Editor’s Note

Change. Change is the only constant. Breast imaging is no exception. While our foundation — life saving screening mammography — is granite, it seems that multiple builders want to remodel our house. Digital breast tomosynthesis, screening ultrasound, molecular imaging, fast MRI, the USPSTF, the popular press and peer reviewed articles have different plans for how the home of breast imaging will look in the near and far future. The 3rd issue of the 2015 newsletter of the SBI is also full of change.

First, there are changes to the newsletter contributors. As you may have noticed, I have inherited the Chief Editor position from Gary Whitman, MD, FACR, FSBI. Gary leaves enormous shoes to fill. With Gary at the helm over four straight years the newsletter grew from 12 pages to 16. Nearly 250 different articles, previews, and meeting summaries benefitted from his red pen. I sincerely hope to maintain the level of quality that Gary has established and thank him dearly for his guidance.

Second, this edition of the newsletter presents a new regular column that I hope will positively impact our readers and ultimately our patients. A series of articles written by the Breast Screening Leadership Group will present critical data and honed talking points regarding different aspects of screening mammography. An introduction, written by former SBI president Debra Monticciolo, MD, FACR, FSBI, describes the inception of the group in this edition of the newsletter. It is accompanied by the first installment about randomized controlled trials, the highest quality data medicine has to offer. The article will appear in the newsletter and on the ACR and SBI websites.

Which brings me to the third change of the newsletter — the move to greater digital integration. You, our readers, continue to value the hard copy print edition and we have no plans to stop it. However, we also recognize our increasingly digital world. To that end, the digital edition of the newsletter will provide everything in the print version and more. For example, we will still feature our interesting cases in the print edition with one or two teaser images but the remaining images will be available online in all their high-resolution digital glory. We will also feature active links in the digital edition to the references listed in the articles.

As I close my first Editor’s column and begin shepherding the newsletter, I want to acknowledge all the members of the SBI. We are more than 2,700 strong! Thank you for your membership in the SBI. Without you there would be no society and no newsletter. If there are particular topics you would like the newsletter to cover, please contact me. If you would like to see other changes in the newsletter, please let me know. If you have some news or learn something newsworthy, get in touch: Peter.eby@virginiamason.org. Thank you for your tireless efforts to provide women with life-saving screening and breast imaging services at all levels: resident, fellow, veteran physician, sonographer, and mammography technologist. You are all critical members of the team. And that will never change.
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**Newsletter Editor:**  
Peter R. Eby, MD, FSBI  

**SBI Newsletter Committee:**  
Stamatia V. Destounis, MD, FACP, FSBI  
Robert L. Gutierrez, MD, FSBI  
Jiyon Lee, MD  

**Contributors:**  
Jessica W. T. Leung, MD, FACP, FSBI  
Ann M. Leylek, MD  
Michael N. Linver, MD, FACP, FSBI  
Louise C. Miller, RT(R)(M)  
Elizabeth A. Morris, MD, FACP, FSBI  
Robert Nishikawa, Ph.D., FSBi  
Liane Philpotts, MD, FSBi  
Christine Puciatto, RT(R)(M)(BS)  
Shadi A. Shakeri, MD  
Gary J. Whitman, MD, FACP, FSBI  
Margarita L. Zuley, MD, FSBI  

**Layout & Design:**  
Graphic Design Associates, Inc.
President’s Column: Preparing for Changes Ahead

It is an honor to serve as the President of the Society of Breast Imaging (SBI) in this historic 30th anniversary year. We are living in exciting times with unprecedented growth in the knowledge of breast cancer. As imagers we have an important role to play as the story of breast cancer plays out. We have just finished our first successful annual SBI/ACR Breast Imaging Symposium where we were reminded that we are in the midst of a revolution in the way breast cancer is detected, staged, and treated. We are in the era of personalized or precision medicine where we have found out that all breast cancer is not alike and possibly each individual breast cancer can vary from every other. Targeted therapies are becoming more and more common so that one drug that works for one cancer may not work for another. Our core mission as members of the SBI (to save lives through early detection, quality education, and trusted information provided to patients, physicians, and organizations worldwide) will become even more complex in this new landscape when we move into the era of therapy monitoring. I am excited about the possibilities to work with the SBI community to find ways where we can contribute to cancer prevention, detection, and treatment.

We are currently experiencing big changes in the practice of mammographic screening. Our field may experience a large shift in screening practices due to the revisions of the screening guidelines put forth by the United States Preventive Services Task Force (USPSTF) and the American Cancer Society (ACS). Luckily the SBI is in a unique position to respond to these more restrictive guidelines with help from our Advocacy and Scientific Advisory Committees. These members have gone above and beyond to respond with facts and science to these new, potentially disastrous recommendations. From the members of the SBI, I would like to give a huge shout-out to Drs. Mark Helvie, Ed Hendrick, Murray Rebner, and Ed Sickles for keeping the message of our society strong. I'd like to give a special thank you to the efforts of our outgoing president Dr. Murray Rebner, who has led the Society over the past two years and who is a passionate and strong advocate of screening. Dr. Rebner has worked hard to get the SBI message out to the media and has made us much more proactive rather than reactive. He has increased our visibility and influence and has engaged the broader public — especially media and government. Additionally, I would like to thank all of you in advance for individual and group efforts to responsibly address the new screening guidelines and respond to local media. These efforts are important and unite us in our mission to save lives through breast cancer screening. We know that screening works. We need to let everyone know.

One of my primary visions for the next few years will be focused on communication. It is clear that as a community we need to share ideas and information and be able to respond rapidly to events. A streamlined integrated approach to sharing information would be beneficial to our members. Communication between platforms such as the website, newsletter, and social media, hopefully will...
President’s Column, continued from previous page

become simple and fluid. We need an engaged membership, and people who are social media users can help us achieve this. If you see something interesting on our site we need you to like it, repost it, tweet it, or comment on it! The SBI is interested in your participation as well as comments. The website is our face to the world, not only our members. With that in mind we also plan to develop the website so that in the future patients can access data and information. In this way we can become the most trusted source of breast imaging.

Our recent SBI/ACR symposium was a smashing success with almost 1,000 registrants and attendees from over 24 countries. SBI will build on that momentum and our plan is to increase national and international membership and make our meeting the most respected meeting for breast imaging education. We need to look outwards to the world and be globally responsible. We have the potential for marked global impact with our educational programs. With our prior growth and anticipated future growth we will need to mobilize our expert membership to participate more in our society. That may mean you! We will continue to provide transformational educational opportunities for members. Through these efforts we need to always remember who we are working for — women who may be our friends, mothers, sisters, and daughters. Our passion is to save their lives.

Finally, we are a society founded on strong education and research. In order to protect our future we need investment in our research to keep pace with the changes that are ahead, particularly those in technology and molecular biology. Rapid changes in the way cancer is diagnosed and treated through improvements in proteomics, metabolomics, genomics, cellular assays and mobile health technology mean that we need to adapt quickly and innovate as a specialty. We are moving toward a patient-driven health care model where patients are active participants in choosing their care. Mobile technology will have a big part to play in this new model with patients able to have more access to their data. New resources and methodologies are needed to engage our patients. We have always put our patients first and will continue do so in the future.

There is a lot of work to do but the SBI is a strong society and we are growing steadily in terms of membership, influence, and as a trusted source of information. My hope for the SBI is to become a force of change. I am very confident that we can face the challenges ahead.

Elizabeth A. Morris, MD, FACR, FSBI
President, Society of Breast Imaging

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The 2015 SBI/ACR Breast Imaging Symposium in Orlando, Florida, for the first time ever included scientific sessions and an e-poster gallery where new and original research was presented. 195 research teams from around the world answered the Society of Breast Imaging's call for abstracts. Twenty-one abstracts were selected for oral presentation in dedicated scientific sessions and forty-one abstracts were displayed in the e-poster gallery throughout the conference.

Two research awards were given to outstanding abstracts in the medical student/resident and fellow in training submission categories. The Gerald D. Dodd Jr. Award for medical student/resident research was given to Dr. Lina Nayak of Stanford University for her work on Potential Impact of Breast Density Legislation on Breast Cancer Risk Assessment Supplemental Screening: A Survey of 110 Radiology Facilities. The Wendell Scott Award for fellow in training research was given to Dr. Yolanda Bryce of Memorial Sloan Kettering Cancer Center for her work on Association of Menstrual Cycle Timing with BI-RADS®, Background Parenchymal Enhancement, and PPV in Screening Breast MRI.

