Supplemental Screening Tests Following Negative Mammography in Women with Dense Breast Tissue



The California Technology Assessment Forum

An Action Guide for Supplemental Cancer Screening for Women with Dense Breasts: Next Steps for Patients, Clinicians, and Insurers

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Introduction

About this guide

Evidence from clinical effectiveness reviews provides a critical foundation for judgments that patients, clinicians, and health insurers must make about treatment choices and coverage policies. Yet that evidence is often not translated in a way that is helpful to inform healthcare decisions. This document is a companion policy guide designed to help patients, clinicians, and insurers make use of the results of a recent technology assessment entitled "<u>The Comparative Clinical Effectiveness and Value of</u> <u>Supplemental Screening Tests Following Negative Mammography in Women with Dense Breast Tissue</u>" developed by faculty at University of California San Francisco, University of Washington, and the Institute for Clinical and Economic Review. This report formed the basis for the deliberations and votes of the California Technology Assessment Forum (CTAF) – an independent body comprised of California-based physicians, methodologists, and technology assessment experts that provides objective guidance on how information from evidence reviews can best be used to improve the quality and value of healthcare services.¹

CTAF held its meeting on supplemental cancer screening for women with dense breast tissue on September 25, 2013 in San Francisco, California. A full report summarizing the discussion and votes taken is available on the <u>CTAF website</u>. We have developed this Action Guide in order to provide a user-friendly overview of the CTAF findings and an associated list of specific evidence-based action steps that patients, clinicians, and insurers can take to improve patient outcomes and the overall value of supplemental screening. The content provided here is for informational purposes only, and is not designed to replace professional medical advice.

A note on CTAF evidence voting

Each public meeting of CTAF involves deliberation and voting on key questions on the comparative clinical effectiveness and value of the various diagnosis and treatment options discussed. When voting on economic impact, CTAF Panel members are not provided with prescribed thresholds or boundaries for how to interpret value. Rather, CTAF is asked to assume the perspective of a state Medicaid program or provider organization making resource allocation decisions within a fixed budget of care.

¹ For more information on CTAF, visit: <u>www.CTAF.org</u>

Screening Options for Women with Dense Breast Tissue

Following laws enacted in several other states, on April 1, 2013 a new law went into effect in California requiring mammography facilities to inform women with dense breasts about the potential for "masking" and the increased risk of breast cancer associated with dense breast tissue. Masking occurs when breast cancers are hidden in a mammogram by dense breast tissue, which, like cancer, appears white. The law requires that the following language be included in reports sent to women who have dense breast tissue:

"Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to inform your conversations with your doctor. Together, you can decide which screening options are right for you. A report of your results was sent to your physician."¹

The primary motivation for the law is to alert women to the masking effect of dense breast tissue on their mammograms. However, dense breast tissue may also play an important role by identifying women at high enough risk for breast cancer to warrant additional imaging with a different technology. A number of new technologies and new applications of existing technologies have been promoted to enhance screening in women with dense breasts. These include hand-held and automated breast ultrasound, digital breast tomosynthesis (DBT), and magnetic resonance imaging (MRI).

First-line screening for women with dense breasts

The primary method used to screen for breast cancer is mammography. Nine large clinical trials established the efficacy of screening mammography by randomizing over 600,000 women and following them for ten to twenty years.²⁻²⁰ There is general consensus that, for women between the ages of 50 and 69 years, screening mammography reduces breast cancer mortality by approximately 20% to 25% after 15 years of follow-up.²¹ For average-risk women between the ages of 40 to 49 years, there remains significant controversy about whether the benefits of routine mammography outweigh the harms, but most guidelines recommend either routine mammography or a discussion of the benefits and risks of mammography.²²⁻²⁵

It has been known for a long time that the sensitivity of film mammography is lower in women with dense breasts than in women with fatty breasts.²⁶ There clearly is a masking effect due to mammographic density. In the BCSC registry, the sensitivity of film mammography decreased markedly with increasing density.²⁷ This study evaluated the results from 463,372 screening film mammograms performed between 1996 and 1998. Among women in the lowest density categories, the sensitivity of mammography was 88% and 82% for density categories 1 and 2 respectively, but this decreased to 69% for women with heterogeneously dense breasts and to 62% for women with extremely dense breasts.²⁷

