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Comparative Effectiveness of Digital Versus Film-Screen Mammography in Community Practice in the United States:

A Cohort Study

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Abstract

Background—Few studies have examined the comparative effectiveness of digital versus film-screen mammography in U.S. community practice.

Objective—To determine whether the interpretive performance of digital and film-screen mammography differs.

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Design—Prospective cohort study.

Setting—Mammography facilities in the Breast Cancer Surveillance Consortium.

Participants—329 261 women aged 40 to 79 years underwent 869 286 mammograms (231 034 digital; 638 252 film-screen).

Measurements—Invasive cancer or ductal carcinoma in situ diagnosed within 12 months of a digital or film-screen examination and calculation of mammography sensitivity, specificity, cancer detection rates, and tumor outcomes.

Results—Overall, cancer detection rates and tumor characteristics were similar for digital and film-screen mammography, but the sensitivity and specificity of each modality varied by age, tumor characteristics, breast density, and menopausal status. Compared with film-screen mammography, the sensitivity of digital mammography was significantly higher for women aged 60 to 69 years (89.9% vs. 83.0%; $P = 0.014$) and those with estrogen receptor-negative cancer (78.5% vs. 65.8%; $P = 0.016$); borderline significantly higher for women aged 40 to 49 years (82.4% vs. 75.6%; $P = 0.071$), those with extremely dense breasts (83.6% vs. 68.1%; $P = 0.051$), and pre- or perimenopausal women (87.1% vs. 81.7%; $P = 0.057$); and borderline significantly lower for women aged 50 to 59 years (80.5% vs. 85.1%; $P = 0.097$). The specificity of digital and film-screen mammography was similar by decade of age, except for women aged 40 to 49 years (88.0% vs. 89.7%; $P < 0.001$).

Limitation—Statistical power for subgroup analyses was limited.

Conclusion—Overall, cancer detection with digital or film-screen mammography is similar in U.S. women aged 50 to 79 years undergoing screening mammography. Women aged 40 to 49 years are more likely to have extremely dense breasts and estrogen receptor-negative tumors; if they are offered mammography screening, they may choose to undergo digital mammography to optimize cancer detection.

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Of the 12 445 accredited mammography machines in the United States as of 1 October 2010, 8748 (70.3%) are full-field digital (1). Despite the rapid dispersion of full-field digital mammography, few studies on the accuracy of digital mammography in the United States have been published (2–4), and no studies have compared this technology with film-screen mammography in U.S. community practice.

Studies comparing digital with film-screen mammography in Europe and the United States have produced conflicting findings (5). DMIST (Digital Mammography Imaging Screening Trial) performed film-screen and digital mammography in asymptomatic U.S. women at the same screening encounter. It found that overall accuracy of film-screen and digital mammography for breast cancer detection was similar (2) but that digital mammography was more accurate in pre- or perimenopausal women younger than 50 years with mammographically dense breasts and less accurate in women aged 65 years or older with non-dense breasts (3). The Oslo II study randomly assigned women aged 45 to 69 years to undergo digital or film-screen mammography and reported higher cancer detection rates and lower specificity with digital than with film-screen mammography (6). In a population-based screening program in Spain, recall rate was higher among women undergoing digital mammography than film-screen mammography, and cancer detection rates were similar (7). The United Kingdom's breast cancer screening program for women aged 50 years or older found no difference in cancer detection or recall rates (8). In a population-based screening program in the Netherlands, recall rate and detection rates for ductal carcinoma in situ (DCIS) were higher among women undergoing digital mammography than those having film-screen mammography, but detection rates for invasive cancer were similar (9).

The inconsistent results across studies may be due to small numbers of digital examinations and, thus, few cases of breast cancer associated with these examinations (n = 25 to 254). In addition, the studies did not account for correlation among mammography examinations performed at the same facility by the same radiologist or for secular trends in mammography performance. Study design also varies considerably, ranging from randomized, controlled trials to paired examinations, retrospective cohorts, and population-based cohorts. Other factors that may contribute to the divergent results include single- versus double-reading, readers' experience, and practice environment (5).

We sought to compare the accuracy of digital mammography with that of film-screen mammography and tumor outcomes according to age, breast density, menopause status, and tumor subtype at diagnosis among women aged 40 to 79 years undergoing screening mammography in the Breast Cancer Surveillance Consortium (BCSC). The BCSC (http://breastscreening.cancer.gov) is a large population-based cohort of community-based imaging facilities in the United States.

Methods

Data Source

Data were pooled from 4 mammography registries that participate in the BCSC (10) and collect data from at least 1 facility that performs digital mammography: San Francisco Mammography Registry, Vermont Breast Cancer Surveillance System, New Hampshire Mammography Network, and Carolina Mammography Registry. These registries collect information on breast imaging examinations performed in their defined catchment areas. Each breast-imaging registry annually links women in its registry to a state tumor registry or regional Surveillance, Epidemiology and End Results program that collects population-based cancer data. Three of the 4 registries also link with pathology databases. Each registry obtains annual approval from its institutional review board for consenting processes or a waiver of consent, enrollment of participants, and ongoing data linkages for research purposes. The BCSC Statistical Coordinating Center and each registry adhere to strict confidentiality procedures; comply with the Health Insurance Portability and Accountability Act; and have a Federal Certificate of Confidentiality and other protections of research subjects, radiologists, and mammography facilities.

Participants

The study sample included bilateral digital and film-screen mammography examinations performed between 1 January 2000 and 31 December 2006 among women aged 40 to 79 years who did not have a history of breast cancer or breast implants. Mammography examinations that occurred after 31 December 2006 were not included to ensure at least 12 months for reporting cases of cancer to tumor registries. Cancer ascertainment from cancer registries is estimated to be more than 94.3% complete (11).

Measurements and Definitions

Demographic characteristics and breast health history were obtained by using a self-administered questionnaire (available at http://breastscreening.cancer.gov) that was completed at each screening examination. Women were considered to have a family history of breast cancer if they reported having at least 1 first-degree relative (mother, sister, or daughter) with breast cancer. Postmenopausal women were defined as those who had had both ovaries removed, those who reported that their periods had stopped naturally, those currently using hormone therapy, and those aged 55 years or older. Women were considered to be premenopausal if their menstrual periods had not stopped and perimenopausal if they were not sure whether their periods had stopped. Women were considered to have missing

menopausal status if they had had a hysterectomy without bilateral oophorectomy and were not using hormone therapy or if their menopause status could not be determined from available information.

We used self-reported race and ethnicity to categorize women as non-Hispanic white, non-Hispanic black, Hispanic, Asian/Native Hawaiian/Pacific Islander, Native American/Native Alaskan, or other/mixed race.

Time between mammography examinations was determined by using the dates of prior mammography examinations recorded in each mammography registry (87%); if these were not available, we used self-reported information (13%) collected at the screening examination. A mammography examination was determined to be the first if a woman reported no previous examination and no prior mammogram was found in a registry.

Mammographic breast density was assigned in clinical practice by a radiologist at the time of mammography interpretation. The Breast Imaging Reporting and Data System (BI-RADS) density categories used were almost entirely fat, scattered fibroglandular densities, heterogeneously dense, and extremely dense (12).

Our primary measure was the initial screening mammography assessment, which we categorized as positive or negative by using standard BI-RADS and BCSC definitions (12, 13) that indicate whether a woman was recalled to undergo additional evaluation on the basis of screening views only (12, 13), and the association of initial assessment with cancer outcomes. Standard BCSC definitions of true-positive, false-positive, true-negative, and false-negative results were used to calculate breast cancer and recall rates and the sensitivity, specificity, and positive predictive value of mammography (13).

A mammography examination was associated with breast cancer if invasive carcinoma or DCIS was diagnosed within 12 months of and before the next screening examination. Women with lobular carcinoma in situ only were not considered to have cancer. Stage at diagnosis was classified according to the tumor, lymph node, metastasis system based on the criteria of the American Joint Committee on Cancer, 6th edition, as stage 0, I, IIA, IIB, III, or IV (14). Invasive cancers were classified according to their estrogen receptor status, lymph node status, tumor size, and grade.