Following the great success of its inaugural year, the scientific sessions for the 2016 SBI/ACR Breast Imaging Symposium in Austin, Texas have been expanded to provide greater exposure for the excellent research being done to advance the field of breast imaging. SBI will soon be accepting submissions for the 2016 Symposium. Guidelines and pertinent dates will be published on the course web page when available: [http://bit.ly/1H4kJFU](http://bit.ly/1H4kJFU).
Abstract

Purpose: Breast density notification laws, passed in 19 states as of September 2014, mandate that patients be informed of their breast density, often without guidance or funding for supplemental screening. The purpose of this study is to assess the impact of breast density notification legislation on radiology practices, including performance of breast cancer risk assessment and supplemental screening studies.

Materials and Methods: A 20-question anonymous web-based survey (exempt from IRB review) was electronically distributed to radiologists in the Society of Breast Imaging between August 2013 and March 2014. Statistical analysis was performed using Fisher’s exact test.

Results: 121 radiologists from 110 facilities in 34 USA states and 1 Canadian site responded. 49% (54/110) of facilities had breast density legislation. 36% of facilities (39/109) performed breast cancer risk assessment (1 facility did not respond). Risk assessment was performed as a new task in response to density legislation in 40% (6/15) of facilities in states with notification laws. However, there was no significant difference in performing risk assessment between facilities in states with a law and those without (P < .831). In anticipation of breast density legislation, 33% (16/48), 6% (3/48) and 6% (3/48) of facilities in states with laws implemented handheld whole breast ultrasound (WBUS), automated WBUS, and tomosynthesis, respectively. The ratio of facilities offering handheld WBUS was significantly higher in states with a law than in states without (P < .001).

Conclusion: In response to breast density legislation, more than 33% of facilities are offering supplemental screening with whole breast ultrasound and tomosynthesis, and many are performing formal risk assessment for determining patient management.

Clinical Relevance: With 19 states thus far passing breast density notification laws and a federal law impending, the impacts are far reaching and may increase the number facilities performing supplemental screening studies and formal breast cancer risk assessment.

Stanford University, Stanford, CA
California Pacific Medical Center, San Francisco, CA
University of California San Francisco, San Francisco, CA
University of California Davis, Davis, CA
Alta Bates Summit Medical Center, Berkeley, CA
University of California Irvine, Irvine, CA

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Abstract

Purpose: To assess whether there is an association between outcome of screening MRI in premenopausal women and the stage of the menstrual cycle in which the study is performed.

Materials and Methods: All premenopausal women who underwent a screening MRI in 2011 who clearly stated their menstrual cycle day where included in the study and among other factors indication, BI-RADS®, background parenchymal enhancement (BPE), presence or absence of prior study, and positive predictive value of any subsequent biopsy (PPV3) were assessed. In total, 759 patients were included in the study. Chi-square test and Fisher’s exact test were used to calculate level of significance.

Results: Results are presented in Table 1. There was no statistically significant association between week of menstrual cycle and BPE (p=0.628), final BI-RADS® assessment (0.463), or PPV3 (p=0.174).

Conclusion: Outcome of screening MRI in premenopausal women does not vary significantly as a function of the week of the menstrual cycle.

Clinical Relevance: Timing screening breast MRI for the second week of the menstrual cycle may not make a difference in outcome and may not be necessary.
The SBI/ACR Breast Imaging Symposium opened on Saturday morning with a line-up of highly distinguished speakers discussing the topic of screening mammography. With the USPSTF draft guidelines just released the preceding week, the screening controversy was a hot topic. The following reflects the highlights of the ensuing discussion.

Robert Smith, PhD, of the American Cancer Society, first discussed the Politics and Policies of Screening. He discussed the different methods of analyzing screening trial data, and emphasized the two most important aspects which are the requirement for very long term follow up and differentiating the number needed to invite (NNI) versus the number needed to screen (NNS). The benefits of mammography are only fully appreciated after long follow up periods, whereby the NNS to save a life steadily improves. The USPSTF uses NNI, which includes women that are invited but do not ultimately undergo screening in their analysis. Using NNI decreases population bias introduced by self-selection to be screened but also dilutes the beneficial effect for the population. Therefore, the final statistics suggest a smaller benefit. He discussed the UK Independent review of Breast Cancer Screening and showed how with adjusted absolute risk analyses and longer follow up the NNS drops significantly (1). Dr. Smith then touched on the issue of overdiagnosis and the wide range of values (0-50%) quoted. He explained how available decision-making tools, such as the New South Wales/Australia version, overestimate false positives and overdiagnosis and underestimate lives saved. What’s more, use of this tool had the detrimental results of fewer women indicating they would attend screening. He also reviewed the argument that modern therapy can overcome the need for mammography screening and how this is absolutely not so. Women with positive nodes fare similarly (poorly) whether diagnosed with screening or clinically. It is important to find cancers when they are small and before they have spread to lymph nodes.

Ed Sickles, MD, FACR, FSBI, then talked about the Evidence to Support Screening. He discussed randomized controlled trials (RCT), case-control studies, incidence-based mortality studies, trend studies, expert opinion, and anecdotal reports. He emphasized how the RCTs underestimate mortality reduction at around 20%. He reiterated the important distinction of NNI versus NNS, stating that accounting for up to 30% non-compliance in some studies, the differences in mortality rates are substantial. When analyzed by decade, the rates are not significantly different for the 40–49 group compared to the 50–59, 60–69, or 70+ groups. He also pointed out that the USPSTF only considers mortality reduction, yet there are many other benefits such as decreased morbidity from decreasing surgery, radiation, and chemotherapy.

Mark Helvie, MD, FACR, FSBI, then discussed the issue of the Harms and Costs of NOT Screening. He pointed out that the USPSTF acknowledges the benefits of screening but places strong emphasis on
the harms such that they may outweigh the benefits for many patients. He gave a humorous but fitting analogy of cholesterol screening that included having to wait for the appointment, return when fasting, experience anxiety over testing, having an intervention (needle stick), not getting immediate results, and so on. This occurs daily to many adults and no one criticizes cholesterol testing! He pointed out that an analysis of UK screening data showed annual screening women ages 40–73 yielded a 131% mortality improvement compared to triennial screening women 50–70 years old. He also discussed the costs of omission (not screening) including the huge costs of treating metastatic disease. He summarized, the harms of omission include death, excess morbidity, costs, lack of high risk identification, and possibly excess incidence of invasive cancer. The harms of omission should be considered as well as harms of commission when discussing screening options. Bottom line — in addition to unnecessary deaths, there are significant harms from NOT screening.

Ed Hendrick, PhD, FACR, FSBI, then tackled the issue of Overdiagnosis? Overdiagnosis means finding non-invasive or invasive cancers that would not otherwise affect mortality. Many critics, including the USPSTF, cite this as a major harm of screening. The specter of overdiagnosis is damaging in multiple ways as it discourages women and referring physicians from screening, raises suspicion in women who have completed diagnosis and treatment, and discourages technology development. The exact degree of overdiagnosis is variable in the published literature, with the USPSTF assuming 19% and RCT data suggesting <10%. Correctly measuring overdiagnosis is extremely challenging, highly susceptible to personal bias, and according to Dr. Hendrick, may be outside the purview of science, at least at this time.

Laurie Fajardo, MD, MBA, FSBI, then discussed Tomosynthesis: Is It What It’s Stacked Up To Be? She described the different commercial systems and summarized the tomosynthesis data, including the STORM and Oslo trials from Europe and the published single and multi-institution studies from the U.S. She emphasized how the additional cancer detection with tomosynthesis consists of primarily invasive ductal and lobular grade 2 cancers, thus minimizing the potential criticism of overdiagnosis. She also discussed challenges to tomosynthesis including learning curve and the increase in radial scar and sclerosing adenosis detection. A published cost analysis showed tomosynthesis to be favorable with a net savings of $21 per patient. She acknowledged that it is still unclear if tomosynthesis suffices for women with dense breast tissue.

