to procedures on real patients.

Breast ultrasound diagnostic scanning skill is something that residents find difficult to acquire during their rotation. Many patients do not wish to be scanned by a resident. Even if residents are amenable to a resident scanning it, it is difficult to find time in a busy breast center for a resident to spend time scanning a patient. I am hopeful that in the future, there will be phantoms with lesions in them that the resident would need to find, image properly (including clock face, orientation and distance from nipple documentation) and describe according to BI-RADS, in order to be deemed competent to graduate to scanning patients. I could envision a phantom that would contain a cyst, a fibrocystic nodule, a fibroadenoma, and a couple of ugly looking cancers. These could be used for end of rotation competency testing.

Now that oral boards are going by the wayside, we need to make sure our residents have the necessary skills for computerized tests. Enter the audience response system (ARS). Many of you have probably attended lectures at meetings where an ARS was used. I began using an ARS as a way of increasing resident participation in lectures. It is relatively easy to transform a pre-existing PowerPoint presentation and add audience response questions with any audience response software. Besides keeping the residents awake, there are other educational benefits. For example, when showing a spiculated mammographic mass, I gave the following choices: invasive ductal cancer, invasive lobular cancer, DCIS and fibroadenoma. I expected the first two answers but to my surprise, 8% chose fibroadenoma. I was able to stop right there, and explain why fibroadenoma was an inappropriate choice; and what the relative merits were of each of the other choices. The same can be done with calcifications or any topic. While I could have simply showed the picture and called on a resident to “take the case”, I would not have been aware that someone in the audience clearly misunderstood the concepts. I was then able to give explanations without embarrassing that person. This system can also be programmed to save answers by each resident; so one can keep track of individual resident scores for each lecture (we do not currently do this) and/or as a group (without individual identification, so one can tell which concepts or learning points need further work/lectures and which are clearly already mastered).

In an attempt to go paperless, we have begun posting the goals and objectives, reading lists, tumor board prep cheat sheets, protocols, teaching files and other tools (e.g. recipe for a Jell-O/olive biopsy phantom) on an interactive tool called BlackboardTM. This is a program used by many universities. Written tests for the end of the rotation (by rotation level) are posted on this site. The resident taking the test is given the password and a time frame in which to take the test appropriate to their rotation level and the test is instantly graded with feedback on the correct answers. Despite the impending end of oral boards, we plan to continue oral end of rotation testing in order to identify areas where the resident candidate may have difficulties.

In summary, as the practice of breast imaging has evolved and continues to evolve, so, too, our approach to residency education must as well. Increasing use of web-based teaching materials, increased use of phantoms for simulation, incorporating audience response for lectures and more interactive skill assessment feedback will help to improve the residency experience.

References
How to Validate a New Modality

Laurie L. Fajardo, MD, MBA, FACR

Radiologists are continually bombarded with various marketing media promoting new technologies for breast imaging and intervention. With respect to screening or diagnostic breast imaging, where mammography is the established gold standard, most technologies can be viewed as adjuncts to or as replacements for mammography. This article focuses on what information a radiologist should consider in deciding whether to purchase a new or evolving technology, including: the evidence supporting a clinical benefit, cost and dose considerations, and clinical implementation.

New modalities should demonstrate evidence of clinical benefit. Clinical benefit should focus not only increased accuracy (sensitivity/specificity), but also on the type of lesion driving the increased accuracy. For instance, if driven entirely by microcalcifications representing low grade ductal carcinoma in situ (DCIS), the value of the technology to policy makers outside of the breast imaging community may be low if the technology is perceived as contributing to overdiagnosis and overtreatment. In the current era of healthcare reform, policy makers demand a greater weight of evidence before committing resources (i.e., new Current Procedural Terminology (CPT) codes for imaging reimbursement) to a new diagnostic technology, knowing that it is easier to withhold coverage initially than to rescind coverage after widespread adoption. National Cancer Institute (NCI)-funded investigators proposing clinical trials to evaluate a new screening technology are now being asked by the sponsoring organization to include analysis of the interval cancer rate, in addition to the usual sensitivity/specificity, positive predictive value (PPV)/negative predictive value (NPV), accuracy measurements. The interval cancer rate is a metric being entertained by the American College of Radiology Imaging Network (ACRIN) protocol development team for inclusion in the proposed ACRIN tomosynthesis trial (see the article by Ms. Cole and Dr. Pisano on page 1). However, variations in the definition, identification (is this a true interval cancer or a missed cancer that was, in fact, detectable on the screening study?) and quantification of interval cancer rates makes this metric difficult to generalize to clinical practice in terms of demonstrating evidence-based clinical benefit.