Statistical Analysis

All analyses were performed by using the screening examination as the unit of analysis; women may have had more than 1 mammography examination during the study period. Frequency distributions of risk factors for breast cancer and BI-RADS density scores and assessments were determined for digital and film-screen examinations.

We modeled mammography performance measures by using binomial generalized linear mixed models with a logit link, including normally distributed facility random effects to account for correlation among mammography examinations performed at the same facility. To account for differences between facilities performing digital mammography and those performing only film-screen mammography, we included a binary indicator of whether a facility performed any digital examinations during the study period. All models were adjusted for factors related to performance and timing of digital examinations: age, examination year, time between screenings (within 1, 2, or ≥3 years, or first screening examination), and BCSC registry. Adjusted performance measures were estimated from these models by using indirect standardization to ensure identical distributions of covariates among digital and film-screen examinations (15, 16), as described elsewhere (17, 18). Performance estimates were calculated for a facility at the median of the distribution of

facility random effects. Standard errors for adjusted performance measures were calculated by using the delta method.

Separate performance measures were calculated and reported for digital and film-screen mammography from facilities that either switched to digital (66% of facilities) during the study period or performed both film and digital mammography. Film-screen examinations (n = 994 000) from facilities that did not perform digital mammography during the study period were also included in all analyses to adjust for possible secular trends in mammography performance.

Two-sided statistical tests resulting in P values less than 0.050 were considered statistically significant, and values between 0.050 and 0.100 were considered borderline significant.

Sensitivity analyses were done to evaluate the effect of correlation among mammography examinations interpreted by the same radiologist by including a random effect for radiologist in addition to facility (Appendix, available at www.annals.org). Allowing for within-radiologist correlation among mammography examinations had no qualitative effect on regression model results; this factor was therefore not included in the main model, as it reduced our sample size (because a radiologist identifier was missing for some examinations).

We also conducted a sensitivity analysis of the effect of adjustment for the proportion of digital examinations performed at a facility (Appendix). In this analysis, we decomposed the effect of type of mammography into between-and within-facility components by using the methods of Neuhaus and Kalbfleisch (19); this had no qualitative effect on results and was therefore not included in the main model. The Appendix shows performance estimates for facilities at the 25th and 75th percentiles of the random effects distribution to quantify variability across facilities.

To assess whether examinations performed in the first year (n= 60 383 [26.1%]) after a facility implemented digital mammography affected performance estimates, we excluded these examinations in additional sensitivity analyses.

Role of the Funding Source

This study was funded by the National Cancer Institute. A senior scientist from the National Cancer Institute participated in the study design and preparation of the manuscript. The views expressed in this article do not represent those of the National Cancer Institute, and this organization had no role in the final decision to submit the manuscript for publication.

Results

Among 329 260 women aged 40 to 79 years, 869 286 screening mammography examinations were performed (231 034 digital and 638 252 film-screen) and breast cancer was diagnosed in 4046 women (1054 digital and 2992 film-screen examinations), primarily at nonacademic facilities (83%). Women undergoing digital compared with film-screen mammography were similar in age, race or ethnicity, and time since last mammography examination, and they were equally likely to have a first-degree relative with breast cancer and dense breasts (Table 1). Women undergoing digital mammography were slightly more likely to have an initial BI-RADS assessment that indicated a need for additional imaging evaluation. The median time that facilities had performed digital mammography was 2.3 years.

Performance Measures for Digital Versus Film-Screen Mammography

Overall—For the most part, digital and film-screen mammography were similar in rates of breast cancer per 1000 examinations (overall, invasive cancer, and DCIS), cancer detection, false-negative results, breast biopsies, and sensitivity. Recall rate and specificity differed significantly, but the differences were small (Table 2). Excluding digital examinations from the first year during which a facility performed digital mammography did not change the significance of any of our comparisons of the performance of digital and film-screen mammography (data not shown).

By Age, BI-RADS Breast Density, and Menopausal Status—Rates of cancer detection per 1000 examinations by decade of age were similar for digital and film-screen mammography (Table 3). Sensitivity to detect invasive cancer or DCIS was borderline significantly higher for digital than for film-screen mammography among women aged 40 to 49 years (82.4% vs. 75.6%; $P = 0.071$), significantly higher among women aged 60 to 69 years (89.9% vs. 83.0%; $P = 0.014$), and borderline significantly lower for women aged 50 to 59 years (80.5% vs. 85.1%; $P = 0.097$). Specificity was similar for digital and film-screen mammography for all decades of age, except women aged 40 to 49 years (88.0% vs. 89.7%; $P < 0.001$).

Rates of cancer detection per 1000 examinations across breast density categories were similar for digital and film-screen mammography (Table 3). Sensitivity was similar for digital and film-screen mammography for all density categories except extremely dense breasts, for which sensitivity was borderline significantly higher for digital than for film-screen mammography (83.6% vs. 68.1%; $P = 0.051$). Specificity was significantly lower for digital than for film-screen mammography (range, 0.6% to 1%) for all breast density categories ($P \leq 0.010$). Sensitivity was borderline significantly higher for digital than for film-screen mammography in pre- or perimenopausal women (87.1% vs. 81.7%; $P = 0.057$) and specificity was lower (88.7% vs. 90.2%, $P < 0.001$) (Table 3).

We examined the subgroups in which DMIST (3) reported that the sensitivity of digital mammography differed from that of film-screen mammography. In pre- or perimenopausal women aged 40 to 49 years with extremely dense breasts, among whom there were 66 cases of breast cancer, a nonsignificant trend was seen toward higher sensitivity for digital than for film-screen mammography (86.8% vs. 62.3%; odds ratio, 4.1 [95% CI, 0.7 to 23.3]; $P = 0.111$). For women aged 65 to 79 years with fatty breasts, among whom there were 48 cases of breast cancer, the sensitivity of digital versus film-screening mammography was similar (83.7% vs. 89.1%; odds ratio, 0.6 [CI, 0.1 to 7.3]; $P = 0.69$).

By Estrogen Receptor Status—Sensitivity was significantly higher for digital than for film-screen mammography among women aged 40 to 79 years who had estrogen receptor–negative cancer (78.5% vs. 65.8%; $P = 0.016$), was higher for all decades of age, and was significantly higher for women aged 40 to 49 years (95.2% vs. 54.9%; $P = 0.007$) (Table 4). Sensitivity was similar for women aged 40 to 79 years who had estrogen receptor–positive cancer (83.5% vs. 82.7%; $P = 0.66$) and for all decades of age except 60 to 69 years, for which sensitivity was higher for digital than for film-screen mammography (90.6% vs. 82.3%; $P = 0.017$) (Table 4).

Tumor Characteristics, by Type of Mammography

The distribution of types of breast cancer by tumor characteristics did not vary for digital and film-screen mammography (Table 5). The proportion of early stage (I and IIA) versus advanced (IIB, III, IV) disease also did not vary by type of mammography ($P = 0.168$).

Discussion

Digital mammography has diffused rapidly in countries in which screening mammography is available, despite limited data on the comparative effectiveness relative to film-screen mammography. We compared digital and film-screen mammography in a large number of U.S. community mammography facilities during a period when cancer detection using film-screen mammography has improved (20) and digital mammography technology has advanced. Overall, we found digital and film-screen mammography to be similar in cancer detection rates and the proportion of cancer cases diagnosed at an early stage. Specificity was similar for all decades of age except women 40 to 49 years, for whom specificity was lower for digital than film-screen mammography. In addition, we found that women with extremely dense breasts benefit from the higher sensitivity of digital than film-screen mammography, and we provide new evidence that digital mammography is better at detecting estrogen receptor–negative breast cancer, particularly in women aged 40 to 49 years.

Breast cancer may not be detected on mammography if a radiologist does not identify a visible lesion or a tumor is obscured by normal breast tissue. In addition, an imperceptible tumor may grow quickly and be discovered clinically before the next screening examination. High mammographic breast density is associated with decreased cancer detection on mammography (18, 21), in part because cancerous and normal fibroglandular tissue have similar radiographic attenuation. Breast tumors that are not detected by film-screen mammography tend to be estrogen receptor–negative, high-grade, and large and have high mitotic activity in women with dense tissue patterns (22, 23).