Digital mammography

Digital image acquisition improves the signal to noise ratio of x-ray detection over a wider contrast range than traditional film techniques.²⁸⁻³⁰ The Digital Mammography Imaging Screening Trial (DMIST) study is the largest trial directly comparing digital mammography to plain film mammography (n=42,760).⁷⁴ Among women of all ages with either heterogeneously dense or extremely dense breasts, digital mammography was more sensitive than film mammography (70% versus 55%, p= 0.02). Similarly, in women with dense breast tissue there was a trend towards greater specificity with digital mammography (91% versus 90%, p=0.09) and the overall accuracy of digital mammography, as measured by the area under the receiver operator curve, was greater than that of film mammography (0.78 versus 0.68, p=0.003).³¹

The BCSC has recently updated their earlier description of the sensitivity of mammography based on a comparison of 231,034 digital mammograms and 638,252 film mammograms performed between January 1, 2000 and December 31, 2006.³² Similar to the prior study, the sensitivity of film mammography decreased from 86% to 68% across the four breast density categories. However, for digital mammography, the sensitivity of digital mammography remained greater than 80% for the highest density categories and did *not* appear to decrease with increasing density.

CTAF Votes and Policy Roundtable Deliberation on Digital Mammography vs. Film Mammography for Women with Dense Breasts

- The majority of CTAF voted that for women with dense breast tissue, digital mammography offers superior diagnostic accuracy (i.e. fewer false positives and false negatives) than film mammography [9 yes; 0 no]
- CTAF also voted that for women with dense breast tissue, digital mammography substantially reduces the risk of "masking" of breast cancers compared to film mammography [8 yes; 1 no)
- The Policy Roundtable participants agreed that digital mammography is superior to film mammography as a first-line screening test for women with dense breast tissue. Even though the published evidence suggests that digital mammography greatly reduces the risk of "masking" of smaller breast cancers, clinical experts emphasized that certain distributions of dense breast tissue can still mask small cancers. Clinical and policy experts also emphasized that no screening test is perfect, and that a broader goal of patient education should be to help women understand that some rapidly-growing cancers will be missed by any screening strategy, that additional screening turns up far more false positive results than additional cancers, and that the underlying biology of cancers varies so much that it is not possible to know when the detection of additional cancers with supplemental screening is helping to save lives and when it is not.
- The Roundtable experts also agreed that digital mammography itself may ultimately be superseded by technological advances and that the early evidence on DBT as a first-line screening test is promising. At the current time, however, further evaluation of DBT among women with dense breast tissue would be needed to help determine what its role might be as a potential supplemental screening test for women after negative mammography.

Breast density and cancer risk

Because high breast density is both a strong risk factor (relative risk of 1.5 for heterogeneously dense and 2 for extremely dense compared to scattered fibroglandular densities) and it is common (about 40% of women are in the heterogeneously dense category and 10% in the extremely dense category) it explains a greater proportion of the risk for breast cancer in the population than any risk factor other than age. For example, having a first-degree relative with breast cancer almost doubles a woman's risk for breast cancer, but only 10% to 20% of women have a positive family history. Similarly, carrying a BRCA mutation increases a woman's risk by a factor of 10 to 20, but less than 0.5% of women have a deleterious mutation.

One of the common concerns raised about the association between breast density and cancer risk is whether the elevated risk is due solely to the dense tissue masking breast cancers that are present at the time of mammography. If there were only masking, then there would be an increase in cancers detected over the next one to two years in women with dense breasts (those missed on mammography that should have been found) compared to those with fatty breasts, but this excess should not continue beyond two to three years. However, two large studies found no decrease in the strength of the association between breast density and breast cancer incidence through ten years of follow-up.^{33,34} This provides strong evidence that the association of mammographic density with breast cancer represents a true association that is not an artifact arising from the masking of prevalent cancers alone.