The final speaker of the morning was Dan Kopans, MD, FACR, FSBI, talking about the Myths and Legends Throughout Screening History. He summarized many of the points already touched on by the other speakers in a way no one else can! No one has done more to promote and defend screening mammography than he has.

REFERENCES

On Sunday, April 26th, with 999 registered attendees, Murray Rebner, MD, FACR, FSBI, conducted the public annual SBI business meeting in a mere 15 minutes and passed the gavel, literally and figuratively to the new President of the Society, Liz Morris, MD, FACR, FSBI. Dr. Rebner also introduced Wendy DeMartini, MD, FSBI, as the new Vice President, Paula Gordon, OB, MD, FRCPC, FSBI, as the new Secretary-Treasurer, and Rita Zuley, MD, FSBI, as a new Director-at-Large.

Lisa A. Newman, MD, MPH, FACS, FASCO, Professor of Surgery and Director of the Breast Care Center at the University of Michigan, delivered the Keynote address for the 2015 meeting: *Disparities in Breast Cancer Outcome: African Ancestry, Early-onset and Triple Negative Disease.* She described how the mortality rate from breast cancer in African-American women exceeds that of Caucasians. She then informed us of the factors that contribute to the difference. Breast cancer in African-American women is more often ER negative, triple negative, and occurs, on average, at a younger age than in Caucasians. Dr. Newman treats women in Ghana with breast cancer where high rates of male breast cancer are observed, and where triple negative breast cancers appear more frequently in young women, a pattern observed in BRCA mutation carriers. African-American women, historically descended from Sub-Saharan Africans, may share an unidentified genetic predisposition to early and aggressive breast cancer.

Dr. Newman described how epidemiologic disparities are compounded by treatment disparities. African-American women in the United States have lower rates of sentinel node biopsy, chemotherapy, referral to plastic surgery, and breast reconstruction. These patterns may reflect lower socioeconomic status, barriers to care, under managed chronic co-morbidities such as diabetes and hypertension that complicate cancer therapy, and known treatment biases against women and minorities.

Dr. Newman called on the audience to help improve access and educate our colleagues. However, she lamented the recent Grade C the USPSTF assigned for screening mammography in 40–49 year old women. Grades A and B mandate insurance coverage for preventive services but a Grade C does not. So while the Task Force suggests that 40–49 year old women can choose to be screened, they may have to pay for it themselves. Such a policy places a disproportionate burden on the young and poor — yet another disadvantage for African-American women that have more aggressive tumors at a younger age.

The 2015 edition of the SBI meeting included scientific sessions for the first time. Over 200 abstracts were received; 21 were selected for oral presentation and 40 were selected for electronic display. Seven studies related to breast MRI were presented in the Sunday afternoon scientific session.

Elle Kwak, MD, from Columbia, espoused a retrospective review of pre-operative breast MRI results correlated with patient and tumor characteristics. The results suggest that additional disease is more
likely in pre-menopausal patients with metastatic adenopathy and tumors that are larger than 2 cm, ER negative, HER2 neu positive and high Ki-67 proliferative index. The authors concluded that, given the cost and unproven benefit, pre-operative breast MRI may be preferentially performed in patients at greater risk for multi-focal or multi-centric disease.

Lauren Green, MD, from Memorial Sloan Kettering, presented a retrospective review of MRI performed to evaluate the extent of pregnancy-associated breast cancer in lactating women. 42% of patients had more extensive disease on MRI, and contralateral malignancy was discovered in two patients. The positive predictive value of biopsy was 36%. The authors concluded that sensitivity of MRI is not compromised by lactational changes.

Jessica Hayward, MD, from UCSF, described a retrospective review of 368 benign and concordant MR-guided biopsy results. 248 women did not return for the recommended follow up exam. Of the 99 benign study lesions, three ultimately were malignant—all of which were small and slow growing. Authors conclude that careful follow up of all women with benign MR-guided biopsy results is paramount.

Safia Cheeney, MD, from the University of Washington, evaluated the correlation between DWI ADC values and upgrade of high-risk lesions found at MR-guided biopsy. While morphology and kinetic features were not different between the 7 lesions that upgraded and 17 that did not, the 7 upgrades occurred in lesions that were larger and had lower ADC values.

Sandra Brennan, MD, from Memorial Sloan Kettering, reported on the upgrade rates of radial scars detected at MR-guided breast biopsy. Retrospective review over 10 years found 27 radial scars. Lesions were dichotomized to those with (10) and without (17) atypia. Radial scars accounted for 2% of all lesions and upgrades were observed in two with atypia and one without atypia. The study group recommended excision of all radial scars.

Elizabeth Valencia, MD, from the University of Washington, presented a comparison of BCSC community data on screening breast MRI performance benchmarks to the recommended performance in the BI-RADS® atlas. 5023 screening studies were analyzed and 17 cancers were detected per 1000 examinations. The sensitivity, specificity, tumor size, node positivity and PPV approach the standards outlined in the BI-RADS® atlas.

Roberta Strigel, MD, from the University of Wisconsin, delivered a paper comparing the positive predictive value of the BI-RADS® 4 sub-categories 4a, 4b and 4c for MRI which confer a level of suspicion of 2–10%, 11–49% and 50–94%, respectively. In their review of 860 screening exams over four years the rate of malignancy for each category fell within the expected range. The authors concluded that the sub-categories could be used for MRI reporting and confer potentially useful information to guide decisions about proceeding with biopsy or managing patient concern and enhancing the MRI audit.
The third day of the 2015 SBI/ACR Breast Imaging Symposium in Orlando featured a dynamic and informative plenary session: Beyond Population Based Screening. An impressive panel of eight engaging speakers presented topics related to the higher risk patient and breast density.

Kevin Hughes, MD, a breast surgeon from Massachusetts General Hospital, opened the morning session with a discussion of breast cancer risk assessment models. Dr. Hughes divided breast cancer risk factors into hereditary, hormonal, and pathologic categories. He gave an overview of the most common risk assessment models: Myriad, Gail, Claus, BRCAPRO, and Tyrer-Cuzick (TC). Dr. Hughes clarified which category of risk factors are addressed by each of these models, allowing us to “determine who needs what intervention,” namely, gene mutation testing, supplemental screening with MRI, chemoprevention, or personalized screening. Dr. Hughes emphasized the inadequacy of the Gail model and reminded us that the American Cancer Society (ACS) does not recommend using Gail to qualify patients for MRI screening. He provided specific examples of when this model may underestimate or overestimate hereditary risk of breast cancer. Keeping in mind that each of the risk assessment models measures different risk factors, BRCAPRO and TC most comprehensively address the aforementioned factors, each with its own nuances. TC, for example, tells us which patients need genetic testing and shows us who is at high risk of developing breast cancer due to presence of pathologic and hormonal factors. Touching on the topic of breast density as a risk factor, Dr. Hughes said that adequate models are not yet available, and that current models incorporating density information are inadequate due to lack of modification for age and body mass index.

Dr. Hughes reviewed ACS and National Comprehensive Cancer Network eligibility guidelines for breast MRI. He made the argument that following these guidelines, using the most current risk assessment models, we should be performing 150 screening MRI exams for every 1000 mammograms. Currently, he added, the number of MRIs being performed is on the order of four per 1000 mammograms. He went on to remind us that eligibility for MRI is age dependent since a woman’s lifetime risk of developing breast cancer decreases with age while short-term risk increases. The speaker emphasized that using the appropriate models to identify BRCA gene mutation carriers allows us to discover which patients are at risk for breast as well as ovarian cancer. Dr. Hughes alerted us that “if you do MRI and don’t do genetic testing” these patients “will die of ovarian cancer,” adding that 95% of patients with genetic mutations remain unidentified. Dr. Hughes ended his presentation by imploring practitioners to incorporate current models in clinical decision-making and patient management.