Digital mammography was developed in part to improve the detection of breast cancer in dense breasts by improving the ability to distinguish normal dense breast tissue from isodense invasive cancer. We would therefore expect digital mammography to improve cancer detection in women who have dense breast tissue and those who present with fast-growing invasive cancer in which the tumor is difficult to discern from normal dense tissue. Our results support this supposition: We found that digital mammography had higher sensitivity than film-screen mammography in women with dense breasts and women with estrogen receptor–negative tumors. Thus, women aged 40 to 49 years may benefit most from digital mammography because the proportion of women in this group with extremely dense breasts (about 12% to 15%) (24) and estrogen receptor–negative tumors (25) is higher than that of women aged 50 years or older; however, they may experience additional harms. If 10 000 women aged 40 to 49 years are screened with digital mammography, 2 additional cases of cancer will be identified for every 170 additional false-positive examinations.

DMIST identified subgroups of women in whom digital mammography may perform better than film-screen mammography (for example, those younger than 50 years, those with radiographically dense breasts, and pre- or peri-menopausal women) (2). The main conclusions of DMIST are based on the area under the receiver-operating characteristic curve, constructed from a 7-point mammography assessment scale. These curves estimated the sensitivity and specificity associated with classifying mammography examinations as normal or abnormal at each level of the assessment scale. This comparison of the performance of digital and film-screen mammography, which is based on an interpretive approach not used in clinical practice, magnifies the difference between modalities and tends to have greater statistical significance that stems from comparing sensitivity and specificity across all possible cut points rather than for an overall mammography result of normal or abnormal. When the DMIST investigators compared the overall sensitivity and specificity of digital versus film-screen mammography by using the 7-point scale, they did not find a difference in sensitivity for women of all ages combined, pre- or perimenopausal women, or

those with dense breasts and borderline higher sensitivity and slightly lower specificity for women younger than 50 years (2), similar to the results we report for women aged 40 to 49 years. Although our estimates of the sensitivity of digital compared with film-screen mammography tend to be higher for pre- or perimenopausal women aged 40 to 49 years with extremely dense breasts and lower for women aged 65 to 79 years with almost entirely fat breast density, similar to data reported in DMIST (2), the differences were not statistically significant, possibly because of the small number of cases of breast cancer in these subgroups and the somewhat different age and breast density groups than those in DMIST.

We classified mammography examinations as normal or abnormal on the basis of initial BI-RADS assessments as collected in clinical practice because the study goal was to evaluate the influence of screening modality. The BI-RADS assessment does not provide a reliable basis for estimating receiver-operating characteristic curves in screening mammography because the BI-RADS scale is not ordinal, but rather a dichotomy of normal or abnormal assessment (26). Our results on the performance of digital and film-screen mammography in community practice are clinically relevant because we report overall sensitivity and specificity based on the main decision by radiologists during interpretation of screening mammography of whether to recall a woman for further diagnostic evaluation. Diagnostic evaluations are typically performed on a different day, which creates anxiety during the waiting period for some women. Diagnostic evaluations also contribute to health care costs and additional radiation exposure and discomfort. False-positive recalls based on the initial BI-RADS assessment are the most common “harm” of mammography and are thus an important and clinically relevant outcome to measure.

Our study included a large, diverse population-based sample and large number of outcomes. We took into account secular trends in mammography performance and adjusted for facility-level differences by including a facility-specific random effect. Although more than 1000 cases of breast cancer were identified among women undergoing digital mammography, we did not have the statistical power to examine subgroups of women with multiple risk factors that may influence breast cancer detection. Misclassification of BI-RADS density because of modest interrater agreement between radiologists (27, 28) could result in under- or overestimation of performance measures by density category. We evaluated numerous comparisons; some may be significant by chance alone.

We found small differences in the proportion of women with abnormal results by screening modality and did not find differences in tumor characteristics or rate of detection of invasive cancer or DCIS. Of note, we found that the sensitivity of digital and film-screen mammography to detect breast cancer is similar and relatively high among women aged 50 to 79 years. Women who have access to only digital or only film-screen mammography should be encouraged by our results, because both modalities seem to be equally effective in detecting breast cancer, in particular among women aged 50 to 79 years.

An important factor that we did not address in our study is the quality of mammography interpretation. Whether mammography examinations are interpreted at large-volume facilities (29) or by radiologists who are experienced in mammography interpretation (30) may influence the accuracy of mammography at least as much as whether the screening modality is digital or film-screen.

In summary, overall, cancer detection with digital and film-screen mammography is similar in U.S. women aged 50 to 79 years undergoing screening mammography. Women aged 40 to 49 years who are being offered screening mammography may choose to undergo digital mammography to optimize cancer detection, because digital mammography is better at

detecting tumors in extremely dense breasts and estrogen receptor–negative tumors, both of which are more likely in this age group.

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Appendix

Results of Regression Models Including Random Effects for Facility and Radiologist

In our primary analyses, we adjusted for clustering at the facility level. However, the same radiologist can interpret multiple mammography examinations leading to clustering among radiologists. Because radiologists are largely nested within facilities, adjustment for facility accounts for much of the correlation between observations that arises from radiologist-level clustering. To explore the sensitivity of our results to within-radiologist clustering, we repeated the analyses reported in Tables 2 to 4, but allowed for both facility and radiologist random effects. Results of these analyses are shown in Appendix Tables 1 to 3

Results Decomposing Digital Effect Into Within- and Between-Components Rather Than Using Binary Indicators of Film-Only Versus Digital Mammography

In our primary analysis, we assumed that between-facility differences can be entirely captured by a binary indicator representing whether a facility performed any digital mammography. We performed a sensitivity analysis to model the between-facility effect by adjusting for the proportion of digital mammography performed, rather than using a dichotomous classification of any digital mammography versus none. This analysis follows the approach of Neuhaus and Kalbfleisch (19). We repeated the analyses reported in Tables 2 to 4 by using separate between- and within-facility components for digital mammography effect.

Results of these analyses are shown in Appendix Tables 4 to 6. In these results we compare the performance of digital mammography with that of film-screen mammography (within-facility effect) while holding the proportion of digital mammograms performed by the facility (between-facility effect) constant. Odds ratios and *P* values for digital versus film-screen mammography represent the within-facility effect of digital mammography.

Performance Measures of Screening Mammography for Facilities at the 25th and 75th Percentiles of the Distributions of Facility Performance

The performance estimates reported in Tables 2 to 4 are for a facility with median performance. To demonstrate the extent of between-facility variability in performance, we report performance estimates for facilities at the 25th and 75th percentiles of the distribution of facility performance for each measure (Appendix Tables 7 to 9). We also report the SDs for the facility random effects in our logistic-normal random intercept model.

Context

Digital mammography is widely adopted despite limited evidence comparing its accuracy with that of film-screen methods.

Contribution

In a large sample of women screened in community settings, digital and film-screen mammography yielded similar cancers detection rates and proportions of early-stage cancer diagnosed. Digital screening had higher sensitivity in women with dense breasts and was better at detecting estrogen receptor–negative cancer, but specificity was lower for women aged 40 to 49 years than for other decades.

Caution

Some subgroups were small, and the study did not examine breast cancer mortality rates.

Implication

Screening methods are similarly effective, but sensitivity and specificity tradeoffs occur in some subgroups.