Breast density and overall breast cancer risk assessment

Mammography screening may be the ideal time for risk assessment because women and their physicians are thinking about breast cancer risk when mammograms are ordered and because mammographic density is the most powerful predictor of breast cancer after age. The new legislation in California requiring notification of women with dense breasts about the potential for dense breast tissue to mask cancers and increase overall risk makes this an opportune moment for such discussions.

When the overall risk of developing breast cancer is low, the harms associated with screening can outweigh the benefits through early detection and treatment of breast cancer. Conversely, for women at higher risks of breast cancer, earlier and more intensive forms of screening offer the possibility of a more favorable risk-benefit ratio. For example, the American Cancer Society (ACS) guidelines recommend annual MRI screening for women with a lifetime risk for breast cancer above 20% to 25%.³⁵ This risk threshold was chosen based on expert opinion.³⁵ The FDA indication for the use of tamoxifen to prevent breast cancer is specifically for women with a five year risk greater than 1.66% and, similarly, the 2013 American Society for Clinical Oncology guidelines recommend that physicians consider the use of medications to reduce the risk of breast cancer in women with a five year risk greater than 1.66%.³⁶ The 1.66% five-year risk threshold was the primary inclusion criteria for the Breast Cancer Prevention Trial, which demonstrated that tamoxifen reduces the risk of breast cancer by about 50%.³⁷

It is worth noting that using a five or ten year time frame for estimating risk is more useful than lifetime risk when deciding when to initiate screening for breast cancer. No one would recommend that a ten

year old girl with a lifetime risk for breast cancer of 25% be screened with MRI for breast cancer. Her short-term risk is too low to justify the cost and potential harms. Similarly, a woman with a 2% five year risk for breast cancer by the Gail model could have a 10% lifetime risk or a 30% lifetime risk; in either case she would be eligible for a discussion of the risks and benefits of tamoxifen to lower her risk for breast cancer.

Investigators at the National Cancer Institute developed the most commonly used model of a woman's risk for breast cancer, the Gail model or Breast Cancer Risk Assessment Tool. This model uses a woman's reproductive history and the number of first-degree relatives with breast cancer to estimate her risk for invasive breast cancer.^{38,39} A web-based calculator is available for women and their physicians to use: <u>http://www.cancer.gov/bcrisktool/about-tool.aspx</u>. The model estimates a women's risk of developing invasive breast cancer in the next five years as well as her lifetime risk for invasive breast cancer. The Gail model remains the most widely used tool for estimating a woman's future risk for breast cancer Prevention Trial.

The limited ability of the Gail model to discriminate high risk women from low risk women ⁴⁰ has encouraged investigators to develop models that incorporate additional risk factors. Because breast density is both common and a strong risk factor for breast cancer, researchers have added it to new models.⁴¹⁻⁴³ Investigators at the BCSC developed a model that uses BI-RADS density in combination with a woman's age, race/ethnicity, family history, and history of breast biopsies to estimate her 5-year risk for breast cancer.⁴¹ A web-based calculator using the BCSC model is available for women and their physicians (<u>https://tools.bcsc-scc.org/BC5yearRisk/calculator.htm</u>). The BCSC model has better risk discrimination than the Gail model and is more accurate in non-white women.⁴¹ Drs. Chen and Gail updated the Gail model by adding a continuous measure of breast density to their model⁴³, but continuous breast density is not routinely calculated or reported with mammography at this time.

Evidence on supplemental screening options for women with dense breast tissue

A number of new technologies and new applications of existing technologies have been promoted as supplemental screening options for women with dense breasts. These include hand-held and automated breast ultrasound, magnetic resonance imaging (MRI), and digital breast tomosynthesis (DBT). All four of these advanced imaging technologies generate multiple two-dimensional images representing slices of the breast. This allows the radiologist to visualize the breast in three-dimensions. This is particularly relevant in mammographically dense breasts because breast cancers may be obscured by superimposed dense tissue.