Consumers of healthcare in the United States are conscious of radiation dose and any new technology (e.g., positron emission mammography (PEM), breast specific gamma imaging (BSGI), molecular breast imaging (MBI) or "two dimensional (2D)-three dimensional (3D) combination" tomosynthesis) must carefully evaluate and balance the risks of radiation dose with the derived benefits of the new technology. For example, moving from two detectors sizes for film screen mammography to a single size detector in digital mammography meant that large-breasted women would require "tilted" imaging for complete screening. For breast cancer screening, the total radiation dose allowed is established by the Mammography Quality Standards Act (MQSA). For diagnostic technologies, no dose limit is mandated, but given the amount of diagnostic work-up performed annually in the United States and the percent yielding a benign or negative outcome, it would behoove the breast imaging community to more closely evaluate the additional radiation dose received by women undergoing additional workup after a BI-RADS 0 screening, as many of these women are returned to the normal screening population.

Cost can drive policy decisions regarding the value of an imaging modality, which includes the downstream cost of diagnostic work-up, biopsy, and therapy. Increasingly, costs will be considered from the perspective of accountable healthcare organizations (see the article by Dr. Redd on page 11). For instance, when a new technology helps to identify cancers that we would otherwise miss, the frequency of "miss," the patient harm caused by the miss and the cost of the modality will be scrutinized. If the new modality only detects a minimal number of cancers over routine screening and is very costly, it may be considered ineffective.

Certain aspects of clinical implementation of new technologies may be overlooked in published studies testing accuracy/diagnostic efficacy. For instance, does the research reporting the effectiveness of the new technology apply to the full range of patients likely to undergo imaging in routine clinical practice, rather than just a subset of highly selected patients who might benefit most? Are there predefined groups for whom little or no benefit would accrue? Are there standardized performance and interpretive criteria for the new technology? For technologies with the potential to identify suspicious lesions not visible by other standard imaging, does the technologies offer the ability to direct or guide biopsy of such suspicious lesions?

Although the quality and clarity of published evidence is improved by initiatives such as the Consolidated Standards of Reporting Trials (STARD) criteria, radiologists still need to be alert to low quality evidence as well as common flaws in the literature. The leaders and experts of the Society of Breast Imaging (SBI) have been helpful in this effort. Knowledgeable experts are needed to make interim decisions on the basis of a mixture of clinical evidence (perhaps incomplete) and the available but imperfect evidence. The experts also need to be flexible enough to reverse those decisions if they are subsequently proved wrong. The SBI should guide its members in the practice of evidence-based radiology to be reliable providers of unbiased and relevant evidence. Technology assessment and validation is complex in regard to breast cancer screening because of the many links in the chain between the interim objective (to make the correct diagnosis) and the ultimate goal (to improve patient care) through the reduction in breast cancer mortality.

References
Radioactive Seed Localization: A Safe Alternative to Wire Localization

Valencia King, MD and Elizabeth Morris, MD

Currently, the most common method for pre-operative localization of lesions that are not clearly palpable on exam is with a hooked wire implanted in the breast using a needle under mammographic, ultrasound, or MRI guidance. Although wire localization is a very effective method of localizing clinically occult lesions prior to surgery, there are limitations. Because the wire is in part external, the wire placement is typically on the day of surgery, linking operating room and radiology schedules and lengthening the day of surgery for the patient. In addition, the wire can be inadvertently pulled/displaced during post-placement confirmatory mammograms or patient transfers, or transected during surgery. Furthermore, the wire skin entry site determined by the radiologist in order to most accurately position the wire is often not at the ideal skin incision site for the surgeon for ease of excision and cosmesis.