D. David Dershaw, MD, FACR, FSBI, from Memorial Sloan Kettering, spoke next on screening patients at higher than average risk for breast cancer. After reviewing breast cancer incidence data as a function of age and age-specific probability of developing breast cancer, Dr. Dershaw led us...
through a detailed discussion of factors imparting 5-20x relative risk. These risk factors include: lobular neoplasias, ductal atypia, previously treated Hodgkin’s disease between the ages of 10 and 30 years, certain childhood malignancies requiring chest radiotherapy (RT) and leukemia and brain tumors without chest RT, neurofibromatosis, and BRCA gene mutation carriers. Dr. Dershaw then summarized studies comparing the utility of mammography, ultrasound, and MRI for screening patients at high risk for breast cancer. He also gave an overview of alternative modalities to consider for screening high-risk patients if obtaining an MRI is not an option.

Three fascinating MRI-focused talks ensued. Debra Monticciolo, MD, FACR, FSBI, Professor and Vice-chair of Radiology at Texas A&M University presented *The Breast Cancer Patient: Staging and Surveillance*. Stating that MRI is both most accurate and controversial in this setting, Dr. Monticciolo discussed data and outcomes related to MRI performed to evaluate the extent of disease in breast cancer patients. She also addressed gaps in knowledge in this area. Dr. Monticciolo summarized data showing that MRI provides accurate staging with superior definition of extent of disease, unsuspected contralateral disease, and response to neoadjuvant chemotherapy. Reviewing more recent studies, she showed that although the data have been sparse, there is emerging evidence suggesting that preoperative MRI may decrease re-excision and reoperation rates. She discussed the difficulties of obtaining data to measure the effect of MRI on recurrence rates, as “it would take very large and long period studies” given that current recurrence rates are low. Dr. Monticciolo said that use of preoperative MRI increases the likelihood of having a mastectomy as a consequence of identifying multicentric disease, and probably without any survival benefit. She stressed that we do not know whether it is tumor burden or biology that determines patient outcomes, reiterating that we need well designed studies to better answer these questions.

Francesco Sardanelli, MD, Professor, University of Milan, President of the European Society of Breast Imaging (EUSOBI), educated the audience on *Experience in European Trials on Breast MRI*. Dr. Sardanelli recounted American and European trials providing evidence for the utility of breast MRI as a screening tool for women at high risk for breast cancer. He also showed data from several trials suggesting that MRI alone may be sufficient for screening BRCA mutation carriers without added benefit from mammography. Dr. Sardanelli also discussed the newer European studies with abbreviated MRI protocols (FAST MRI) with one pre- and one post-contrast T1 weighted sequence and maximum intensity projection (MIP) images (1).

The past-president of EUSOBI, Thomas Helbich, MD, MSc, MBA, from the Medical University of Vienna, Austria, presented *Advanced Applications of MR Imaging of the Breast (multi-parametric MRI)*. Dr. Helbich gave a riveting presentation on the need for addressing the many molecular hallmarks of breast cancer with an array of “potent MRI sequences” rather than single MRI techniques. Making the case for using different sequences in a complementary fashion, he stated that we might be able to decode the various cancer molecular hallmarks. By combining the strengths of contrast enhanced,
diffusion weighted, spectroscopy and hyperpolarized MR, we may better be able to detect and characterize tumors as well as reduce overdiagnosis.

The last three speakers of the morning concentrated on breast density. Jessica Leung, MD, FACP, FSBI, from MD Anderson, discussed Supplemental Screening for Dense Breasts. Dr. Leung touched on the hot topic of breast density reporting legislation now in existence in 22 states and federal legislation under consideration in response to strong patient advocacy groups. She added that only four of the 22 states mandate insurance coverage for supplemental screening. Dr. Leung explained the common premise of these laws is reporting breast density information to the patient and recommendation for follow-up discussion with primary providers regarding supplemental screening. Dr. Leung reviewed the Breast Imaging Reporting and Data System (BI-RADS®) 5th edition density assessment changes and noted that this places a greater emphasis on the masking effect of density rather than the prior quartiles-based system.

In a perfect segue from Dr. Leung’s talk, the next presentation was a debate: Breast Density as a Risk Factor. Jennifer Harvey, MD, FACP, FSBI, Professor of Radiology at the University of Virginia, represented the pro-position with her talk, Mammographic Breast Density IS a Breast Cancer Risk Factor. John Lewin, MD, FACP, FSBI, from Diversified Radiology of Colorado, took the opposite viewpoint, arguing that breast density is not a risk factor for breast cancer. This debate was informative as well as entertaining. If nothing else, it delivered one message loudly and clearly: stay tuned, there will certainly be more arguments on each side to come!

REFERENCES

The program on Tuesday morning, April 28th, at the SBI/ACR Breast Imaging Symposium, titled Accessing Information in Breast Imaging for Patients & Doctors, included three lecture sessions, a debate, and a panel.

Elizabeth S. Burnside, MD, MPH, MS, from the University of Wisconsin, opened the program with a talk titled Technology Assessment: What is Needed to Validate? Dr. Burnside noted that policy development studies and technology assessment studies occurred earlier in the lifespan of digital breast tomosynthesis (DBT), compared to full field digital mammography (FFDM). Dr. Burnside commented that as we aim to assess efficacy and effectiveness of new technologies, we must count on high quality observational research because we won’t be able to perform randomized controlled trials for every modality due to time constraints and expense.

Katrina N. Glazebrook, MBChB, FSBI, from the Mayo Clinic, provided an update on molecular breast imaging (MBI). She focused on her recent experience at Mayo Clinic in Rochester, MN, noting that MBI allows visualization of metabolically active cells regardless of breast density. Any focal uptake on MBI without a known benign correlate on mammography or sonography should be considered suspicious. At Mayo Clinic, patients with BI-RADS® category 3, 4 and 5 findings on MBI are evaluated with mammography and ultrasound first, and if the work-up is negative, MRI is performed.

The initial dose for MBI at Mayo Clinic was 20 mCi in 2011. The current dose is 8 mCi, and further dose reduction is likely possible. Dose reduction has been facilitated with collimator optimization and imaging patients in the fasting state in a warm room. Dr. Glazebrook noted that MBI has been well tolerated by patients. At Mayo Clinic, MBI serves as the predominant modality for supplemental screening in women with mammographically dense breasts.

Christopher E. Comstock, MD, FACR, FSBI, from Memorial Sloan Kettering, provided an update on contrast-enhanced digital mammography (CEDM). Dr. Comstock outlined the current technique for CEDM, including the administration of 1.5 ml/kg of iodine-based contrast (iohexol) and the use of a dual energy technique, with two exposures (one below the K-edge of iodine and one above the K-edge of iodine). Compared to MRI, CEDM takes less time and costs less. In staging studies, MRI has found more occult lesions compared to CEDM, but MRI has more false positive identifications.

Margarita L. Zuley, MD, FSBI, from the University of Pittsburgh, then discussed How to Implement DBT and DBT Biopsy in Your Practice. Dr. Zuley noted that with current systems, it takes twice as long to interpret a DBT study compared to FFDM. DBT provides multiple images, leading to more work per case for the interpreting radiologist. Dr. Zuley discussed workflow, noting that in a DBT screening environment, there will be fewer recalls and fewer diagnostic studies. Furthermore, in a DBT screening environment, there is a decreased need for additional diagnostic mammographic views; a
A large proportion of non-calcification DBT screening call-backs can proceed directly to ultrasound without the need for diagnostic mammography. In the diagnostic setting, when evaluating non-calcified abnormalities, DBT can be used instead of supplemental spot compression and magnification views. When evaluating calcifications, magnification mammography remains the current standard. Dr. Zuley discussed how DBT biopsy is useful for architectural distortions and amorphous calcifications.

Wendie A. Berg, MD, PhD, FACR, FSBI, from the University of Pittsburgh and Ellen B. Mendelson, MD, FACP, FSBI, from Northwestern, debated Automated Breast Ultrasound (ABUS) vs. Hand-held: What Should I Use If I’m Going to Screen? Dr. Berg noted that in the multicenter American College of Radiology Imaging Network 6666 trial, with standardized technology and sonography performed by radiologists, the supplemental cancer detection rate for hand-held ultrasound was 4.1 cancers per 1000 women. Dr. Berg discussed successful efforts to train mammography technologists and sonographers to perform high quality breast ultrasound. She described how, in Japan, two-day educational programs are held to train mammography technologists and doctors in real-time scanning.

