

Higher Mammography Screening Costs Without Appreciable Clinical Benefit: The Case of Digital Mammography

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Low sensitivity of film-screen mammography in women aged 40 to 49 years paved the way for digital mammography (1), which improves screening sensitivity relative to film-screen mammography in women with dense breasts, pre- and perimenopausal women, and those aged 40 to 49 years (2,3). Digital mammography now accounts for 94% of mammography units in the U.S. (4). New evidence reported in this issue of the Journal describes the diffusion and annual cost of digital mammography in the Medicare population. Killelea et al. describe the rapid increase in digital mammography use from 2.0% in 2001–2002 to 29.8% in 2008–2009 (5). Transition to digital mammography increased Medicare screen-related costs from \$666 million to \$962 million with most cost increase due to the higher cost of digital than film-screening mammography and uptake of computer-aided detection (CAD).

Consistent with other studies (3), Killelea et al. found that the digital mammography transition has not resulted in a downstaging of disease in older women (5). While a shift toward earlier stage disease would not necessarily be expected given comparable cancer detection accuracy for digital and film-screen mammography among women aged 50 to 79 years, this may allay concern about the transition exacerbating overdiagnosis (3). It is reassuring that there appears to be little evidence of increased harm with the shift to digital in the Medicare population; diagnostic mammography use increased slightly and biopsy rate decreased slightly, consistent with studies reporting similar specificity for digital and film-screen mammography in older women (3,6).

The study by Killelea et al. adds to the literature documenting higher costs for digital mammography among women aged 65 years and older without a clear added benefit to women. While early modeling based on the Digital Mammographic Imaging Screening Trial suggested older women may be harmed by the digital transition (7), more recent projections based on mammography screening performance described by the Breast Cancer Surveillance Consortium (BCSC) mirror the findings of Killelea et al. (8). Stout et al. reported a health gain of 0.73 days per woman and increased costs of \$0.35 million per 1000 women if women aged 50 to 79 years received biennial mammography screening with digital rather than film screen (8). The uptake of CAD with digital mammography from 3.2% to 33.1%, as reported by Killelea et al., adds to the cost of mammography without a convincing added benefit (5,9). Thus, the transition to digital breast cancer screening in the U.S. has increased screening mammography costs

for possibly small or no health gains, resulting in screening mammography being less cost efficient than in the past.

With U.S. health care costs burgeoning and mammography screening costing an estimated \$7.8 billion in 2010 (10), it is not surprising that Medicare's payment policies, which reimburse more for digital than film-screen mammography, are controversial (11). One approach to contain costs is to decrease the frequency of screening by using a risk-based screening approach, whereby low-risk women could stop screening or continue to be screened at longer intervals, reducing the number of screening examinations, false-positive examinations and biopsies, and possible overdiagnosis (12,13). A recent study demonstrates that biennial vs annual mammography does not increase the risk of advanced-stage tumor incidence and lowers the false-positive rate among women aged 66 to 89 years (14). Breast imaging registries or organized screening programs are well positioned to evaluate risk-based breast cancer screening strategies because they collect breast cancer risk factor information (eg, family history of breast cancer and breast density) and link this information to screening and cancer outcomes. Using breast imaging registries or organized screening programs will be particularly important for comparing the effectiveness of new technologies, such as tomosynthesis to digital mammography in community practice.

In older women, risk-based screening may incorporate strategies to discontinue screening for women who are unlikely to benefit. Killelea et al. report that among the Medicare population undergoing screening mammography over 40% of women have at least one comorbidity and more than 55% are aged 75 years or older (5). Yet, there is no direct evidence from randomized controlled trials to suggest improvement in life expectancy or deaths averted from breast cancer among screened women aged 70 years and older (15). The results of the Swedish Two-Country trial did not show a statistically significant reduction in breast cancer mortality in a subgroup analysis of women aged 70 to 74 years screened every 24 to 33 months compared to those not offered screening (16). Results from collaborative modeling of screening in the U.S. estimate about two additional breast cancer deaths are averted per 1000 women screened by continuing biennial screening mammography from ages 70 to 74 years (17). Presumably, mammography is offered to women beyond age 74 years because breast cancer incidence increases with age and detection of early stage breast cancer is possible (3,18). However, the likely benefit of screening is reduced among older women with moderate or severe comorbidities and limited life expectancy, and harms likely increase as the risk

of overdiagnosis increases with age (17,19). Risk-based screening that incorporates defined stopping ages based on breast cancer risk in combination with comorbidities and life expectancy may further improve the balance of benefits vs harms for older women, because screening would not be offered to elderly women with limited life expectancy who are unlikely to benefit.

Money directed at technologies not shown to have meaningful clinical benefit beyond the conventional technology result in wasted health care dollars that may have been better spent on care with demonstrated evidence for improving health. To be responsible advocates for high-quality medical care, our enthusiasm for new technologies should not replace strong, consistent evidence that the benefits of the new technology outweigh the harms in a clinically important way. Once manufacturers demonstrate at least comparable performance, timely evaluation of emerging technologies using breast imaging registry risk factor and performance data can provide important comparative effectiveness evidence for guiding clinical applications. Tomosynthesis is the newest breast cancer screening technology rapidly diffusing into community practice with minimal comparative effectiveness evidence that the benefits of the new technology outperform digital mammography in a clinically important way. To paraphrase the noted baseball philosopher Yogi Berra, will this be *deja vu* all over again?

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Funding

This work was supported by the National Cancer Institute-funded Breast Cancer Surveillance Consortium (P01 CA154292 and HHSN261201100031C).

Notes

The preparation, review, and approval of the manuscript do not reflect the views of the National Cancer Institute, and this organization had no role in the final decision to submit the manuscript for publication. The authors have no conflicts of interest to disclose.

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