Due to these limitations, alternative methods of pre-operative localization have been developed. Radio-guided occult lesion localization (ROLL) was developed in the mid-1990s as one of the first alternatives to wire localization. ROLL entails injecting 99mTc technetium(Tc)-labelled colloidal serum albumin directly into the target lesion under ultrasound or mammographic guidance. Benefits of this procedure are that issues related to a partially external wire are no longer problematic. A major limitation of this technique is that the 140 keV 99mTc source used for ROLL cannot be reliably distinguished from the 99mTc used for sentinel node mapping. Also, due to the relatively short half-life of technetium, this procedure also generally needs to be performed within a day of surgery.

Radioactive seed localization (RSL) is a recently developed alternative to wire localization and ROLL using an implanted iodine-125 (I-125) labeled titanium seed. Unlike wires, the I-125 seed placed with an 18-gauge needle is fully implanted, and unlike 99mTc which has a half-life of 6 hours and 140 keV photon peak, I-125 has a half-life of 59 days and a 27 keV photon peak. RSL, therefore, can be performed a day or more before the time of surgery and also can be performed in conjunction with sentinel node mapping using 99mTc. Currently, RSL can be done under mammographic or ultrasound guidance. RSL can also be performed at up to two sites in the same breast or in both breasts. In addition, evidence has suggested that RSL produces fewer positive margins and reoperation rates than wire localization, and that RSL results in shorter operating times than wire localization.

With appropriate radiation safety procedures in place, RSL has been shown to be safe for the patient, physician, technical staff, and support staff. All seeds are assayed to ensure appropriate strength before and after placement. Seed removal is documented with activity confirmed within the specimen, and the seed also can be documented on the specimen radiograph. The seed is extracted in pathology and returned to Radiation Safety for proper disposal. It has been shown, that for a specimen with a mean diameter of 4 cm, the radiation dose to the residual breast tissue after RSL and excision is similar to that of a two-view mammogram, approximately 2 cGy. It also has been shown that no significant increase in radiation badge exposure occurs for the staff caring for patients who have received the seed. As an extra precaution to minimize exposure to those particularly susceptible to the effects of radiation, patients who have received the seed are advised not to hold any small child close to them for greater than 30 minutes until the seed is removed. After that point, there is no residual radiation source within the breast.

Although RSL can be done in advance, it is important that the surgery be planned and scheduled, and that the patient be cleared for surgery prior to seed placement. Since the seed requires surgical removal, problems could arise if, for example, excision of a benign lesion were planned, but the patient is unable to safely undergo surgery due to a cardiac condition. Similarly, if review of pathologic material from an outside institution is planned, this should occur before the seed is placed since there is always a possibility of downgrading a lesion, such as from atypical ductal hyperplasia (for which surgical excision is indicated) to usual ductal hyperplasia (for which surgery is not indicated).

In summary, evidence suggests that with appropriate radiation safety precautions in place, RSL is a relatively safe alternative to wire localization for the pre-operative localization of otherwise clinically occult breast lesions. Since RSL can be performed a day or more before surgery, it has the potential to uncouple radiology and operating room schedules. Furthermore, because the seed is fully implanted, it is also uncoupled radiology and surgical approach, facilitates ease of surgical approaches, and is likely less susceptible to inadvertent displacement prior to surgery.

References

Accountable Care Organizations Part I: What Are They?

Bernadette Redd, MD

One of the purposes of the Patient Protection and Affordable Care Act (PPACA), signed into law in March of 2010, was to address rising health care costs. A number of new programs addressing cost were developed. The concept of accountable care organizations (ACOs), although not new, was one of the programs formally adopted by the federal government to address the growth of health care spending.

Currently the main method for paying health care providers is via a fee for service (FFS) model. This model has been criticized for encouraging and rewarding providers who perform more procedures at the expense of cost-efficient health care. Some observers have noted that the traditional FFS model incentivizes physicians and facilities to perform services but not to coordinate care and improve patients’ overall health. ACOs are intended to create a different model for provider reimbursement, hoping to link payment with quality of performance rather than volume of performance, resulting in higher quality care at lower cost.

ACOs are made up of a network of providers, including primary care physicians, specialists, hospitals and academic medical centers, all of whom voluntarily agree as a collective to be accountable for the full cost and quality of health care for a particular population. The thought is that by combining resources and coordinating care, ACOs can cut costs and improve quality of care. ACOs are different from the more familiar model for integrated coordinated care provided by health maintenance organizations (HMOs). With HMOs, it is the health care provider who is a member of the organization. With ACOs, it is the patient who is a member of the organization. ACOs are the health care provider who is a member of the ACO, not necessarily the patient. The patient is free to choose his or her preferred provider and he or she is free to obtain care from other providers using FFS if he or she desires. Unlike HMOs, ACOs incorporate quality metrics in an effort to promote high quality care.

