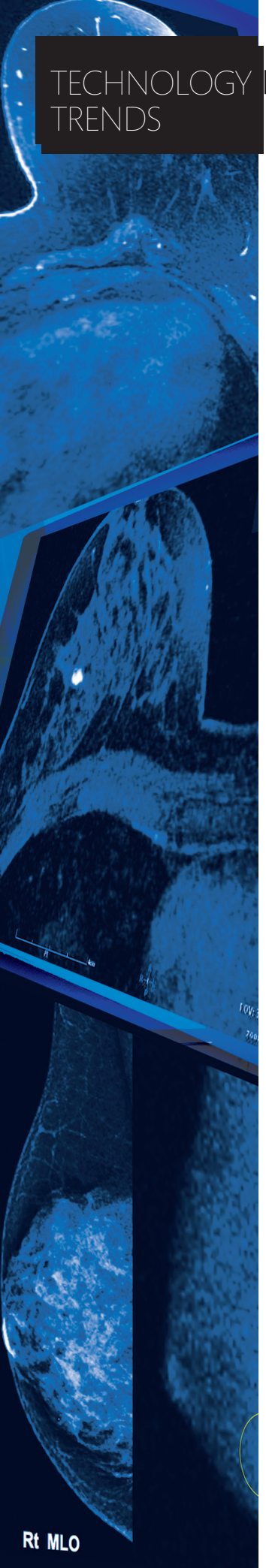

Breast Imaging Update: Guidelines, Recall Rates and Personalized Care

Mary Beth Massat

In the last two years, guidelines for mammography screening have taken divergent paths.

The U.S. Preventative Services Task Force (USPSTF) recommends biennial mammographic screening for women aged 50 to 74, while the American Cancer Society (ACS) recommends annual mammograms for women aged 45 to 54. Nevertheless, the ACS says those women between 40 and 44 should still have access to mammograms and those 55 and older should be able to choose between yearly or biennial mammograms.

The American College of Radiology (ACR) and the Society for Breast Imaging (SBI), meanwhile, both agree with the ACS that mammography saves lives and although both organizations support these (the ACS?) guidelines, the ACR and SBI encourage women to begin annual mammograms at age 40.

Then in June, the American College of Obstetricians and Gynecologists (ACOG) weighed in, stating that women should be offered screening mammography at age 40 and start no later than age 50. However, the ACOG also said the decision on when to start breast screening ultimately should be made by each woman and her healthcare provider.

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Also in June, the ACR Commission on Breast Imaging published a paper recommending annual mammography screening for average-risk women starting at age 40 based on a review of data, studies and peer reviewed literature.[1]

"We are trying to save the most lives," says Debra Monticciolo, MD, FACR, chair of the Commission and Chief, Section of Breast Imaging at Baylor Scott & White Health (Temple, TX). Dr. Monticciolo was lead author on the paper published in the Journal of the American College of Radiology. "There is a statistically significant reduction (in breast cancer) with mammography screening."

Dr. Monticciolo also points out that both ACS and USPSTF used mortality rates as the only benefit. Yet, she says, finding tumors at earlier stages can help patients avoid more toxic and rigorous treatment, which can further impact overall health.

"Another benefit of screening is our ability to find an atypical ductal hyperplasia (ADH) lesion," she says. "Women who have this can undergo a risk reduction strategy to decrease their chance of developing ductal carcinoma in situ (DCIS)."

Not all women with ADH will develop DCIS, a non-invasive cancer. However, left untreated, DCIS can spread to surrounding breast tissue, and as Dr. Monticciolo points out, 120 years of data clearly demonstrates that

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the survival rate for cancer is 0% without treatment.

While acknowledging that clinicians may be overtreating a variety DCIS cases in older women, Dr. Monticciolo argues that shouldn't be used to convince women not to wait to get their mammogram and wait very two years.

Stacey Vitiello, MD, a radiologist in breast imaging at Montclair Breast Center (Montclair, NJ), believes the difference in guidelines reflects different goals. Dr. Vitiello says if the goal of screening is to find cancer as early as possible, to decrease mortality and offer less onerous treatment options, then "starting yearly screening at age 40 is clearly the way to go." If the goal is cost savings, then the agenda would be to screen fewer people over fewer years.

Suggesting women cease receiving yearly mammograms at age 70 or 75 should also be looked at more closely, Dr. Vitiello says, especially since the incidence of breast cancer increases with age. "There are plenty of women enjoying vigorous lives in their 80s and even in their 90s," she says.