Using current digital mammographic techniques in the United States, it can be estimated that for every 1000 women having a screening mammogram, approximately 100 will be recalled for additional tests, 10 will have a breast biopsy, 5 will be diagnosed with breast cancer, and 1 additional cancer will be diagnosed in the subsequent year.^{32,44,45} The false positive mammography results lead to additional time

lost for the women who must schedule time to come in for additional tests and adds cost to the medical system. The women may also experience unnecessary anxiety about a cancer diagnosis.

Even without masking, approximately 1 in 5 cancers can still be missed by digital mammography, raising questions about the potential for benefits of additional screening, especially among women at highest risk for breast cancer. The available literature consistently has shown that all four of the advanced imaging technologies evaluated in the CTAF assessment can detect additional breast cancers in women with negative mammograms. The most convincing data on cancer detection rates come from the ACRIN 6666 trial⁴⁶: in the third round of screening, the combination of mammography and HHUS detected 7 additional cancers (cancer detection rate 11.4 per 1000), and MRI detected an additional 9 cancers (incremental cancer detection rate 18.2 per 1000). However, the addition of MRI increased the number or recalls from 100 to 159 and the number of recommended biopsies from 38 to 81. The positive predictive value of MRI in women with negative mammograms (22%) was much higher than that of HHUS in women with negative mammograms (7%). Thus the yield per biopsy of MRI was higher than HHUS. If the costs and logistics of the two were identical, MRI would be preferred as it has greater cancer detection with fewer harms from false positive biopsies. If the goal is to maximize the cancer detection rate without worrying about false positive results due to a high recall rate, then MRI is clearly the best choice. However, there is little direct evidence about the utility of MRI in the population that is the focus of this assessment: women with dense breasts and a negative mammography assessment. MRI also requires an IV, carries the risk of complications from the injection of the contrast agent, and is the most time-consuming and expensive option.

DBT, on the other hand, decreased the recall rate in the four studies considered in this assessment, particularly in women with high breast density.⁴⁷⁻⁵¹ At the same time, DBT increased the cancer detection rate by about 2 per 1000 examinations compared to digital mammography alone. One of the studies also reported that the biopsy rate decrease from 15.2 to 10.6 per 1000 examinations.⁴⁹ In the subgroup of women with dense breasts and negative mammograms, DBT identified an additional 2.7 cancers per 1000 examinations with a recall rate of 21.3 per 1000 examinations. This is an equivalent cancer detection rate to HHUS with a much lower recall rate. DBT has the advantage of being easy to incorporate into routine mammography screening, requiring little extra time from the woman being screened.⁵¹ However, it uses additional ionizing radiation (about the same amount again as digital mammography).^{51,52} There are also technical aspects that are still under development, such as accurate biopsy techniques for abnormalities identified on DBT, but not visible on the digital mammogram.⁵³

The incremental cancer detection rate of adding HHUS to mammography is likely to fall somewhere in between DBT and MRI, although there is considerable uncertainty in the data for all three technologies. The incremental cancer detection rate is about 3 per 1000 examinations for HHUS vs. mammography alone, while it is about 2 to 3 per 1000 examinations for DBT. However, DBT has a much lower recall rate and biopsy rate while HHUS markedly increases the recall rate and biopsy rate. There are far more studies on HHUS than the other technologies, but the study results vary dramatically, which introduces considerable uncertainty into the estimates of the potential impact of supplementary HHUS for women with dense breast tissue. HHUS approximately doubles the recall rate of mammography alone and

quadruples the biopsy rate. HHUS has the advantage of being readily available at most breast imaging centers and not utilizing ionizing radiation. However HHUS requires substantial training and experience of the technicians and radiologists to guarantee high quality results and it involves a substantial investment in radiologists' time.

Finally, there is much less data on screening ABUS.⁵⁴⁻⁵⁶ The incremental cancer detection rates ranged from 0 to 7.3 per 1000 examinations. One of the studies reported a reduction in the recall rate with ABUS⁵⁶, but the other two had substantial recall rates that were equivalent to those seen with ultrasound.^{54,55} Two of the studies^{54,56} have a low biopsy rate and a high PPV3 suggesting that very few women are inappropriately being referred for biopsy. ABUS also has the advantage of little operator dependency, which addresses one of the major concerns with HHUS.