ACOs are being established by private organizations nationally; however, I will be now focus on the Medicare ACO programs, specifically the Medicare Shared Savings Program (MSSP), because standards established by Medicare for ACO programs will likely influence the behavior of private insurance companies. Under provisions of the PPACA the Centers for Medicare and Medicaid Services (CMS) developed the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations. The MSSP “will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care and putting patients first”2. To participate in the program, ACOs must meet eligibility criteria and program requirements, must serve at least 5,000 Medicare FFS patients and must agree to participate in the program for at least three years.2

Under MSSP, ACO participants still receive payment using the FFS model, but they can also benefit from a shared savings program if the overall cost of care for the beneficiaries is lower than predicted.3 The lower cost, however, has to be achieved while providing quality care. An ACO has to satisfy 33 quality measures in four key domains2 in order to receive the shared saving benefit:


2. Care Coordination/Patient Safety (six measures): Percent of Primary Care Physicians who successfully qualify for an electronic health record incentive payment: Screening for fall risk.

A recent report from FierceHealthcare on June 12, 2012 indicates ACO development is increasing. More than 200 ACOs were identified nationally, up from 160 in November 2011.3 The development of ACOs is very much a work in progress. A study by the National Institute of Health Care Reform reported by Becker’s Hospital Review in February 2011 identified four universal challenges to developing ACOs5: “ACO-like improvements require substantial investment in both time and money that may not be reimbursed directly, … staff members are resistant to assuming new responsibilities or delegating work they use to perform, … [practice improvements require] changes in workflow that [affect] productivity of clinical and administrative staff, and … efforts to improve care coordination and delivery require a great deal of accurate data.”4 Organizations also raised concerns about sharing patient data under privacy regulations.5

ACOs are likely to become more and more common in the coming years and will likely affect how radiology services are delivered. An upcoming Part II article in this series on ACOs will focus on the pros and cons of ACOs.

References

Breast Imaging Outreach in Low-Resource Countries

Kristen DeStiger, MD and Ginger Merry, MD, MPH

Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death among women worldwide. Unfortunately, breast cancer is an often overlooked disease in low-resource countries. In Africa, breast cancer has the second highest cancer incidence and mortality among women, after cervical cancer.

Breast cancer guidelines for developing countries are limited. In Uganda, the guidelines are targeted at the diagnosis and treatment of breast cancer in urban centers with resources that are not accessible to the vast majority of women who live in remote, rural areas. A study of breast cancer survival at Mulago Hospital in Kampala, Uganda showed that the peak age of women with breast cancer was 30-39 years, compared with the peak age of 60-69 years in the United States. Additionally, women in Uganda presented with later stage (77% were stage III or IV) and more aggressive cancers (1). In Uganda, breast cancer is a disease that significantly impacts the lives of young women, their families and their communities.

A clear diagnostic and treatment pathway is not available for frontline health providers taking care of Ugandan women who present at rural health units with palpable breast masses. Based on a review of the literature, results from expert publications, current breast cancer guidelines for Uganda, and discussions with Ugandan health care leaders, Imaging the World (ITW, www.imagingtheworld.org) developed a breast mass algorithm for diagnostic evaluation that is appropriate for rural settings with the goal of early breast cancer detection and treatment.

ITW was founded in 2008 in Vermont at Fletcher Allen Health Care by two radiologists, Kristen DeStigter, MD and Brian Garra, MD. ITW’s mission is to bring ultrasound technology and training to remote areas in low-resource countries. The ITW approach is to train frontline health workers with limited knowledge of anatomy or pathology to generate ultrasound images using a volume-based technique, based on surface anatomic landmarks. These images are captured as cine clips and sent via the local cellular network to the internet to be accessed for remote expert interpretation. Findings and recommendations are sent back to the rural clinics as text messages or emails. This model, incorporating low-cost and low-power ultrasound machines, has been successfully developed and tested for obstetric ultrasound imaging in rural Uganda, with implementation at 11 different healthcare facilities.