—*The Editors*

Table 1

Characteristics of Women Undergoing Digital Versus Film-Screen Mammography

Characteristic	Digital Mammography, *n* (%)*	Film-Screen Mammography, *n* (%)†
Total examinations	231 034	638 252
Cancer cases within 1 y of mammography	1054 (0.5)	2992 (0.5)
Age		
40–49 y	77 392 (33.5)	221 696 (34.7)
50–59 y	78 514 (34.0)	216 073 (33.9)
60–69 y	47 277 (20.5)	123 870 (19.4)
70–79 y	27 851 (12.1)	76 613 (12.0)
Previous mammography		
First	10 215 (4.4)	22 071 (3.5)
Subsequent	219 550 (95.6)	611 900 (96.5)
Family history of breast cancer	30 470 (15.3)	79 427 (14.2)
Postmenopausal	141 995 (69.3)	391 752 (68.1)
BI-RADS breast density		
Almost entirely fat	14 203 (8.8)	26 475 (7.4)
Scattered fibroglandular densities	63 377 (39.4)	158 994 (44.7)
Heterogeneously dense	73 004 (45.4)	143 353 (40.3)
Extremely dense	10 184 (6.3)	27 240 (7.7)
BI-RADS assessment		
Negative	147 818 (64.0)	320 400 (50.2)
Benign finding	56 383 (24.4)	254 389 (39.9)
Probably benign	933 (0.4)	5392 (0.8)
Need additional imaging evaluation	25 503 (11)	56 820 (8.9)
Suspicious	366 (0.2)	1099 (0.2)
Malignant	31 (0.0)	152 (0.0)
Time since previous mammography		
No previous mammography	10 215 (4.6)	22 071 (3.8)
9–18 mo	149 580 (67.4)	387 038 (65.8)
19–30 mo	37 416 (16.9)	110 162 (18.7)
>30 mo	24 655 (11.1)	68 770 (11.7)
Race		
White, non-Hispanic	157 353 (69.3)	442 960 (73.4)
Black, non-Hispanic	6847 (3.0)	28 213 (4.7)
Asian/Native Hawaiian/Pacific Islander	47 560 (20.9)	93 538 (15.5)
American Indian/Alaskan Native	544 (0.2)	1372 (0.2)
Hispanic	10 615 (4.7)	26 424 (4.4)
Other	4134 (1.8)	11 115 (1.8)

BI-RADS = Breast Imaging Reporting and Data System.

*Missing values include 1.5% for previous mammography, 14.1% for family history, 12.2% for menopausal status, 24.6% for BI-RADS breast density, 8.1% for time since previous mammography, and 5.3% for race or ethnicity.

†Missing values include 0.5% for previous mammography, 14.0% for family history, 11.3% for menopausal status, 30.4% for BI-RADS breast density, 4.0% for time since previous mammography, and 1.7% for race or ethnicity.

Table 2

Performance Measures of Screening Mammography Among Women Undergoing 231 034 Digital Versus 638 252 Film-Screen Examinations [*]

Performance Measure [†]	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
Cases of cancer per 1000 examinations				
Total [‡]	4.5 (4.0–5.0)	4.6 (4.2–5.0)	1.0 (0.9–1.1)	0.62
Invasive cancer	3.3 (3.0–3.8)	3.4 (3.1–3.8)	1.0 (0.9–1.1)	0.58
DCIS	1.1 (0.9–1.3)	1.1 (1.0–1.3)	1.0 (0.8–1.2)	0.81
Cancer detection per 1000 examinations [§]	3.8 (3.4–4.2)	3.8 (3.4–4.1.0)	1.0 (0.9–1.1)	0.98
False-negative results per 1000 examinations [‖]	0.7 (0.6–0.9)	0.8 (0.7–1.0)	0.9 (0.7–1.1)	0.165
Biopsies per 1000 examinations	11.0 (7.3–16.6)	10.6 (7.0–15.9)	1.0 (1.0–1.1)	0.37
Sensitivity, % [¶]	84 (80.8–86.8)	81.9 (79.4–84.2)	1.2 (0.9–1.5)	0.21
Specificity, %	90.4 (88.7–91.9)	91.0 (89.4–92.4)	0.9 (0.9–1.0)	<0.001
Positive likelihood ratio [**]	8.8 (7.3–10.2)	9.1 (7.6–10.6)		
Negative likelihood ratio [**]	0.18 (0.15–0.21)	0.20 (0.17–0.23)		
Recall rate, %	10 (8.5–11.7)	9.3 (7.9–11.0)	1.1 (1.1–1.1)	<0.001
Positive predictive value, %	3.8 (3.2–4.5)	4.0 (3.4–4.6)	1.0 (0.9–1.1)	0.43
Cancer yield per biopsy, %	25.3 (20.4–31.0)	24.7 (20.5–29.4)	1.0 (0.8–1.3)	0.73

DCIS = ductal carcinoma in situ.

[*] Values in parentheses are 95% CIs.

[†] Adjusted for site, age, year, and time between screening examinations. Estimates are based on median facility performance.

[‡] Invasive cancer or DCIS within 12 mo of a positive screening examination (Breast Imaging Reporting and Data System [BI-RADS] assessment of needs additional imaging, suspicious, or malignant) or negative screening examination (BI-RADS assessment of negative or benign finding).

[§] Invasive cancer or DCIS within 12 mo of a positive screening examination.

[‖] Invasive cancer or DCIS within 12 mo of a negative screening examination.

[¶] Sensitivity to detect invasive cancer or DCIS within 12 mo of a screening examination.

[**] Ratio of women with disease to women without disease for a given test result.

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Table 3

Performance Measures of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age, BI-RADS Breast Density, and Menopausal Status [*]

Performance Measure[†]	Examinations, *n*	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
By age					
Cancer detection per 1000 examinations[‡]					
40–49 y	272 371	2.5 (2.1–3.0)	2.3 (2.1–2.6)	1.1 (0.9–1.3)	0.40
50–59 y	276 316	3.6 (3.1–4.2)	3.8 (3.4–4.2)	0.9 (0.8–1.1)	0.52
60–69 y	161 502	5.3 (4.5–6.1)	5.1 (4.6–5.8)	1.0 (0.9–1.2)	0.78
70–79 y	99 718	5.5 (4.6–6.7)	5.8 (5.1–6.6)	1.0 (0.8–1.2)	0.67
Sensitivity, %[§]					
40–49 y	905	82.4 (75.5–87.7)	75.6 (70.8–79.8)	1.5 (1.0–2.4)	0.071
50–59 y	1205	80.5 (74.7–85.3)	85.1 (81.7–88.0)	0.7 (0.5–1.1)	0.097
60–69 y	956	89.9 (85.1–93.3)	83.0 (79.3–86.2)	1.8 (1.1–3.0)	0.014
70–79 y	650	86.0 (79.2–90.8)	84.6 (80.6–88.0)	1.1 (0.7–1.9)	0.70
Specificity, %					
40–49 y	271 466	88.0 (85.9–89.9)	89.7 (87.8–91.3)	0.8 (0.8–0.9)	<0.001
50–59 y	275 111	90.9 (89.2–92.3)	90.9 (89.3–92.4)	1.0 (1.0–1.0)	0.65
60–69 y	160 546	92.1 (90.6–93.3)	91.9 (90.4–93.2)	1.0 (1.0–1.1)	0.39
70–79 y	99 068	92.8 (91.4–94.0)	93.1 (91.8–94.2)	1.0 (0.9–1.0)	0.23
By BI-RADS breast density					
Cancer detection per 1000 examinations[‡]					
Almost entirely fat	38 672	1.8 (1.2–2.7)	1.7 (1.3–2.4)	1.0 (0.7–1.7)	0.86
Scattered fibroglandular densities	211 535	3.3 (2.8–4.0)	3.1 (2.7–3.5)	1.1 (0.9–1.3)	0.41
Heterogeneously dense	206 609	4.8 (4.1–5.6)	4.5 (3.9–5.1)	1.1 (0.9–1.3)	0.43
Extremely dense	35 379	5.1 (3.6–7.2)	3.8 (3.0–4.9)	1.3 (0.9–2.0)	0.168
Sensitivity, %[§]					
Almost entirely fat	92	78.3 (59.4–89.9)	85.7 (72.7–93.1)	0.6 (0.2–2.0)	0.41
Scattered fibroglandular densities	835	86.6 (80.3–91.1)	85.1 (80.8–88.5)	1.1 (0.7–1.9)	0.64