Regarding ABUS, Dr. Mendelson noted the goal should be to increase specificity with little loss in sensitivity. She discussed that for ABUS to gain acceptance, case-based training is needed. Dr. Mendelson also noted the value of the coronal plane on ABUS. She commented that the coronal plane is often the best plane to visualize architectural distortions.

During the BI-RADS® Panel update, Dr. Carol Lee, MD, FACP, FSBI, from Memorial Sloan Kettering, reminded us that breast density categories 1, 2, 3, and 4 have been replaced by A, B, C, and D. Dr. Lee described the important change regarding solitary dilated ducts. Data have shown that these have a positive predictive value for malignancy of 10% and, therefore, should no longer receive a BI-RADS® 3 assessment. Rather, a BI-RADS® 4 assessment is recommended.

In summary, the Tuesday morning program provided a potpourri of current topics with a heavy emphasis on how new technology continues to advance. We were reminded that part of our job as breast imagers is to lead critical research and constantly reassess our field to determine what tests to use in appropriate clinical situations.
The 2015 Annual Meeting for the American Roentgen Ray Society was held in Toronto, during Sunday, April 19 to Friday, April 24. Jonathan S. Lewin, MD, FACR, the incoming President of the ARRS, articulated his inspirational vision for our profession: “Radiology remains the best of all medical fields, and it is up to us to take on the mantle of change leadership in order to guide radiology into its new future of providing the greatest possible value to our patients and to society.”

This article is about the highlights of the meeting. But to really appreciate the highs, we need to acknowledge the lows. For this year’s meeting, they occurred on Sunday morning. How perfectly poignant both in place and in time to hold this year’s Great Debate on screening mammography in Canada, the home of the Canadian National Breast Screening Study (CNBSS), on the eve of the release of the USPSTF’s 2015 draft recommendations for screening mammography. Anthony Miller, MD, and Cornelia Baines, MD, defended their study, inadequately countering the critical and fair presentations of Daniel Kopans, MD, FACR, FSBI, and Paula Gordon, MD, FSBI. For the first time, those present heard several live testimonials from Canadian radiologists who were readers in the CNBSS. Their pained accounts of lack of prior experience in reading mammography and inadequate training in preparation for the study did not receive direct replies from study authors. The prevailing mood was somber, bitter without any sweet. And the session was a stark reminder of how much is still at stake for the women we serve, with every incarnation of the CNBSS data and in light of the USPSTF’s 2015 draft recommendations. All the highlights in breast imaging — all of our earnest work in advancing technology and refining our diagnostic and clinical acumen — will realize limited benefit if women do not receive optimal screening care.

Tuesday’s Scientific Session focused on the topics of Screening and Staging and featured three keynote speakers. Jessica Leung, MD, FACR, FSBI, specified that breast density is important for its potential masking of cancer and its association with future breast cancer risk. She proposed that it may be more effective to implement supplemental screening in patients with dense breasts based on individual risk assessment. Murray Rebner, MD, FACR, FSBI, tackled the thorny subject of overdiagnosis or overdetection to conclude that with proper analysis and review, limited only to valid studies, the rate of overdetection with screening is 1–10% with most studies showing rates <5% rather than the 20–50% asserted by critics of screening. This is a “small price to pay” to reduce breast cancer mortality by 30% with screening. In her keynote, Stamatia Destounis, MD, FACR, FSBI, reminded us of the significant disease incidence in older women, which was emphasized in the first abstract, by Maya Hartman, MD, from Cornell. Their retrospective review found 5.9 cancers detected per 1000 screens in patients ≥75 years old, and most malignancies were invasive. Vilert Loving, MD, from Banner MD Anderson, presented poll data that showed 88% of U.S. breast surgeons recommend annual mammography for women ≥40 years for their patients, family, and friends. Even more
ARRS Review: Highlights from the 2015 Meeting, continued from previous page

compelling is the 88–97% personal attendance to screening of female surgeons ≥40 years. Laura Billadello, MD, from Northwestern, found that 21% of newly diagnosed patients who underwent bilateral ultrasound had additional cancer detection, reminding us that US may also be a useful preoperative test.

For Wednesday’s Scientific Session on Emerging and Novel Technologies, the two keynote addresses were delivered by Zeynep Yilmaz, MD, who provided an update on molecular breast imaging, and Kate Klein, MD, who presented her perspectives on Practice Quality Improvement (PQI) projects for breast imagers. Laurie Margolies, MD, from Mt. Sinai, demonstrated a novel breast arterial calcium scoring method that favorably compared to coronary calcium scoring and Framingham Risk Scores; the ROC curve improved by adding their breast arterial score to the Framingham risk score. Ashraf Zytoon from Menoufiya University and Shebin El-Koom, Egypt, reported normal breast FDG uptake at dual-time point FDG PET/CT can significantly vary between dense and non-dense tissue, and can be affected by age and hormonal status. Delayed phase imaging may more accurately define pathology. Initial clinical experience of a stationary DBT with a carbon nanotube-enabled device was presented by Yueh Lee, MD, PhD, from UNC; this method could allow better depiction of calcifications than conventional DBT. Gary Whitman, MD, FACP, FSBI, from MD Anderson, presented retrospective data that incidental, sonographically-detected, suspicious regional lymph nodes may not need sampling if full work up is otherwise negative for suspicious etiology. This may impact management given the continued upward trend in supplemental screening ultrasound.

Thursday’s course on Breast Screening Ultrasound was delivered by Jean Weigert, MD, FACP, from Connecticut and Regina Hooley, MD, FSBI, from Yale. The course was thorough in providing eagerly-awaited, emerging efficacy data from Connecticut where screening ultrasound urgently began in response to breast density legislation, along with a comprehensive tutorial on optimizing US sensitivity and specificity. With subsequent examinations in years three and four, (presumed incident) detection holds steady at approximately three invasive cancers (variable grades, low stage) per 1000 screens with improved PPV of up to 20.1. This improvement in PPV is hopeful news.

Friday’s Scientific Session focused on tomosynthesis and tissue density analysis. The keynote address by Debbi Copit, MD, from Albert Einstein Medical Center, presented the established data on the effect of DBT on CDR and recall rate, and then delved into what studies have shown of its performance when stratifying according to density level. Melissa Durand, MD, from Yale, provided case examples with references to illustrate DBT allowing higher CDR and its second important function — clarifying and confirming benign diagnoses that obviate recall for false alarms. Laura Sheiman MD, from Yale, demonstrated in their retrospective analysis of baseline mammography cases how implementation of DBT led to significantly lower recall rate and a trend to higher CDR; this argues for using DBT at the first point of care — at screening. Devrim Ersahin, MD, from Yale, presented retrospective, reader study data suggesting that diagnostic magnification views for DBT-
recalled calcifications may not always be necessary; 2D + 3D screening may obviate need for some recalls, while minimizing the diagnostic process for others. MRI features of background parenchymal enhancement (BPE) was explored in several abstracts. Niveditha Pinnamaneni, MD, from NYU, showed qualitative decreases in BPE at initial and multiple time points after tamoxifen or aromatase inhibitor therapy, suggesting it may be more accurate as a radiologic marker than density. Jiyon Lee, MD, from NYU, reported that qualitative measures of mammographic breast density, MRI-fibroglandular tissue pattern, and BPE are not reliable imaging biomarkers to predict triple negative versus non-triple negative tumor profile. Habib Rahbar, MD, from the University of Washington, presented a case-control matched cohort study of women undergoing high risk screening MRI, and demonstrated that novel quantitative measurements of BPE were more accurate predictors of future cancer compared with qualitative measures of BPE.
On Sunday, April 19th at the American Roentgen Ray Society Annual Meeting in Toronto, the early main event was a debate on screening mammography. The panel included Paula Gordon, OBC, MD, FRCPC, FSBI, Clinical Professor and Medical Director from the University of British Columbia; Daniel Kopans, MD, FACR, FSBI, Professor of Radiology, Harvard Medical School, Massachusetts General Hospital; and two researchers from the Canadian National Breast Screening Study (CNBSS), Anthony Miller, MD, FRCPC, FRCPC(C), FHPHM, FACE, Director of the CNBSS and Professor Emeritus at the University of Toronto, and Cornelia Baines, MD, MSc, FACE, Professor Emerita at the University of Toronto. Charles Kahn, MD, MS, of the University of Pennsylvania served as moderator.