Currently, the USPSTF guidelines state insufficient evidence exists to assess the balance between harm and benefit of screening mammography in women 75 and older.

The difference in guidelines also reflect a difference in perspective, says Susan Harvey, MD, Director, Johns Hopkins Breast Imaging Section and Assistant Professor of Radiology and Radiological Science, Johns Hopkins University,(Baltimore, MD.

"The USPSTF is looking at this from a population-based view at a national level, not at a personal level," Dr. Harvey says. "The ACS sits in the middle—they want better outcomes but also have an obligation to make realistic and sustainable decisions. As a radiologist, I see my role as finding every cancer as early as possible. It's these perspectives that change how recommendations are put forward."

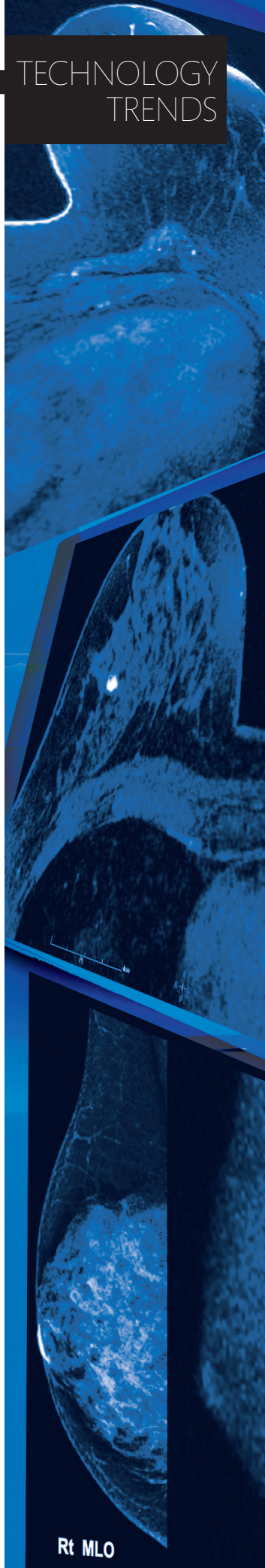
Recall rates and false positives

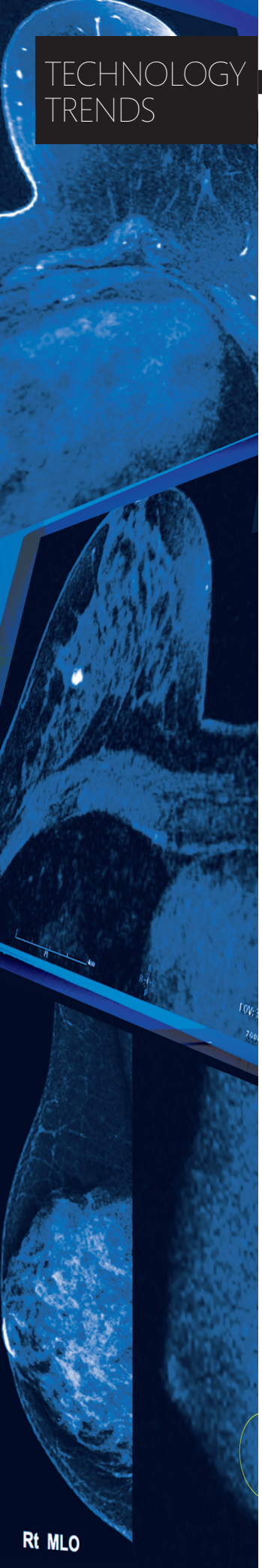
High recall rates and false positives have been a key topic of discussion at conferences and published studies in peer-reviewed journals. Technologies such as full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) have been developed to further enhance mammography's sensitivity.

Dr. Harvey recently was primary investigator of a study on reducing recall rates while maintaining performance metrics.2 She explains, "Looking at the sequence of breast imaging steps, it really starts with screening mammography. If that is interpreted accurately, then everything else falls into place."

The study looked at two strategies. In the first, each radiologist consistently reviewed their own work, including their recalls and outcomes. "The idea was to identify recall strategies that worked well and didn't—suspicious areas that were ultimately not cancer," Dr. Harvey explains.

The second strategy called for consensus double reading of all recalls with two radiologists required to agree a recall was necessary. The study followed recall rates, cancer detection rates, and positive predictive value 1 (PPV1).