In October 2011, ITW conducted a feasibility study to investigate adding a diagnostic breast ultrasound protocol at these same 11 sites. This successful pilot study validated the ability of mid-level health care providers at rural health units to perform high quality breast diagnostic ultrasound using a volume-based scan protocol and demonstrated the ability of district hospital physicians to perform ultrasound-guided breast procedures. The pilot project confirmed that collaboration with local and national providers (surgeons, radiologists, pathologists, and oncologists) can create appropriate diagnostic and treatment algorithm. The project established cost estimates for ultrasound-based diagnosis of breast cancer in rural Uganda, and it secured the input and endorsement of key Ugandan healthcare and governmental stakeholders.

The next steps include the implementation of the breast cancer diagnostic protocol at existing ITW sites. A prospective study is planned to evaluate the clinical effectiveness as well as the number and the quality of the ultrasounds performed, including tracking imaging-pathologic concordance of the ultrasound-guided biopsies. Plans include the use of proprietary ITW outcomes tracking tools to interface with a registry and performance of a qualitative analysis of the community outreach programs.

References

How to Improve Physician-Patient Communication

Phan T. Huynh, MD, FACR

Communication is the exchange of thoughts, messages, or information, as by speech, signals, writing, or behavior. Feedback is critical to effective communication between participants.

Breast imagers can be proud to be among the leaders/pioneers in radiology in improving communication with patients and referring physicians. It is noteworthy that this year marks the 20th anniversary of the first edition of the Breast Imaging-Reporting and Data System (BI-RADS) and the passage of the Mammography Quality Standards Act (MQSA), mandating reports in lay language that summarized examination results to all patients within 30 days of their mammograms. Standardization with BI-RADS is unique among imaging reports. BI-RADS greatly aids in communication and improves the quality of care delivered by all members of the multidisciplinary breast care team.

On a daily basis, breast imagers discuss the results of diagnostic mammograms, ultrasounds and the need for biopsy directly with patients. At some centers such as the Ellen Shaw de Paredes Institute for Women’s Imaging in Richmond VA, screening mammograms are interpreted when the patients are present, and the results are immediately communicated to the patients. Patients have been found to prefer speaking with a radiologist immediately after their screening mammograms unless they have been educated on the benefits of double reading, which may result in the detection of additional cancers. Recently, Virginia became the third state, after Connecticut and Texas, to pass a bill requiring that radiologists put information about breast density in post-mammogram letters to patients. Dr. Paredes feels strongly that direct face-to-face communication with her patients provides an opportunity to educate patients on topics such as the significance of breast density. In addition, she carefully crafted a paper on considerations and management of patients with dense breasts to be sent to all her referring physicians in anticipation of the passage of the breast density bill.

Effective communicators display sensitivity, courtesy, compassion, appropriateness, honesty and openness. Patient-physician communication should occur in a quiet and private place. The first few minutes of a patient encounter are crucial in building trust and moving toward a lasting, healthy patient-physician relationship. Appropriate introductions, including handshakes with the patient and every family member present in the room should be
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made. Dr. Michael Cohen at Emory University in Atlanta, GA stresses the importance of being at eye level with the patient. He also keeps notes on each specific patient conversation and enters the notes on computerized files to facilitate future recalls.

In my practice at St. Luke’s Episcopal Hospital in Houston, TX, I try to discuss any test or procedure in language that the patient can understand. I usually show the patient her imaging studies to point out and explain key imaging findings. Most importantly, I try to listen to the patient and allow her/him to ask questions. If bad news is conveyed, I aim to accentuate the positives and provide the patient with a concrete course of action. When appropriate, I may touch patients to convey a sense of concern.

As indicated previously, feedback is critical to effective communication. Recently, my practice randomly selected a group of our former and current patients and invited them to a patient advisory brunch. A moderator provided questions on all aspects of the patient experience in our breast center including the process of scheduling an appointment, travel, parking, registration, waiting area/time, types of procedures, staff professional manners and skills, and communication of test results. Listening to our patients’ positive and negative experiences allowed us to rectify our center’s weaknesses and expand on our strengths.

Communication using social media between patients and health care providers is evolving. Recently, I had a "friend request" from a patient whose breast cancer was diagnosed by me a year earlier. She had now moved to a different country and wanted to keep me updated on her health progress. When such requests are considered, professional-patient boundaries need to be well defined and care must be taken to ensure patient confidentiality. Social media, such as Facebook and Twitter, offers transformational changes on how members of our society communicate.