The panel concentrated their discussion on the controversy over whether screening mammography should or should not be recommended and performed. Particular attention was paid to the CNBSS initial results and follow-up findings. Drs. Miller and Baines from Toronto discussed their study and took the stand against routine mammography, as they feel it offers no benefit. Speaking in support of screening were Drs. Gordon and Kopans.

Dr. Miller reviewed results from the CNBSS conducted in the 1980s that included over 89,000 women (1, 2). This study has been reviewed and publicized numerous times over the years. More recently, in 2014, additional information was reported in the British Medical Journal (3). During the debate, Dr. Miller maintained that 25 years later the follow-up data confirm the initial study results: annual mammography for women between the ages of 40 and 59 does not reduce breast cancer mortality any more than clinical breast examination or other routine care. In addition, Dr. Miller reported that a tremendous amount of harmful overdiagnosis exists with routine screening.

Dr. Baines went through all of the criticisms of the CNBSS including lack of randomization or biased randomization, patients with palpable abnormalities included in the screening arm, poor image quality with no quality control measures in place, no training for the technologists in performance of the mammogram, no training on how to interpret the mammogram for the radiologist, and outdated poor quality equipment. The issue, according to Drs. Miller and Baines, is not access to mammography, or who or how they get to mammography screening; it is about whether screening is warranted at all. They do not believe it is.

Dr. Gordon spoke on the findings of the Canadian study and how, as an outlier, it is the only one that has not shown a benefit to women undergoing screening mammography. She spoke of all the other studies that have shown a benefit and mortality reduction following screening mammography. In particular, a recent study published in the Journal of the National Cancer Institute by Dr. Andrew Coldman and colleagues from the British Columbia Cancer Agency was discussed (4). This Pan-Canadian study aimed at comparing breast cancer mortality in participants versus non-participants.
invited into their screening program. The data were obtained over a 19-year period with approximately 3,000,000 screening participants. The average cancer mortality reduction was 40% for patients participating in screening.

Dr. Kopans spoke of looking at all the data carefully and cautioned that the Canadian study did not follow the rules and regulations of randomized controlled trials. A clinical breast examination was performed prior to assigning women to either arm of the study. In the screening arm, more women with advanced cancers were assigned and this influenced the screening mammography outcomes negatively and falsely.

The panel took questions from the audience and many relevant comments were made regarding the leaps and bounds of the current technology that we have available to diagnose breast cancer. Some expressed that mammography has improved drastically since the 1980s, making reliance on data from the CNBSS irrelevant to breast imaging today. This is especially true because the internal audit, published by Drs. Miller and Baines in 1990, found that the mammograms, the foundation of the landmark CNBSS, were satisfactory for only 49–60% of examinations through the first four years (5).

The panel concluded the session with their final thoughts about screening mammography. Dr. Miller stated he does not recommend screening mammography and Dr. Baines discussed the issue of overdiagnosis. Drs. Gordon and Kopans both expressed the importance of starting annual screening mammography at age 40, stating that it clearly saves lives and women should be well-informed regarding their health care in order to make the most educated decision.

REFERENCES


Breast screening with mammography significantly decreases mortality from breast cancer. The scientific evidence for this is overwhelming. Population-based studies show a 40% reduction in mortality for women age 40 and older who participate in mammography programs. In spite of this, there is continual national debate about the utility of mammography. Several national leaders in breast imaging have been on the front lines of this war against mammography for decades. A key figure in this process is Daniel Kopans, MD, Professor of Radiology at Harvard University and current Chair of Fellows of the SBI. Dr. Kopans recognized that he and other leaders have critical knowledge and presentation strategies that will be lost if not transferred in an organized way to a new generation of leaders.

In early 2014, Dr. Kopans brought his concern to Barbara Monsees, MD, who at the time was Chair of the ACR Commission on Breast Imaging and who also served on the SBI Board for many years. At the final ACR National Conference on Breast Cancer in Spring of 2014, Dr. Monsees, Geraldine McGinty, MD, (Chair of the ACR Economics Commission), and Debra Monticciolo, MD, (Chair of the ACR Quality and Safety Commission and Education Chair for the Breast Commission) discussed this educational challenge and the Breast Screening Leadership Group idea began. The concept was fairly simple: to train new leaders in screening. Our goal was to ensure that future breast imaging leaders have the knowledge and tools to understand breast cancer screening and defend it with solid science. We decided to hold an extensive educational training course via webinars, given by the leaders in breast cancer screening today.

Initially this was an ACR project. Pam Wilcox, RN, MBA, ACR Executive Vice-President, was at the ACR NCBC and supported the concept. We needed approval from the ACR Executive Director, Bill Thorwarth, MD, and we needed to have the project align with the ACR strategic plan. Ms. Wilcox was instrumental in making that happen. Once the concept was solidified (outlined below), we contacted Murray Rebner, MD, then President of the SBI, and Yasmeen Fields, CAE, Executive Director of the SBI, to gauge their interest. They enthusiastically joined us in planning the first course.

Drs. Kopans and Monsees designed the first curriculum, which was then edited by Dr. McGinty, Dr. Monticciolo, and many of the faculty. For the faculty, we asked the best of our leaders to volunteer their time and expertise, which all did without hesitation. Their commitment, dedication, and patience throughout the course cannot be overstated. We are grateful to the following teachers who donated their efforts so unselfishly: Shawn Farley (ACR Public Relations), Mark Helvie, MD, Edward Hendrick, PhD, Daniel Kopans, MD, Carol Lee, MD, Geraldine McGinty, MD, Edward Sickles, MD, and Robert Smith, PhD (American Cancer Society). The course topics covered screening basics, randomized control trial (RCT) analysis, other non-RCT types of evidence, methods for evaluating the scientific literature, modeling, harms and benefits of screening other than mortality reduction, economics of breast imaging, outcomes measures, and how to present information to the public and press. These topics were presented in nine evening webinars. Each webinar was 30–40 minutes with
Breast Screening Leadership Group and Course, continued from previous page

the remainder of the hour left for questions. A final face-to-face media training session was held at the SBI 2015 national meeting in Orlando.

We wanted the course to be challenging yet accessible to the trainees, so we kept the teacher-to-student ratio low. Twenty-one individuals were invited to the training; 19 accepted and completed the course. All participants were required to commit to attending all nine webinars and the face-to-face meeting and all needed a letter of support from their department Chair. We also asked that they commit to future service in the breast imaging community. All agreed.

This was not a passive educational exercise. We wanted the participants to have a sense of commitment and to produce tangible results. Participants read seminal articles for each webinar and discussed them during the sessions. Faculty made themselves available at any time for inquiries about all aspects of screening. Questions and writing exercises were submitted to the learners as the course progressed and the results were made available to both teachers and participants. Several educational deliverables were also outlined. The SBI newsletter articles that will follow this introduction to our leadership course are part of that concept.

We hope that our faculty has inspired a new generation of breast imagers to take leading roles in breast cancer screening education nationally. All showed great enthusiasm and tenacity during the training, to which all committed a great deal of time and effort. Congratulations to all of the participants: Drs. Kate Appleton, Elizabeth Arleo, Jay Baker, Lora Barke, Wendy DeMartini, Peter Eby, Amy Fowler, Phoebe Freer, Sarah (Sally) Friedewald, Bonnie Joe, Jessica Leung, Linda Moy, Bethany Niell, Mary (Mimi) Newell, Brett Parkinson, Elissa Price, Jocelyn Rapelyea, Dana Smetherman, and Janice Sung.

Note: The planners, speakers and participants would like to thank Tiffany Lipp for her assistance in making this course possible.

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Breast Cancer Screening
Reimbursement Update

By Geraldine McGinty, MD, FACR, FSBI

Despite much fanfare over the CMS decision to finalize CPT codes for digital breast tomosynthesis (DBT), much confusion and uncertainty remains around various aspects of reimbursement for breast cancer screening. Add to that the doubts that continue to be cast on the efficacy of screening for breast cancer with mammography and it’s easy to see why some of us are tearing our hair out. Here are some basics and updates on the landscape of reimbursement for breast screening with full field digital mammography (FFDM) and DBT as well as links to some excellent ACR resources that should help clarify things.