Performance Measure†	Examinations, *n*	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
Heterogeneously dense	1069	82.1 (76.6–86.6)	79.3 (74.9–83.2)	1.2 (0.8–1.8)	0.35
Extremely dense	163	83.6 (69.7–91.9)	68.1 (58.4–76.4)	2.4 (1.0–6.0)	0.051
Sensitivity, %§					
Almost entirely fat	38 580	94.7 (93.6–95.7)	95.4 (94.5–96.3)	0.9 (0.8–0.9)	0.002
Scattered fibroglandular densities	210 700	91.2 (89.5–92.7)	91.6 (89.9–93.0)	1.0 (0.9–1.0)	0.014
Heterogeneously dense	205 540	87.3 (85.0–89.3)	88.0 (85.8–89.9)	0.9 (0.9–1.0)	<0.001
Extremely dense	35 216	88.7 (86.5–90.6)	89.8 (87.9–91.5)	0.9 (0.8–1.0)	0.002
By menopausal status					
Cancer detection per 1000 examinations‡					
Pre- or perimenopausal	229 760	5.2 (4.4–6.2)	4.5 (3.9–5.1)	1.2 (1.0–1.4)	0.105
Postmenopausal §	504 301	3.6 (3.2–4.1)	3.8 (3.5–4.2)	1.0 (0.9–1.1)	0.40
Sensitivity, %§					
Pre- or perimenopausal	874	87.1 (81.6–91.1)	81.7 (77.2–85.4)	1.5 (1.0–2.4)	0.057
Postmenopausal	2588	83.9 (80.0–87.2)	83.1 (80.3–85.6)	1.1 (0.8–1.4)	0.69
Sensitivity, %§					
Pre- or perimenopausal	228 886	88.7 (86.7–90.5)	90.2 (88.5–91.7)	0.9 (0.8–0.9)	<0.001
Postmenopausal	501 713	91.5 (89.9–92.8)	91.5 (90.0–92.8)	1.0 (1.0–1.0)	0.60

BI-RADS = Breast Imaging Reporting and Data System.

*Values in parentheses are 95% CIs.

†Adjusted for site, year, and time between screening examinations. Estimates are based on median facility performance.

‡Invasive cancer or ductal carcinoma in situ within 12 mo of a positive screening examination (BI-RADS assessment of needs additional imaging, suspicious, or malignant).

§Sensitivity to detect invasive cancer or ductal carcinoma in situ within 12 mo of a screening examination.

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Table 4

Sensitivity of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age and Estrogen Receptor Status

Performance Measure	Examinations, *n*	Sensitivity (95% CI), %*		Odds Ratio (95% CI)	*P* Value
		Digital Mammography	Film-Screen Mammography		
Estrogen receptor–positive tumor		701	1676		
Age 40–79 y	2377	83.5 (79.7–86.8)	82.7 (79.6–85.3)	1.1 (0.8–1.4)	0.66
Age 40–49 y	562	77.7 (68.9–84.6)	76.6 (70.6–81.7)	1.1 (0.6–1.8)	0.81
Age 50–59 y	768	80.7 (73.5–86.2)	85.6 (81.4–88.9)	0.7 (0.4–1.1)	0.141
Age 60–69 y	614	90.6 (84.7–94.4)	82.3 (77.6–86.2)	2.1 (1.1–3.9)	0.017
Age 70–79 y	433	86.9 (79.2–92.0)	87.1 (82.4–90.8)	1.0 (0.5–1.9)	0.95
Estrogen receptor–negative tumor		143	350		
Age 40–79 y	493	78.5 (69.2–85.6)	65.8 (58.3–72.6)	2.0 (1.1–3.4)	0.016
Age 40–49 y	134	95.2 (72.4–99.3)	54.9 (42.7–66.6)	17.2 (2.2–138.0)	0.007
Age 50–59 y	169	69.5 (54.3–81.4)	68.2 (56.9–77.7)	1.1 (0.5–2.4)	0.88
Age 60–69 y	127	82.7 (64.2–92.8)	74.9 (63.9–83.4)	1.6 (0.5–4.9)	0.39
Age 70–79 y	63	82.2 (56.9–94.2)	65.2 (48.9–78.6)	2.5 (0.6–10.6)	0.21

*Adjusted for site, year, and time between screening examinations. Estimates are based on median facility performance. Values are the sensitivities to detect invasive cancer within 12 mo of a screening examination.

Table 5

Characteristics of Invasive Breast Cancer Among Women Undergoing Digital Versus Film-Screen Mammography*

Characteristic	Digital Mammography	Film-Screen Mammography	*P* Value†
Cancer stage			
Patients, *n*	1026	2915	
Stage, %			
0	25.6 (22.8–28.6)	24.7 (22.9–26.6)	0.078
I	42.5 (39.2–45.8)	44.6 (42.4–46.8)	
IIA	20.1 (17.5–23.1)	16.8 (15.2–18.5)	
IIB	6.1 (4.6–8.1)	5.6 (4.7–6.8)	
III	5.1 (3.9–6.6)	7.3 (6.1–8.7)	
IV	0.7 (0.3–1.6)	1.1 (0.7–1.6)	
Tumor size			
Patients, *n*	750	2120	
Tumor size, %‡			
<10 mm	38.4 (34.6–42.4)	37.5 (35.0–40.1)	0.82
11–15 mm	23.9 (20.8–27.4)	23.9 (21.8–26.2)	
16–20 mm	13.1 (10.7–15.9)	14.3 (12.6–16.2)	
>20 mm	24.7 (21.4–28.3)	24.3 (22.2–26.7)	
Nodal status			
Patients, *n*	762	2157	
Nodal status, %‡			
Positive	30.7 (27.1–34.5)	28.8 (26.5–31.2)	0.39
Negative	69.3 (65.5–72.9)	71.2 (68.8–73.5)	
Tumor grade			
Patients, *n*	727	1983	
Tumor grade, %‡			
I	22.4 (19.2–25.9)	21.8 (19.8–24.0)	0.38
II	42.8 (39.0–46.8)	46.1 (43.5–48.8)	
III or IV	34.9 (31.1–38.8)	32.2 (29.7–34.8)	
Estrogen receptor status			
Patients, *n*	726	2002	
Status, %‡			
Positive	80.9 (77.4–83.9)	81.7 (79.4–83.7)	0.69
Negative	19.1 (16.1–22.6)	18.3 (16.3–20.6)	

*Values in parentheses are 95% CIs.

†Based on likelihood ratio test for difference between film and digital in any level of the cancer characteristic vs. no difference after adjustment for age, screening interval, examination year, and registry.

[‡]Percentages are based on all women with invasive cancer within 12 mo of screening examination.

Appendix Table 1

Performance Measures of Screening Mammography Among Women Undergoing 223 900 Digital Versus 611 098 Film-Screen Examinations, Allowing for Facility and Radiologist Random Effects*

Performance Measure†	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
Cases of cancer per 1000 examinations				
Total‡	4.4 (4.0–4.9)	4.6 (4.2–5.0)	1.0 (0.9–1.1)	0.62
Invasive cancer	3.3 (3.0–3.8)	3.4 (3.1–3.8)	1.0 (0.9–1.1)	0.60
DCIS	1.1 (0.9–1.3)	1.1 (1–1.3)	1.0 (0.8–1.2)	0.77
Cancer detection per 1000 examinations§	3.7 (3.3–4.2)	3.7 (3.4–4.1)	1.0 (0.9–1.1)	0.93
False-negative results per 1000 examinations‖	0.7 (0.6–0.9)	0.8 (0.7–1)	0.9 (0.7–1.1)	0.169
Biopsies per 1000 examinations	10.6 (7.2–15.5)	10.4 (7.1–15.1)	1.0 (0.9–1.1)	0.64
Sensitivity, %¶	84.3 (81–87.1)	82.2 (79.7–84.5)	1.2 (0.9–1.5)	0.22
Specificity, %	91.7 (90.5–92.8)	91.9 (90.7–93)	1.0 (0.9–1.0)	0.012
Recall rate, %	8.7 (7.6–9.9)	8.5 (7.4–9.7)	1.0 (1.0–1.1)	0.013
Positive predictive value, %	3.8 (3.3–4.5)	4.0 (3.5–4.6)	1.0 (0.9–1.1)	0.40
Cancer yield per biopsy, %	25.4 (20.4–31)	24.6 (20.5–29.3)	1.0 (0.8–1.3)	0.71

DCIS = ductal carcinoma in situ.

*Values in parentheses are 95% CIs.

†Adjusted for site, age, year, and time between screening examinations. Estimates are based on median facility and radiologist performance.

‡Invasive cancer or DCIS within 12 mo of a positive screening examination (Breast Imaging Reporting and Data System [BI-RADS] assessment of needs additional imaging, suspicious, or malignant) or negative screening examination (BI-RADS assessment of negative or benign finding).