References

Frederick Ronald Margolin, MD, FACR (1936-2012)

Jessica Leung, MD, FACR

Dr. Frederick Ronald Margolin exemplified the best of a remarkably balanced and happily fulfilled life. At age 76, Dr. Margolin passed away peacefully on May 10, 2012. Throughout most of his career, he was deeply committed to his multifaceted approach to breast imaging. Throughout his life, he displayed an indomitable spirit and found wonder and joy in his loving family and great friends.

Dr. Margolin founded and served as Medical Director of the Breast Health Center at the California Pacific Medical Center in San Francisco from 1984 to 2007. From the onset, he was instrumental in promoting the breast imaging audit in community practice, laying the groundwork for the Breast Imaging Reporting and Data System (BI-RADS) audit to ensure quality patient care. He served as a charter member of the American College of Radiology (ACR) Committee on Mammography Interpretative Skills Assessment and was the only community-based radiologist on the committee at that time. His work on the committee contributed to classic case files that radiologists throughout the country and around the world have studied for decades. For his contributions and achievements, Dr. Margolin was elected Fellow of American College of Radiology and Fellow of Society of Breast Imaging and was named, in 2001, as one of America’s Best Doctors for Breast Care.

I first met Dr. Margolin when I was a resident. I was just one of many residents and students that he volunteered to mentor over the years as Clinical Professor of Radiology at the University of California, San Francisco (UCSF). He was an inquisitive investigator, having authored 36 articles while overseeing the largest breast imaging practice in the Bay Area. He aimed to practice evidence-based medicine before "evidence-based medicine" became part of our clinical parlance.

While he promoted research and education, Dr. Margolin always emphasized the importance of patient care and community outreach. As Senator Barbara Boxer entered in the June 4, 2012 Congressional Record, "Throughout his distinguished career, Dr. Margolin worked not only to provide the best possible care to his patients but to extend access to care to poor women and underserved populations."

Dr. Margolin was a great, loyal friend to many, and some of his closest friends were his colleagues in the Society of Breast Imaging (SBI). Despite living great distances from each other, they gathered at meetings (often making time for the occasional golf game) and remained lifelong friends who supported each other through life's various milestones.

Dr. Margolin was also a devoted father to his two daughters and one son and super-cool grandfather to his seven grandsons. Together with his beloved wife Myrna of 58 years, Dr. Margolin explored the world with a zest for life and lifelong learning.

It has certainly been my great honor to have known Dr. Margolin. He was kind and generous to me, as he was to all those around him. He demonstrated to me that it was possible to be a great clinician and contribute to research and teaching at the same time. He inspired me to work with passion and compassion and to make what we do matter. His sense of wonder and joy and his legacy in both his personal and professional life shall live on always.
With each new breast imaging modality, the issue of image storage arises. This began with the implementation of full field digital mammography (FFDM), and continues with digital breast tomosynthesis (DBT). FFDM has a file size of 150 MB (megabytes). In comparison, computed ray (CR) mammography has a file size of 180 MB. Historically breast MRI has been the biggest user of storage space, with an average file size of 500 MB. Now as breast tomosynthesis may become a mainstay in breast imaging, it requires an average file size of 2 GB (gigabytes). This has left facilities attempting to incorporate tomosynthesis into clinical practice scrambling to find the best option for image storage. Increased size of images means more storage is being used faster, which is more costly.

Cloud storage is a recent development for image storage. Cloud storage allows an organization to store files that can be accessed over a network. Images are stored off-site, which makes it an option for disaster recovery as well. For breast imaging, this would give an organization the ability to store patient medical records, including reports and images, somewhere that could be accessed by referring physicians, surgeons, or oncologists. Cloud storage is available through the internet, so it can be accessed from any computer through a web-based interface. Accessing stored images is also done through a cloud storage gateway or a web service application programming interface (API). There are many benefits of using cloud storage. For example, cloud storage provides scalability at a low cost. Additionally, as stated previously, users are able to access the data from any location, on devices that include desktop computers, laptops, tablets, and smartphones, at any time. This is a major advantage for many physicians, as when they are out of the office, they can still have access to the records of their patients.