Reimbursement for tomosynthesis?

Linked here is an excellent ACR article on coding for DBT which includes a table of all the breast imaging codes with estimated reimbursement:
http://www.acr.org/Advocacy/eNews/Archive/2014/20141114-Issue/Information-on-Coding-Value-and-Coverage-for-Tomosynthesis

CMS (Medicare) is paying for DBT using two codes: a CPT code for screening and a G code for diagnostic DBT. The screening code is an add-on code, i.e., it must be billed in conjunction with a FFDM screening G code. The diagnostic DBT code is also theoretically an add-on code but in rather confusing guidance, CMS has stated that it can be billed in conjunction with the FFDM diagnostic G code (either unilateral or bilateral) whether or not planar images were acquired. Please see the full ACR statement here:
http://www.acr.org/Advocacy/eNews/20150327-Issue/20150327-CMS-Correction-Notice-Clarifies-Diagnostic-DBT

Private or commercial payers have been much slower to start paying for DBT, unfortunately. They cite the ACR's lack of a Practice Parameter detailing its appropriate use (this is in preparation) as evidence that the technology remains experimental. The ACR strongly disputes this and has prepared an information packet that can be downloaded if you are speaking to your local payers to try and convince them to reimburse DBT. You can find this packet at:

If your facility is offering DBT and your commercial payers are not covering it, here are a few things to bear in mind:

• DBT is a covered service under Medicare so you cannot charge beneficiaries a co-pay for screening as it is covered without beneficiary cost sharing but you can charge the usual co-pay for diagnostic DBT.
• You may be able to bill patients who have commercial insurance for DBT.

Reports from our community suggest varying approaches to DBT reimbursement including some facilities who are not charging at all.

**What is the future for DBT and mammography reimbursement?**

The imperative to transition our healthcare delivery and payment system from volume to value and the implementation of the Affordable Care Act is impacting breast cancer screening. Draft recommendations from the USPSTF that give mammography screening a C grade and state that there is insufficient evidence to recommend coverage of DBT do not bode well even though the evidence clearly demonstrates a benefit from both technologies. As you know, the SBI and ACR have submitted extensive comments refuting the USPSTF’s draft recommendations, but the terms of the ACA that mandate no-cost sharing coverage of screening tests with a USPSTF A or B grade mean that if the recommendations are finalized, coverage for screening for millions of women could be at risk. This already happened in 2009 but legislative intervention saved the day and is certainly an avenue we will pursue should the taskforce finalize its misguided recommendations.

At the more granular level, CMS has expressed concerns that the G codes with which we bill for FFDM have been in place for almost 14 years and they believe that a review and a conversion to CPT codes is a good idea. There is a trend towards bundled codes, a trend that negatively impacted reimbursement for image-guided breast biopsy in 2014, and the future for breast cancer screening may involve some form of bundled codes. It’s too early to say how these will be structured, but rest assured that your team at the ACR Economics Commission will be advocating strongly for fair reimbursement to protect access to these life-saving services.
Screening mammography has been shown to decrease breast cancer mortality across multiple trials, and across many different study designs. Despite this, some opponents continue to question the value of mammography. Thus, it is increasingly important that breast imaging care providers understand the nature and results of the randomized controlled trials (RCTs), which have definitively demonstrated that screening mammography in women 40–74 years of age decreases deaths from breast cancer.

Cancer localized in the breast is not what causes death; it is breast cancer spread (metastasis) to other organs that causes mortality. The goal of mammographic screening (and other breast cancer screening tests) is to detect breast cancer earlier than it would otherwise manifest clinically, when it is less likely to have spread. Data clearly show that detection of breast cancers at smaller sizes and lower stages is associated with better patient outcomes from lower morbidity and reduced breast cancer deaths.

RCTs are the gold standard for proving that early detection with mammography decreases mortality from breast cancer. It is important to understand that the key evidence measure is the breast cancer death rate observed in the experimental group (women invited to have screening mammography) compared to that in the control group (women not invited to have screening mammography). It is not sufficient to use survival time (the time of discovery of the cancer to the date of death) between the groups, as this may reflect “lead-time” bias, in which a cancer is found earlier so survival time appears longer, but the date of death is not altered. RCTs avoid “lead-time” bias and have shown that the primary benefit of screening is decreased breast cancer mortality rates.

RCTs for screening mammography are performed by assigning, in a blinded fashion (randomizing), women into two identical groups; the experimental group (women invited to screening mammography) and the control group (women not invited to screening). When properly randomized, the same number of women in the experimental and control groups will develop breast cancer.
Breast Cancer Screening: Understanding the Randomized Controlled Trial, continued from previous page

cancers over the years, and if no screening were done in either group, the same number of women
would die of breast cancer in each group. In effect, every woman has an equivalent “twin” in the
opposite group. If a woman in the experimental group develops and dies from a breast cancer, then
her “twin” in the control group will die from breast cancer. If screening works, long-term surveillance
after the intervention period will show that the breast cancer death rate in the invited group is less
than the breast cancer death rate in the control group. The difference in the breast cancer death rates
between these two groups determines the mortality reduction from mammography screening.

The first RCT of screening mammography (Health Insurance Plan, or HIP Trial) was performed in
New York in the 1960s (1). The HIP Trial demonstrated a 23% decrease in the death rate in women
who were invited to screening. Seven additional prospective RCTs were performed after the HIP trial.
The individual trials, as well as numerous subsequent meta-analyses combining trial results, continue
to demonstrate a mortality reduction from mammography screening of 15–30%.

In fact, the mortality benefit to women screened regularly is actually greater. RCTs underestimate
the mortality benefit of screening. RCT analyses include women in the invited to screen group who
did not actually undergo mammography (non-compliance). If they died from breast cancer they
have still been counted as a death among the screened women. This increases the death rate in the
invited group. On the other side of the coin, there were women in the not invited to screen group
who had mammography on their own, outside of the trial (contamination). They may have had their
lives saved by that mammogram but are still counted with the unscreened controls. This decreases
the death rate in the unscreened group. Together, non-compliance in the screened group and
contamination in the unscreened group decrease the observed difference in breast cancer mortality
in the RCTs. As a result, the true mortality benefit of screening mammography is even greater than
what has been shown in the RCTs.
Breast Cancer Screening: Understanding the Randomized Controlled Trial, continued from previous page

Smith et al. published an excellent summary of the RCTs (2). All demonstrated a substantial reduction in the death rate from breast cancer in women invited to undergo screening mammography, with the exception of the Canadian National Breast Screening Study (CNBSS) (3,4). The flaws in the CNBSS have been described in peer-reviewed publications (5–8) and will be discussed in depth in a subsequent article.

Although all of the mammography screening trials have some limitations, RCTs consistently demonstrate a reduction in breast cancer deaths of 15–30% in women 40 to 74 years of age invited to screening mammography. Unfortunately, in an often quoted study by Gotzsche and Olsen, all but two of the RCTs are excluded from the analysis (9). The Gotzsche and Olsen papers overstate the limitations of the studies that they excluded and ignore the flaws of the CNBSS.

To summarize, all of the well-executed RCTs have demonstrated that screening mammography decreases breast cancer deaths, proving the importance of early detection: breast cancers can be cured if detected and treated early.

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Interesting Case: The Importance of Radiologic-Pathologic Correlation

By Jennifer R Kohr, MD

A 63-year-old woman presents with a palpable lump in her right breast, 10 o’clock position. She has a history of benign and concordant right breast needle biopsy with marker clip placement in the same area three and a half years ago. She is up-to-date on annual screening mammograms and the most recent was negative. A unilateral diagnostic mammogram was performed demonstrating an irregularly shaped mass with associated architectural distortion corresponding to the area of palpable concern at 10 o’clock. Note that this mass contains a metallic biopsy marker clip (Figure 1). The radiologist ordered a targeted right breast ultrasound.

Targeted right breast ultrasound shows an irregular hypoechoic mass with posterior acoustic shadowing measuring up to 18 mm at 10 o’clock (Figure 2).

Given the palpable nature of the mass and suspicious features, the patient underwent ultrasound-guided biopsy and marker clip placement yielding grade 2 invasive ductal carcinoma at final pathology. Post biopsy mammogram demonstrates two clips in the same mass (Figure 3).