§Invasive cancer or DCIS within 12 mo of a positive screening examination.

‖Invasive cancer or DCIS within 12 mo of a negative screening examination.

¶Sensitivity to detect invasive cancer or DCIS within 12 mo of a screening examination.

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Appendix Table 2

Performance Measures of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age, BI-RADS Breast Density, and Menopausal Status, Allowing for Facility and Radiologist Random Effects [*]

Performance Measure[†]	Examinations, *n*	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
By age					
Cancer detection per 1000 examinations[‡]					
40–49 y	262 414	2.5 (2.1–2.9)	2.3 (2–2.6)	1.1 (0.9–1.3)	0.45
50–59 y	264 426	3.5 (3–4.1)	3.7 (3.3–4.2)	0.9 (0.8–1.1)	0.47
60–69 y	154 452	5.2 (4.4–6)	5.1 (4.5–5.7)	1.0 (0.9–1.2)	0.83
70–79 y	95 158	5.5 (4.5–6.6)	5.7 (5–6.5)	1.0 (0.8–1.2)	0.66
Sensitivity, %[§]					
40–49 y	881	82.7 (75.8–88)	76.1 (71.3–80.2)	1.5 (1–2.4)	0.078
50–59 y	1173	80.8 (75–85.6)	85.6 (82.2–88.3)	0.7 (0.5–1)	0.086
60–69 y	925	90.3 (85.5–93.6)	83.3 (79.6–86.4)	1.9 (1.1–3.1)	0.012
Specificity, %					
70–79 y	630	85.9 (79.1–90.8)	85.1 (81.1–88.4)	1.1 (0.6–1.8)	0.80
40–49 y	261 533	89.6 (88.1–91)	90.7 (89.3–91.9)	0.9 (0.9–0.9)	<0.001
50–59 y	263 253	92.1 (90.9–93.2)	91.8 (90.6–92.9)	1.0 (1–1.1)	0.031
60–69 y	153 527	93.2 (92.1–94.1)	92.7 (91.6–93.7)	1.1 (1–1.1)	0.005
70–79 y	94 528	93.8 (92.8–94.7)	93.8 (92.8–94.7)	1.0 (0.9–1.1)	0.96
By BI-RADS breast density					
Cancer detection per 1000 examinations[‡]					
Almost entirely fat	37 877	1.7 (1.2–2.6)	1.7 (1.2–2.3)	1.0 (0.6–1.7)	0.89
Scattered fibroglandular densities	204 315	3.1 (2.6–3.7)	3.0 (2.6–3.4)	1.1 (0.9–1.3)	0.56
Heterogeneously dense	201 870	4.6 (3.9–5.4)	4.4 (3.9–5.0)	1.0 (0.9–1.2)	0.66
Extremely dense	34 355	4.7 (3.3–6.7)	3.7 (2.9–4.8)	1.3 (0.8–1.9)	0.24
Sensitivity, %[§]					
Almost entirely fat	92	78.2 (58.8–90.1)	86.2 (73.1–93.5)	0.6 (0.2–2)	0.38
Scattered fibroglandular densities	800	86.8 (80.3–91.3)	85.8 (81.5–89.3)	1.1 (0.6–1.9)	0.78

Performance Measure[†]	Examinations, *n*	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
Heterogeneously dense	1049	82.8 (77.1–87.3)	80.1 (75.6–84)	1.2 (0.8–1.8)	0.37
Extremely dense	158	82.8 (68–91.6)	68.4 (58.4–76.9)	2.3 (0.9–5.7)	0.079
Specificity, %					
Almost entirely fat	37 785	95.4 (94.6–96.1)	96 (95.2–96.6)	0.9 (0.8–1)	0.007
Scattered fibroglandular densities	203 515	92.4 (91.2–93.5)	92.4 (91.2–93.5)	1.0 (1.0–1.0)	0.89
Heterogeneously dense	200 821	89.1 (87.4–90.6)	89.5 (87.9–90.9)	1.0 (0.9–1.0)	0.042
Extremely dense	34 197	91.0 (89.5–92.3)	91.0 (89.5–92.3)	1.0 (0.9–1.1)	0.95
By menopausal status					
Cancer detection per 1000 examinations[‡]					
Pre- or perimenopausal	221 440	5.1 (4.3–6.1)	4.4 (3.9–5.1)	1.1 (1–1.4)	0.128
Postmenopausal	482 787	3.6 (3.2–4.1)	3.8 (3.4–4.2)	0.9 (0.8–1.1)	0.36
Sensitivity, %[§]					
Pre- or perimenopausal	853	87.2 (81.7–91.2)	81.9 (77.5–85.7)	1.5 (1–2.4)	0.064
Postmenopausal	2509	84.2 (80.3–87.5)	83.5 (80.7–86.0)	1.1 (0.8–1.4)	0.73
Specificity, %					
Pre- or perimenopausal	220 587	90.3 (88.8–91.6)	91.2 (89.9–92.3)	0.9 (0.9–0.9)	<0.001
Postmenopausal	480 278	92.6 (91.5–93.6)	92.4 (91.2–93.4)	1.0 (1.0–1.1)	0.015

BI-RADS = Breast Imaging Reporting and Data System.

[*] Values in parentheses are 95% CIs.

[†] Adjusted for site, year, and time between screening examinations. Estimates are based on median facility and radiologist performance.

[‡] Invasive cancer or ductal carcinoma in situ within 12 mo of a positive screening examination (BI-RADS assessment of needs additional imaging, suspicious, or malignant).

[§] Sensitivity to detect invasive cancer or ductal carcinoma in situ within 12 mo of a screening examination.

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Appendix Table 3

Sensitivity of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age and Estrogen Receptor Status, Allowing for Facility and Radiologist Random Effects

Performance Measure	Examinations, *n*	Sensitivity (95% CI), %*		Odds Ratio (95% CI)	*P* Value
		Digital Mammography	Film-Screen Mammography		
Estrogen receptor–positive tumor		679	1628		
Age 40–79 y	2307	84.1 (80.2–87.4)	83.1 (80–85.8)	1.1 (0.8–1.5)	0.61
Age 40–49 y	544	78.7 (69.9–85.4)	77.2 (71.3–82.3)	1.1 (0.6–1.9)	0.76
Age 50–59 y	750	81.3 (74.1–86.8)	86 (81.9–89.3)	0.7 (0.4–1.1)	0.153
Age 60–69 y	592	91.1 (85.3–94.7)	82.7 (78–86.5)	2.2 (1.2–4)	0.014
Age 70–79 y	421	87.1 (79.5–92.2)	87.5 (82.8–91.1)	1.0 (0.5–1.9)	0.91
Estrogen receptor–negative tumor		142	340		
Age 40–79 y	482	78.5 (69–85.7)	66.2 (58.6–73)	1.9 (1.1–3.3)	0.020
Age 40–49 y	132	95 (70.7–99.3)	55.3 (42.8–67.1)	16.2 (2–134)	0.010
Age 50–59 y	168	69.8 (54.4–81.7)	68.9 (57.5–78.4)	1.0 (0.5–2.3)	0.92
Age 60–69 y	122	82.8 (64–92.9)	75.3 (64.1–83.9)	1.6 (0.5–4.9)	0.41
Age 70–79 y	60	82.7 (57.2–94.4)	65 (48.5–78.6)	2.6 (0.6–11.3)	0.195

*Adjusted for site, year, and time between screening examinations. Estimates are based on median facility and radiologist performance. Values are the sensitivities to detect invasive cancer within 12 mo of a screening examination.