The major unanswered question is whether the identification of additional cancers through supplemental screening improves outcomes for women. Some advocates of supplemental screening will argue that the majority of the cancers identified through supplemental screening are early stage cancers with an excellent prognosis following treatment. These represent the spectrum of cancers identified with mammography that led to the reduction in mortality seen with the randomized trials of screening mammography. In their view, there can be no question that patient outcomes will be improved with supplemental screening. Others will argue that many of these supplemental screen-detected cancers would have been cured when detected on physical exam or subsequent screening mammograms and that some of these cancers represent overdiagnosis, which leads to net harm for the patient. They will highlight the growing evidence for significant overdiagnosis with mammography alone. These individuals will suggest that much of the incremental cancer detection rate with HHUS (2 to 6 or more per 1000 examinations), which is much higher than the expected interval cancer rate (1 per 1000 examinations), can only represent overdiagnosis. Only large randomized trials can definitively answer this question.

CTAF Votes and Policy Roundtable Deliberation on Supplemental Screening Tests for Women with Dense Breasts

Benefit of Supplemental Screening by Overall Cancer Risk

- For women with dense breast tissue with 5-year risks of breast cancer considered "low" (<1.7%) or "moderate" (1.7%-3%), a majority of CTAF voted that the harms of supplemental screening outweigh the benefits at the population level when compared with no supplemental screening.
- However, for women with dense breast tissue with an overall "high" 5-year risk of breast cancer (>3%), a majority of CTAF voted that supplemental screening provides more benefit than harm at the population level compared with no supplemental screening (*8 yes; 1 no*). A majority of CTAF (*5/9*) voted MRI as the supplemental screening modality they would most highly recommend based on existing evidence.

Comparative Value of Supplemental Screening Tests for Women with Dense Breasts

HHUS is the lowest cost supplemental screening test. When asked to judge the value of performing supplemental screening in women with dense breast tissue using each test (MRI, ABUS, and DBT) compared to HHUS, a majority of CTAF voted that MRI (6/9) and ABUS (5/9) represented high or reasonable value. A majority of CTAF voted that DBT represented low value compared to HHUS (5/9).

Action Steps for Patients

The following information is designed to help women with dense breast tissue understand their screening options for breast cancer and engage with their physicians about these choices. These action steps are based on CTAF's judgment of the most up-to-date evidence on the risks and benefits of different screening options for women with dense breasts.

1. Understand what it means to have dense breast tissue and how breast density affects breast cancer screening.

Breasts are made up of different types of tissue that appear differently on your mammogram. Your breasts are considered dense if you have a lot of fibrous or glandular tissue but not much fatty tissue. Having dense breast tissue is very common – approximately 50% of women have dense breasts. Dense breast tissue makes it more difficult for doctors to spot cancer on mammograms, and may also increase your risk for developing breast cancer, but breast density only has a small impact on your overall risk for developing the disease. You should not be alarmed if you have dense breasts, but you should seek information about your overall risk for breast cancer and discuss with your doctor what screening options make the most sense for you.

2. Understand your overall risk for breast cancer.

Understanding your overall risk for breast cancer can help you make choices about whether you should consider more screening after you get the results of your mammogram. Having dense breast tissue does not mean that you are at "high" risk for developing cancer in your lifetime. Other risk factors such as age, breast cancer in a first-degree family member (mother, daughter, or sister), certain inherited gene mutations, and lifestyle should also be considered. Talk to your doctor about how to judge your overall risk for breast cancer. Having this knowledge will help you and your doctor decide what the potential benefits and risks are of additional breast screening tests for you.