Stacey Vitiello, MD, a radiologist in breast imaging at Montclair Breast Center, Montclair, NJ

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By examining PPV1, the study helped demonstrate that practices can reduce recall rates while maintaining or increasing performance metrics. Recall rates dropped from 11.1% to 9.2% for FFDM and from 7.6% to 6.6% for DBT, yet PPV1 increased from 3.4% to 5.7% for FFDM and from 6.0% to 9.0% for DBT. Cancer detection rates—3.8/100 for FFDM and 4.8/1000 for DBT—did not significantly change after implementing each of the two strategies.

According to Dr. Harvey, one challenge of implementing both strategies is the low reimbursement levels that lead to high-volume reading in breast imaging. "In breast imaging, we are asked to produce more with fewer resources."

Yet, it was important in the study design to demonstrate that scaling down recall rates with additional exam reviews—both individually and with colleagues—is reasonable. The study reported an overall average of 2.3 minutes was spent consulting with colleagues for each recall.

Recall rates have often been compared between the U.S. and Europe. The comparison, however, doesn't account for the difference in practice patterns or access to data, says Dr. Harvey.

"We don't have the same advantages as Europe with national screening programs and access to data," she says. "Also, in Europe mammograms are read by two radiologists and many European countries will add ultrasound onto screening mammography, so operationally we are different."

Montclair Breast Center has taken a step in this direction. Dr. Vitiello says the center doesn't have call backs from screening mammography because all mammograms are reviewed while the patient is at the center. If a lesion needs further evaluation, it is performed immediately.

"I've seen no other test where patient anxiety is used as a reason to not have a certain study performed," Dr. Vitiello says, referring to the guidelines' reference to anxiety as a "harm." "It is a nefarious argument that is offensive… the anxiety of a breast cancer diagnosis is huge compared to getting a recall or even a biopsy, and I don't understand how that became part of the conversation."

Personalized care

In July, the Breast Cancer Surveillance Consortium (BCSC) received a $17 million grant renewal from the National Cancer Institute to study the effectiveness of different breast cancer screening and surveillance strategies—FFDM, DBT and breast MRI.

"It is important to look at tomosynthesis and MRI as there are pluses and minus to both," says Dr. Monticciolo. "MR is by far the most sensitive and is better than anything we have, but it is expensive, we have to inject gadolinium, and exam times are long, although people are working to shorten the time. We need to find a way to offer this technology at an acceptable cost and

time in the machine so it can be the test of choice for high-risk women."

While breast ultrasound has limitations—low specificity and a high rate of false positives—Dr. Harvey is surprised that ultrasound will not be included in the study. She believes in the clinical utility of breast MRI, however, "to go from mammography to MRI seems like a big leap. It is interesting that ultrasound is not paired with FFDM or DBT," she adds.

Dr. Harvey and colleagues employ ultrasound for breast screening. They began to routinely use the technology during her clinic's involvement in the American College of Radiology Imaging Network (ACRIN) 6666 trial. Recently, she had a patient with seven cancers not visible on DBT in the left breast. On ultrasound, the lesions were not particularly subtle. "If we threshold ultrasound, then the specificity issue could improve," she says.

"Forty percent of the women we perform mammography on have dense breasts," Dr. Vitiello says. "Adding breast ultrasound to their screening approach is very important." Each patient at Montclair also receives an estimated lifetime risk of breast cancer, helping to identify those who would benefit from supplemental screening with ultrasound and MRI.

The same is true at Dr. Monticciolo's practice, Scott & White Clinic – Temple, a high-risk clinic that helps identify women who should receive DBT or breast MRI due to breast composition, family history, or other risk factors.

Dr. Monticciolo has looked closer at molecular breast imaging (MBI) for both her practice and the ACR. She says the ACR will be releasing its first practice parameter on the technology. While there is an effort by certain groups to reduce overall dose of MBI studies below the current average of 10 mCi, dose remains a limitation of its use.

Dr. Harvey has also looked at MBI. "What is really interesting is to find a marker specific to breast cancer that we can tag," she says. "hen, potentially we can have a therapeutic radiotracer to that same marker that could deliver the 'magic bullet.' As we develop more sophisticated molecular tools, I just believe that MBI is something we should have."

Consider prostate cancer, where surveillance is often recommended for less aggressive forms of the disease. "That's the challenge with breast cancer, we don't know which ones to let go. With the information that we have today, we are doing the right thing until we know more through research," Dr. Harvey says.

Dr. Monticciolo adds that abundant data shows the benefit of screening mammography. "I encourage radiologists and breast imagers to get involved in patient screening decisions," she says. "The most lives are saved when women are screened annually at 40. The more we can communicate that fact with other physicians, the more we can make a dent in the mortality rate of this disease."

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