Appendix Table 4

Performance Measures of Screening Mammography Among Women Undergoing 231 034 Digital Versus 638 252 Film-Screen Examinations, Allowing for Between- and Within-Facility Effects [*]

Performance Measure[†]	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
Cases of cancer per 1000 examinations				
Total[‡]	4.5 (4.0–5.0)	4.5 (4.2–4.7)	1.0 (0.9–1.1)	0.94
Invasive cancer	3.4 (3.0–3.9)	3.4 (3.2–3.6)	1.0 (0.9–1.1)	0.97
DCIS	1.1 (0.9–1.3)	1.0 (1–1.1)	1.0 (0.8–1.2)	0.84
Cancer detection per 1000 examinations[§]	3.8 (3.4–4.3)	3.7 (3.5–4)	1.0 (0.9–1.1)	0.58
False-negative results per 1000 examinations[‖]	0.7 (0.5–0.9)	0.7 (0.7–0.8)	0.9 (0.7–1.1)	0.30
Biopsies per 1000 examinations	11.0 (8.4–14.4)	10.6 (8.2–13.6)	1.0 (0.9–1.1)	0.40
Sensitivity, %[¶]	85.6 (81.6–88.8)	83.4 (82.0–84.8)	1.2 (0.9–1.6)	0.23
Specificity, %	91.3 (90.3–92.2)	91.9 (91.0–92.7)	0.9 (0.9–1.0)	<0.001
Recall rate, %	9.1 (8.2–10.0)	8.5 (7.7–9.4)	1.1 (1.1–1.1)	<0.001
Positive predictive value, %	4.1 (3.6–4.8)	4.3 (3.9–4.7)	1.0 (0.9–1.1)	0.59
Cancer yield per biopsy, %	26.5 (21.7–31.8)	25.1 (22.5–27.9)	1.1 (0.9–1.3)	0.52

DCIS = ductal carcinoma in situ.

[*] Values in parentheses are 95% CIs.

[†] Adjusted for site, age, year, and time between screening examinations. Estimates are based on within-facility effects, holding between-facility effects constant and evaluated at median facility performance.

[‡] Invasive cancer or DCIS within 12 mo of a positive screening examination (Breast Imaging Reporting and Data System [BI-RADS] assessment of needs additional imaging, suspicious, or malignant) or negative screening examination (BI-RADS assessment of negative or benign finding).

[§] Invasive cancer or DCIS within 12 mo of a positive screening examination.

[‖] Invasive cancer or DCIS within 12 mo of a negative screening examination.

[¶] Sensitivity to detect invasive cancer or DCIS within 12 mo of a screening examination.

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Appendix Table 5

Performance Measures of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age, BI-RADS Breast Density, and Menopausal Status, Allowing for Between- and Within-Facility Effects [*]

Performance Measure[†]	Examinations, *n*	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
By age					
Cancer detection per 1000 examinations[‡]					
40–49 y	272 371	2.5 (2.0–3.2)	2.3 (2.1–2.5)	1.1 (0.9–1.4)	0.33
50–59 y	276 316	3.8 (3.2–4.7)	3.7 (3.4–3.9)	1.1 (0.9–1.3)	0.58
60–69 y	161 502	5.1 (4.2–6.3)	5.1 (4.8–5.5)	1.0 (0.8–1.2)	1.00
70–79 y	99 718	5.6 (4.3–7.2)	6.0 (5.5–6.5)	0.9 (0.7–1.2)	0.53
Sensitivity, %[§]					
40–49 y	905	86.3 (77.8–91.9)	77.2 (74.0–80.1)	1.9 (1.1–3.3)	0.023
50–59 y	1205	80.6 (72.3–86.9)	83.4 (81.1–85.4)	0.8 (0.5–1.3)	0.41
60–69 y	956	92.0 (86–95.5)	86.7 (84.5–88.6)	1.8 (1.0–3.2)	0.053
70–79 y	650	83.5 (72.1–90.8)	86.7 (84.2–88.8)	0.8 (0.4–1.5)	0.44
Specificity, %					
40–49 y	271 466	89.0 (87.8–90.2)	90.3 (89.3–91.3)	0.9 (0.8–0.9)	<0.001
50–59 y	275 111	91.7 (90.8–92.6)	92.0 (91.1–92.8)	1.0 (0.9–1.0)	0.146
60–69 y	160 546	93.0 (92.1–93.8)	92.9 (92.1–93.6)	1.0 (1.0–1.1)	0.44
70–79 y	99 068	93.6 (92.7–94.4)	93.8 (93.1–94.5)	1.0 (0.9–1.0)	0.31
By BI-RADS breast density					
Cancer detection per 1000 examinations[‡]					
Almost entirely fat	38 672	1.8 (0.8–4.1)	1.7 (1.4–2.1)	1.1 (0.5–2.5)	0.90
Scattered fibroglandular densities	211 535	3.8 (3.0–4.8)	3.3 (3.0–3.5)	1.2 (0.9–1.5)	0.199
Heterogeneously dense	206 609	4.9 (3.9–6.0)	4.4 (4.0–4.7)	1.1 (0.9–1.4)	0.29
Extremely dense	35 379	4.9 (2.7–8.9)	4.2 (3.6–4.8)	1.2 (0.7–2.1)	0.57
Sensitivity, %[§]					
Almost entirely fat	92	90.2 (54.5–98.6)	81.9 (74.6–87.5)	2.1 (0.2–17.5)	0.51
Scattered fibroglandular densities	835	86.2 (75.7–92.7)	86.6 (84.3–88.6)	1.0 (0.5–1.9)	0.93

Performance Measure[†]	Examinations, *n*	Digital Mammography	Film-Screen Mammography	Odds Ratio	*P* Value
Heterogeneously dense	1069	85.3 (78.1–90.5)	81.2 (78.9–83.3)	1.4 (0.8–2.2)	0.21
Extremely dense	163	88.4 (68.1–96.5)	73.0 (67.0–78.3)	2.9 (0.8–9.9)	0.091
Specificity, %					
Almost entirely fat	38 580	94.5 (93.3–95.5)	95.8 (95.3–96.3)	0.7 (0.6–0.9)	0.001
Scattered fibroglandular densities	210 700	91.8 (90.7–92.7)	92.3 (91.4–93.2)	0.9 (0.9–1.0)	0.001
Heterogeneously dense	205 540	89.2 (87.9–90.4)	89.6 (88.3–90.7)	1.0 (0.9–1.0)	0.052
Extremely dense	35 216	89.6 (88.0–91.1)	90.7 (89.5–91.7)	0.9 (0.8–1.0)	0.028
By menopausal status					
Cancer detection per 1000 examinations[‡]					
Pre- or perimenopausal	229 760	5.6 (4.4–7.0)	4.4 (3.9–4.8)	1.3 (1.0–1.6)	0.024
Postmenopausal	504 301	3.7 (3.2–4.2)	3.8 (3.6–4.0)	1.0 (0.8–1.1)	0.51
Sensitivity, %[§]					
Pre- or perimenopausal	874	90.6 (84.4–94.4)	82.7 (79.4–85.6)	2.0 (1.2–3.4)	0.007
Postmenopausal	2588	83.8 (78.5–88)	84.4 (82.6–85.9)	1.0 (0.7–1.3)	0.82
Specificity, %					
Pre- or perimenopausal	228 886	89.6 (88.5–90.7)	90.9 (89.9–91.8)	0.9 (0.8–0.9)	<0.001
Postmenopausal	501 713	92.3 (91.4–93.2)	92.5 (91.6–93.2)	1.0 (1.0–1.0)	0.22

BI-RADS = Breast Imaging Reporting and Data System.

[*] Values in parentheses are 95% CIs.

[†] Adjusted for site, year, and time between screening examinations. Estimates are based on within-facility effects, holding between-facility effects constant and evaluated at median facility performance.

[‡] Invasive cancer or ductal carcinoma in situ within 12 mo of a positive screening examination (BI-RADS assessment of needs additional imaging, suspicious, or malignant).

[§] Sensitivity to detect invasive cancer or ductal carcinoma in situ within 12 mo of a screening examination.