The websites provided on the following page feature patient guides and information to help women with dense breast tissue understand their overall risks for breast cancer:

- a. American Cancer Society: <u>http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-risk-factors</u>
- b. University of California, San Francisco: http://www.ucsfhealth.org/education/breast_cancer_risk_factors/
- c. Cancer Research, UK: <u>http://www.cancerresearchuk.org/cancer-help/type/breast-</u> <u>cancer/about/risks/definite-breast-cancer-risks</u>
- **d.** California Breast Density Information Group: <u>http://www.breastdensity.info/</u> (with permission, November 4, 2013)
- e. Are You Dense? <u>http://www.areyoudense.org/</u>

3. Get your mammogram regularly, based on your doctor's advice.

A third of women who should get regular mammograms do not. For these women, breast cancer may be detected in more advanced stages when it is not as easily treated. Dense breast tissue can make mammograms more difficult to interpret, but it is important that all women with dense breasts continue to receive mammograms at regular intervals, based on their doctor's advice.

4. Seek out digital mammography for your regular mammograms.

The best available evidence suggests that digital mammography is more accurate than film mammography for women with dense breast tissue. Studies found that the risk of missing a small cancer hidden within dense breast tissue is substantially reduced when using the digital test. Most facilities now offer digital mammography so if you have dense breasts and your clinic does not offer digital mammography, you might ask your doctor for a referral to a center that offers this technology. Always check with your health insurance company first, though, to understand your out-of-pocket costs for screening.

5. Talk to your doctor about the potential harms and benefits of having additional screening.

There are additional tests that can be used after mammography. These include magnetic resonance imaging (MRI) and breast ultrasound. Further screening with these tests may help find breast cancers that can't be seen on a mammogram, but all these tests turn up many more findings that are not cancer, leading to added testing and biopsies to investigate something suspicious that ultimately may be a false alarm. Costs are another important issue. Your health insurance policy may not cover additional testing for you, and unnecessary tests increase overall costs in the health system.

Your overall risk for breast cancer is an important piece of the decision about what will be best for you. If your overall risk for breast cancer is low, there is a higher chance that more screening will lead to false alarms rather than finding a cancer. In contrast, for the smaller number of women who are at high risk of breast cancer, the balance of benefits and risks of additional screening may make more sense. But there is no single right answer. Ask your doctor about your overall risk for breast cancer and discuss your options to help you decide if additional screening is the right choice for you.

To help facilitate conversations with your physician about the Action Steps above, we've provided sample questions to ask your doctor about breast cancer screening:

Five Questions for Women with Dense Breast Tissue to Ask Their Doctors about Screening:

- 1. **Q.** How often should I receive screening mammography, and is my test being performed with digital mammography?
 - Α.
- Q. What is my overall risk for breast cancer given my breast density, family history, and other factors?
 A.
- Q. Given my overall risk, what are the potential benefits and the potential risks for me with additional screening?
 A.
- 4. **Q.** If more screening is recommended, which screening test has the best evidence to suggest it would be right for me?
 - Α.
- Q. Are there important differences in my out-of-pocket costs for the different options?
 A.

Action Steps for Clinicians

If you are a clinician assessing a patient with dense breast tissue, the following steps are recommended to help you develop a care management plan that incorporates the best available evidence.

1. The issue of supplemental screening for women with dense breast tissue should be considered within the larger policy context of efforts to improve breast cancer screening among all women.

In California, 30% of the nearly 7 million women eligible for breast cancer screening do not receive screening of any kind. On a population basis, therefore, the clinical value of increasing first-line screening for these women dwarfs the potential benefit of supplemental screening among women with dense breast tissue. Further efforts are therefore needed to engage with the public in order to educate women on the importance of mammography screening and follow-up at regular intervals. Some examples of programs designed to increase the number of eligible women receiving mammography are provided below:

NHS Breast Screening Program: In England, all women aged 50 - 73 are automatically invited for regular breast cancer screening. Invitations are mailed to patient homes and include guidance on how to schedule an appointment with the local screening unit or their PCP. Some women outside this age range are also screened as part of this program, based on their unique circumstances and risks. More information on the screening program is available at: http://www.cancerscreening.nhs.uk/breastscreen/index.html.