Figure 1a: CC spot compression view of the right breast. Mass with clip at 10 o’clock is circled. A triangle skin marker, indicating the palpable area, is seen in tangent.

Figure 1b: MLO spot compression view of the right breast with triangular marker at the palpable area. The mass and marker clip at 10 o’clock are circled.
Interesting Case, continued from previous page

Figure 2: Diagnostic ultrasound demonstrates an irregular mass with indistinct margins at 10 o’clock at the site of the palpable lump and mammographic mass and marker clip.

Figure 3: Post biopsy mammogram demonstrates two clips in the same mass.
What happened here? Three and one half years earlier the patient was recalled from screening mammogram for a focal asymmetry in the right upper outer quadrant. Those mammographic images are not available. Per report, additional views demonstrated a mass with spiculated margins and associated architectural distortion at 10 o’clock 6 cm from the nipple. Ultrasound demonstrated an irregular hypoechoic mass with posterior acoustic shadowing and anti-parallel orientation measuring 8 mm at 10 o’clock, 4 cm from the nipple. Internal vascularity was present.

Findings were assessed as BI-RADS® 4, suspicious, and ultrasound guided biopsy was recommended. Ultrasound guided biopsy was subsequently performed with a 14 gauge core biopsy device and 4 samples were obtained.

Final pathology was benign breast tissue without atypia. Addended biopsy report stated that “review of the cine clips from the biopsy clearly demonstrate that the lesion was appropriately sampled. The findings are concordant.” The radiologist then stated that a short interval follow up with diagnostic mammogram and possible ultrasound should be performed in 3 months. Giving a final assessment of BI-RADS® 3, probably benign.

From the records provided, the patient returned to routine screening without undergoing recommended follow up until presenting three and a half years later with a palpable lump at the biopsy site.

**Teaching points**

While ultrasound guided core needle biopsy is a widely accepted alternative to surgical biopsy, false negative results are still possible at just under 3% of biopsies, and as such methodical radiologic-pathologic correlation is critical to avoiding missed malignancy (1,2). The primary error in this case was to accept a non-specific result of “benign breast tissue” as an acceptable explanation for a mammographically and sonographically suspicious mass. Per BI-RADS® 5th Edition (3), “a tissue diagnosis is considered to be discordant if the cytological or histological diagnosis rendered by the pathologist is not consistent with the imaging findings of the biopsied lesion.” Since the radiologist concluded the lesion was adequately sampled at the time of biopsy, surgical biopsy would have been the next best step in management. If available, repeat biopsy with a larger gauge, vacuum assisted device could have also been offered. While there are specific benign pathological results
that explain suspicious imaging findings including fat necrosis, mastitis, diabetic mastopathy, and sclerosing adenosis, a non-specific diagnosis of benign breast tissue is not one of them.

Another point raised by this case is the recommendation for short interval imaging follow up after benign biopsy. It is important to note this practice is reserved for benign, concordant cases and is not an acceptable alternative in the current case. Currently, there are no evidence-based consensus guidelines regarding necessity or timing for short interval imaging follow-up after benign image-guided biopsies. Furthermore, there is mounting evidence that short interval follow up at 6 months provides little additional benefit in uncovering missed malignancy (4). The recommendation for 3 month follow up in this case is almost certainly too short an interval to demonstrate any meaningful mammographic or sonographic change, even in the setting of missed malignancy.

One final point is that this patient underwent a few screening mammograms between the initial biopsy and the ultimate diagnosis of cancer. Keep in mind that if a mass appears mammographically suspicious, it may be worth re-evaluating the radiologic-pathologic concordance even if it contains a marker clip. If it seems discordant, recall the patient for additional evaluation.

REFERENCES
Implementing Direct and Interactive Public Education

By Jiyon Lee, MD

The USPSTF’s 2015 draft recommendations for screening mammography essentially perpetuate the same suboptimal guidelines that were announced in 2009, and according to the estimate from Avalere Health, 17 million women between ages 40–49 could be excluded from insurance coverage for the exam. More than ever, as experts in this field, we can make a difference. Should we choose to embrace this as opportunity rather than burden, we collectively are charged with the task of proactively making accurate information accessible to the public, not just the women who are already our patients. As important as are the online radiology public service announcements, they are still “doc-in-a-box,” albeit an electronic box. We can complement those with warm, in-person, tailored communication, to audiences as intimate as a few to as large as hundreds. A so-called drop in the bucket is still a drop, and many drops are still impactful, especially to every single individual who feels more informed.

Where: Go where you are welcomed. Expand your social reach and utilize your direct and indirect contacts. Example venues should naturally include wherever you are already socially involved and where members know of your profession and favorably regard your passion for voluntary outreach. Hosts of community spaces such as your library, town hall, women’s club, or place of worship may invite you or welcome your offer to speak. Hospital-sponsored on-site and off-site events can feature you alone or in concert with other clinicians, and can be timed to synergize with breast cancer awareness month, or capitalize on other scheduling prompts. As you come into contact with new people or new organizations, you can be a willing and accessible resource for individuals with questions, and notice when opportunities present themselves to you, through them, for larger group impact. These educational lectures are usually not fee-for-service encounters. However, if your talk is part of a larger event (especially a fun one!), a fee may be involved but typically not direct compensation to you. Make every lecture a worthwhile experience; successful encounters should naturally lead to more invitations. Do forge respectful professional ties with clinical colleagues, especially with family practitioners and primary care physicians who might mostly abide by the USPSTF guidelines. Opportunities to collaborate with them in community outreach and directly lecture to their colleagues may occur more quickly than you might imagine. The potential benefits are self-evident if done right.

When: Schedule lectures to reach various audiences according to their availability. To reach people, you need go where they are and where they feel safe, during the times they can and do wish to make themselves available. Aim for variety. Morning lectures at American Cancer Society and Gilda’s Club community centers, daytime lectures at corporate wellness lunch-and-learn programs, evening events at a private university alumni club are examples of prescheduled time slots that usually occur on weekdays. Weekends provide different opportunities for outreach, so seek audiences...
Implementing Direct and Interactive Public Education, continued from previous page

who may not have the job structure or scheduling flexibility to attend during the weekdays. Whether your department or practice allows time off or otherwise supports your work may depend on when you lecture.

**How: Practical logistics. Illustrated slides are useful, arguably essential, to enable comprehensive presentations.** These should be appropriately updated before every event, and I believe only slightly modified according to audience. Your core messages and components should stay consistent. Most venues should have the audio-visual setup that you would require, but for smaller social gatherings, using your own laptop can suffice. At the opposite end of the spectrum, organizations such as large multi-office or multi-city corporations can allow you to simultaneously speak personally with some and connect remotely with others to address hundreds of people at once. Before I start my lecture, I will often solicit any preexistent questions and comments to gauge the audience’s mindset and learn of any burning curiosity; this is even more helpful for the remote attendees since I may not be able to see them. This process already jumpstarts the mental connection so that I can be sure to answer any questions that might not already be addressed in my talk. Travel with your presentation on more than one medium. If you send a pdf in advance, your host could supply printed copies for audience members to jot down minimal notes as you speak. Bring your business cards and share your contact information for follow-up questions and comments. Do solicit feedback on ways to improve.

These are all suggestions, and not meant to be narrowly prescriptive nor proscriptive. I imagine that many of you conduct public outreach too, so let’s welcome sharing of experiences and mutual guidance. There is always room for improvement when it comes to effective communication. I sincerely thank you for your interest.

**REFERENCES**

1. Lee J. Public Education on Breast Screening. SBI Newsletter 2014 Issue 2, p16-17
3. Lee J, Gordon PB, Whitman GJ. “Do unto others as you would have them do unto you.” Breast imagers’ perspectives regarding screening mammography for others and for themselves…*Do they practice what they preach?* AJR 2015; 204: 1336-1344

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**Upcoming Events & Activities**

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<td>September 26 - 27- San Diego, CA</td>
<td>Radiological Society of North America (RSNA)</td>
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<td>November 29 - December 4 – Chicago, IL</td>
<td>For a listing of other society events please check out the SBI Calendar of Events at <a href="http://www.sbi-online.org">www.sbi-online.org</a></td>
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