Cloud storage has many benefits, but it is also considered vulnerable to outside threats. In the medical field, this is important, as the cloud would hold private health information of patients, which needs to be protected. This is one reason cloud storage has not been adopted on a larger scale. Cloud developers need to invest in ensuring that security concerns are addressed. The choice of which type of cloud to utilize can be influenced by the particular security requirements of the facility. The options with cloud storage include private, community, public, or a hybrid cloud, depending on the needs of the organization. For example, a private cloud is designed solely for a single organization and can be managed internally or externally, whereas a public cloud is accessible by the general public, and is available only through the internet. A community cloud would be shared through multiple organizations that have a specific common purpose. A community cloud can be managed internally or externally. A hybrid cloud is a combination of two or more clouds (private, community or public).

My facility chose to utilize cloud storage for disaster recovery only. It was decided that for a facility our size, with image data as large as we handle, cloud storage is not an option for short and long term storage, but is a good option for disaster recovery. We chose to have a copy of all our images on site which translates into faster network access to images. We have to manage and provide hardware, and purchase more disks when space becomes an issue, but accessing image data is faster than using cloud storage.

As technology continues to advance, and image files require more storage space, facilities will continue to be faced with the decision of how best to store their data. Cloud storage is one option that facilities may choose to implement, but should be thoroughly researched to decide if it is a good fit for the particular needs of the organization.
Benign Calcifications: An Update

James Vasek, MD

The vast majority of calcifications that are encountered on a screening mammogram are due to benign processes and have characteristic morphologies that preclude any additional evaluation. A biopsy is not required for diagnosis and the experienced radiologist will dismiss the calcifications as benign. Occasionally, benign calcifications may be mistaken for suspicious intramammary deposits and recommended for additional work-up or even biopsy. Two of the more commonly encountered types of benign calcifications recommended for further investigation are milk of calcium and skin calcifications. The ability to prove that these calcifications are indeed benign is imperative to prevent unnecessary and/or unsuccessful biopsies.¹

Milk of calcium has a characteristic appearance and is accounted for by precipitated calcium that collects within the dependent portions of cysts. On the standard craniocaudal view, the calcium pools dependently in the bottom of the cyst and appears amorphous, potentially prompting concern. The standard mediolateral oblique view may demonstrate more conspicuous linear or curvilinear calcifications. Since milk of calcium only occupies a small portion of each cyst, spot magnification craniocaudal and lateral views are most helpful to demonstrate this characteristic disparity in appearance between the two views.² While the calcifications may still appear relatively amorphous on the craniocaudal view, the spot magnification lateral view will demonstrate layering calcification projecting as small crescents or “teacups.” The disparity between the two views and characteristic appearance on the lateral view should allow the radiologist to make a confident diagnosis of milk of calcium and avert an unnecessary biopsy.

Benign calcifications in the skin are frequently encountered on screening mammographic examinations and nearly all project over the breast on standard craniocaudal and/or mediolateral oblique views. When calcifications are encountered near the periphery of the skin surface and have a rounded/spherical or polygonal morphology with lucent centers, a dermal location should be suspected. Often, indeterminate calcifications suspicious for having a dermal location can be confirmed on additional evaluation with spot magnification views. However, if a dermal location is not confirmed with these views, a skin localization work-up should be performed.

For skin localizations, a fenestrated compression device is used and the the breast is placed in compression with the opening at the skin surface thought to contain the calcifications, based on the prior mammographic images. For example, if the calcifications are thought to be in the superior skin surface, the breast should be placed in the craniocaudal projection with the alphanumeric grid opening at the superior breast surface. Using the alphanumeric grid and with the breast still in compression, the coordinates of the calcifications are obtained and a radiopaque skin marker is taped over them. A repeat image is then acquired to confirm accurate placement of the radiopaque marker. The breast is taken out of compression and a magnification view is obtained in the orthogonal plane so that the marker is tangential to the x-ray beam. Skin calcifications will project within the dermis adjacent to the radiopaque marker while parenchymal calcifications will be distant from the marker and the skin surface.

The characterization of calcifications is oftentimes challenging when encountered on the screening mammographic examination. Being able to recognize and reliably characterize milk of calcium and skin calcifications as benign is imperative to avoid unnecessary biopsies as well as undue concern for the patient. ◆

References
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