HealthPartners: In the U.S. some health centers have created systems where eligible women receiving healthcare for any reason can be scheduled for a same-day mammography screening. At HealthPartners, women referred for a same-day mammogram are sent to radiology following their office visit with a card that reads "Same Day Mammogram", indicating that they have spoken with their physician and are aware of the program. The radiologist technologist then works to fit the women into their schedule – usually within 30 minutes to an hour. More about the HealthPartners program is available here:

http://www.healthpartners.com/public/newsroom/featured-news-stories/mammograms/.

2. Digital mammography should be recommended over film mammography as a first-line screening test for women with dense breast tissue.

The published evidence suggests that digital mammography greatly reduces the risk of "masking" of smaller breast cancers. Certain distributions of dense breast tissue, however, can still mask small cancers. Patients should be informed that no screening test is perfect, and some rapidly-growing cancers will be missed by any screening strategy. It is also important for patients to know that additional screening turns up far more false positive results than additional cancers,

and that the underlying biology of cancers varies so much that it is not possible to know when the detection of additional cancers with supplemental screening is helping to save lives and when it is not.

3. Adopt consistent messaging with patients around notification of breast density.

Patients who are notified of their breast density status are likely to have a range of questions for their providers. It is important that communication with patients is clear and concise, and a) helps women to understand the cancer risk associated with breast density, b) emphasizes that breast density alone has a minimal impact on overall breast cancer risk; c) stresses the importance of continued mammography screening; and d) provides a clear pathway for patients to seek further information and/or a conversation with a clinician to discuss the risks and benefits for the individual of supplemental screening.

Sample FAQs and educational information that practice groups in California have provided to their patients to help them understand their breast density status and future screening options are provided in the <u>Appendix</u>.

4. Consideration of supplemental screening for women with dense breast tissue should be integrated with systems that assess their overall breast cancer risk.

Though dense breast tissue does carry some increased risk for breast cancer, breast density by itself should not be a reason to consider a woman at "high risk" of developing the disease. Therefore systems are needed that integrate the management of questions arising from the mandated breast density notification policy in California with a reliable, efficient method for assessing patient's overall risk for breast cancer.

Achieving this goal will require automated processes for capturing breast cancer risk information and a detailed workflow model for how that information is recorded and communicated across providers and settings. A range of mathematical models are available to calculate breast cancer risk, including the Gail Model and the Breast Cancer Surveillance Consortium (BCSC) model.

Whichever model is used, once breast cancer risk information is gathered it should be made readily available to clinicians and patients during any future encounter in the health system. The individual provider tasked with capturing risk information will vary by practice and setting, and may include genetic counselors, radiologists, mammogram technologists, primary care physicians, or other appropriately trained staff. Ideally, automated systems for gathering family history and other risk information from women would be available at multiple points in the health care process, including not only at the time of mammography but also annual physical exams and urgent visits to ensure that information is gathered from patients who may not be compliant with mammography screening. Best practice examples for automated risk assessment and workflow models based on the experiences of California-based experts are described below:

A centralized approach: Kaiser Permanente + University of California Athena Breast Health Network

In the Kaiser system, all patients receiving dense breast notifications are encouraged to speak with their primary care clinicians, but referral to a specialty genetic counseling clinic is recommended when specific questions arise regarding possible supplemental screening. At the genetic counseling clinic, a woman's overall risk for breast cancer can be determined and individualized care plans developed.

The University of California Athena Breast Health Network relies on multiple platforms to capture patient information, including web-based patient-reported outcome tools that record and calculate a patient's overall risk of breast cancer when she goes through mammography screening. The risk assessment is then sent to a Breast Health Specialist who is trained genetic counselor, who then follows up with high risk patients, refines the risk estimation, and assists with referrals to appropriate services: either genetic counseling, or a high risk clinic to discuss additional screening or chemoprevention options.

A decentralized approach: Palo Alto Medical Foundation/Sutter Health

At Sutter Health, mammogram technologists systematically capture breast cancer risk and breast density information from patients, who then embed this information into a report for ordering physicians to discuss with the patient and determine the merit of supplemental screening.