Appendix Table 6

Sensitivity of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age and Estrogen Receptor Status, Allowing for Between- and Within-Facility Effects

Performance Measure	Examinations, *n*	Sensitivity (95% CI), %*		Odds Ratio (95% CI)	*P* Value
		Digital Mammography	Film-Screen Mammography		
Estrogen receptor–positive tumor	2377	701	1676		
Age 40–79 y	562	85.0 (80.1–88.8)	83.5 (81.7–85.1)	1.1 (0.8–1.6)	0.49
Age 40–49 y	768	83.0 (71.5–90.5)	75.6 (71.6–79.3)	1.6 (0.8–3.0)	0.160
Age 50–59 y	614	80.2 (69.8–87.7)	84.0 (81.2–86.5)	0.8 (0.4–1.3)	0.36
Age 60–69 y	433	92.8 (85.6–96.6)	86.3 (83.5–88.7)	2.1 (1.0–4.2)	0.046
Age 70–79 y	2377	82.4 (67.4–91.4)	87.9 (85.1–90.3)	0.6 (0.3–1.5)	0.28
Estrogen receptor–negative tumor		143	350		
Age 40–79 y	493	85.4 (74.6–92)	74.2 (70–78)	2.1 (1.1–4)	0.029
Age 40–49 y	134	98.4 (81.7–99.9)	74.7 (61.8–84.3)	22.2 (2.5–197.1)	0.005
Age 50–59 y	169	74.3 (52.6–88.3)	72 (65.4–77.8)	1.1 (0.4–2.9)	0.81
Age 60–69 y	127	87.2 (57.5–97.2)	80.6 (74–85.8)	1.6 (0.3–7.9)	0.53
Age 70–79 y	63	84.1 (45.3–97.1)	80.8 (70.6–88.1)	1.3 (0.2–8.1)	0.81

*Adjusted for site, year, and time between screening examinations. Estimates are based on within-facility effects, holding between-facility effects constant and evaluated at median facility performance. Values are the sensitivities to detect invasive cancer within 12 mo of a screening examination.

Appendix Table 7

Performance Measures of Screening Mammography Among Women Undergoing 223 900 Digital Versus 611 098 Film-Screen Examinations for Facilities at the 25th and 75th Percentiles of Performance

Performance Measure*	25th-Percentile Facilities		75th-Percentile Facilities		SD†
	Digital Mammography	Film-Screen Mammography	Digital Mammography	Film-Screen Mammography	
Cases of cancer per 1000 examinations					
Total‡	4.2	4.3	4.8	4.9	0.16
Invasive cancer	3.1	3.2	3.6	3.7	0.17
DCIS	1.0	1.0	1.2	1.2	0.24
Cancer detection per 1000 examinations§	3.5	3.5	4.0	4.0	0.17
False-negative results per 1000 examinations‖	0.7	0.8	0.7	0.9	0.21
Biopsies per 1000 examinations	9.3	8.9	18.1	17.3	0.82
Sensitivity, %¶	83.5	81.3	84.6	82.5	0.20
Specificity, %	87.8	88.5	92.0	92.5	0.46
Recall rate, %	8.2	7.7	12.5	11.8	0.44
Positive predictive value, %	3.3	3.5	4.6	4.8	0.36
Cancer yield per biopsy, %	22.4	21.8	29.3	28.6	0.44

DCIS = ductal carcinoma in situ.

*Adjusted for site, age, year, and time between screening examinations.

†SD of the distribution of the logistic-normal facility random intercept.

‡Invasive cancer or DCIS within 12 mo of a positive screening examination (Breast Imaging Reporting and Data System [BI-RADS] assessment of needs additional imaging, suspicious, or malignant) or negative screening examination (BI-RADS assessment of negative or benign finding).

§Invasive cancer or DCIS within 12 mo of a positive screening examination.

[//] Invasive cancer or DCIS within 12 mo of a negative screening examination.

[¶] Sensitivity to detect invasive cancer or DCIS within 12 mo of a screening examination.

Appendix Table 8

Performance Measures of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age, BI-RADS Breast Density, and Menopausal Status, for Facilities at the 25th and 75th Percentile of Performance

Performance Measure*	25th-Percentile Facilities		75th-Percentile Facilities		SD†
	Digital Mammography	Film-Screen Mammography	Digital Mammography	Film-Screen Mammography	
By age					
Cancer detection per 1000 examinations‡					
40–49 y	2.4	2.2	2.7	2.5	0.15
50–59 y	3.3	3.5	3.8	4.0	
60–69 y	4.9	4.8	5.6	5.4	
70–79 y	5.2	5.4	5.9	6.1	
Sensitivity, %§					
40–49 y	81.7	74.6	83.3	76.7	0.23
50–59 y	79.7	84.4	81.5	85.9	
60–69 y	89.4	82.3	90.5	83.9	
70–79 y	85.3	83.9	86.7	85.4	
Specificity, %					
40–49 y	84.8	86.8	90.1	91.4	0.46
50–59 y	88.3	88.4	92.5	92.5	
60–69 y	89.8	89.6	93.4	93.3	
70–79 y	90.7	91.0	94.1	94.3	
By BI-RADS breast density					
Cancer detection per 1000 examinations†					

Performance Measure*	25th-Percentile Facilities		75th-Percentile Facilities		SD†
	Digital Mammography	Film-Screen Mammography	Digital Mammography	Film-Screen Mammography	
Almost entirely fat	1.7	1.6	2.0	1.9	0.19
Scattered fibroglandular densities	3.1	2.9	3.6	3.3	
Heterogeneously dense	4.4	4.2	5.1	4.8	
Extremely dense	4.7	3.6	5.5	4.1	
Sensitivity, %§					
Almost entirely fat	77.4	85.0	79.5	86.6	0.27
Scattered fibroglandular densities	85.9	84.3	87.4	86.0	
Heterogeneously dense	81.3	78.4	83.1	80.5	
Extremely dense	82.8	66.9	84.6	69.6	
Specificity, %					
Almost entirely fat	93.2	94.1	95.9	96.5	0.48
Scattered fibroglandular densities	88.8	89.2	93.1	93.4	
Heterogeneously dense	84.0	84.9	89.9	90.5	
Extremely dense	85.7	87.1	91.0	92.0	
By menopausal status					
Cancer detection per 1000 examinations†					
Pre- or perimenopausal	4.8	4.2	5.5	4.7	0.15
Postmenopausal	3.4	3.6	3.9	4.1	
Sensitivity, %§					
Pre- or perimenopausal	86.5	80.9	87.8	82.6	0.23
Postmenopausal	83.2	82.4	84.7	84.0	

Performance Measure*	25th-Percentile Facilities		75th-Percentile Facilities		SD†
	Digital Mammography	Film-Screen Mammography	Digital Mammography	Film-Screen Mammography	
Specificity, %					
Pre- or perimenopausal	85.6	87.5	90.6	91.9	0.46
Postmenopausal	89.0	89.1	92.9	93.0	

BI-RADS = Breast Imaging Reporting and Data System.

*Adjusted for site, year, and time between screening examinations. Estimates are based on median facility performance.

†SD of the distribution of the logistic-normal facility random intercept.

‡Invasive cancer or ductal carcinoma in situ within 12 mo of a positive screening examination (BI-RADS assessment of needs additional imaging, suspicious, or malignant).

§Sensitivity to detect invasive cancer or ductal carcinoma in situ within 12 mo of a screening examination.

Appendix Table 9

Sensitivity of Screening Mammography Among Women Undergoing Digital Versus Film-Screen Examinations, by Age and Estrogen Receptor Status, for Facilities at the 25th and 75th Percentiles of Performance

Performance Measure	Sensitivity, %*				SD†
	25th-Percentile Facilities		75th-Percentile Facilities		
	Digital Mammography	Film-Screen Mammography	Digital Mammography	Film-Screen Mammography	
Estrogen receptor–positive tumor					
Age 40–79 y	82.8	81.9	84.1	83.3	0.23
Age 40–49 y	76.7	75.6	78.5	77.4	0.26
Age 50–59 y	79.7	84.8	81.3	86.1	
Age 60–69 y	90.1	81.4	91.0	82.9	
Age 70–79 y	86.2	86.5	87.4	87.6	
Estrogen receptor–negative tumor					
Age 40–79 y	77.7	64.8	79.1	66.6	0.28
Age 40–49 y	95.0	54.0	95.4	55.7	0.26
Age 50–59 y	68.7	67.3	70.2	68.9	
Age 60–69 y	82.1	74.2	83.2	75.5	
Age 70–79 y	81.6	64.3	82.7	65.9	

*Adjusted for site, year, and time between screening examinations. Estimates are based on median facility performance. Values are the sensitivities to detect invasive cancer within 12 mo of a screening examination.

†SD of the distribution of the logistic-normal facility random intercept.