5. The decision regarding whether to perform supplemental screening should be strongly guided by considerations of an individual woman's overall risk for breast cancer.

The emphasis on overall cancer risk is critical due to the fact that the potential benefits from supplemental screening are directly related to how high the underlying risk of breast cancer is, and when that risk is very low the potential harms of further screening -- false positive results and unnecessary biopsies -- weigh more heavily in the balance.

6. Specialty societies, review groups, and others should seek to use a consistent set of thresholds to define risk categories in order to avoid confusion among clinicians and patients.

Many existing screening guidelines and coverage policies currently use a >20% lifetime risk of breast cancer as a threshold for high-risk status. This threshold is based largely on expert consensus, whereas empirically-derived risk calculators produce estimates of breast cancer risk within either 5 or 10-year horizons. There is general agreement that the 5-yr horizon used in the CTAF report is appropriate for judgments of the potential added clinical value of supplemental

screening since the risk for cancer in the shorter time horizon is most closely related to the chance that additional cancer would be detected by supplemental screening during the near term after a negative mammogram. Further discussion among stakeholders may be warranted to help develop a consistent approach, but all providers in an integrated care system should use the same risk thresholds in conversations with patients and as standards for internal decisions regarding supplemental screening options.

7. Engage patients in shared decision making about their options for supplemental screening.

Shared-decision making creates an opportunity for physicians to counsel women on their best options for supplemental screening given their overall risk for breast cancer. Information about the potential harms and benefits of supplemental screening, and steps patients can take for prevention should be made part of these conversations. Honest discussions that help patients better understand what to reasonably expect from supplemental screening and prepare for the risk of false positives are vitally important.

Resources are available to help facilitate conversations with your patients around the various options for supplemental screening, one good example of which is the following:

Healthwise Patient Decision Aid:

Breast Cancer Screening and Dense Breasts: What Are My Options? This decision aid provides patients with information on breast density, compares various choices for supplemental screening, and provides tools to help your patients weigh their different priorities and preferences when making a decision about screening: http://decisionaid.ohri.ca/AZsumm.php?ID=1648

California Breast Density Information Group:

Density Scenarios for Providers

Another important resource for providers is from the California Breast Density Group, which provides succinct information around the evidence for different supplemental screening options, and guidance for how to discuss these options with patients. The website includes a brochure for clinicians that simulates a wide range of patient scenarios to help inform provider communication and decision-making around supplemental screening with women with dense breast tissue: http://www.breastdensity.info/ (With permission, November 4, 2013).

8. For women with dense breast tissue at "high risk" of breast cancer (>3%) over the next 5 years, evidence supports the likelihood of a positive net health benefit from supplemental screening, with MRI offering the best diagnostic performance at a reasonable value.

The CTAF report used a 3% threshold for the 5-year risk of breast cancer to define women as "high risk." This risk threshold mirrors that used by the United States Preventive Services Task Force (USPSTF) in its most recent recommendations regarding preventive therapy for breast cancer. This threshold also serves as a useful dividing line between risk categories when the most important common risk factors for breast cancer -- age, family history, and breast density -- are entered into the BCSC risk calculator.

While acknowledging that breast MRI has not been studied for use of supplemental screening, the CTAF voted that MRI had the strongest evidence to support its use, noting that all women should understand the potential benefits and harms of supplemental screening, and that many women might choose not to seek further screening. HHUS, although a lower-cost alternative, produces more false-positive results than MRI and was also viewed generally as impractical for widespread supplemental screening because of its dependence on physician operators and the time requirements for an adequate exam. Neither ABUS nor DBT were viewed by CTAF as being important supplemental screening options for most patients at this time given the limited existing data from studies of women with dense breast tissue.

For women at low risk (<1.7% 5-year risk) of breast cancer, the CTAF Panel judged that the evidence is inadequate to demonstrate that the benefit of supplementary screening outweighs the harms. Current insurer coverage policies do not cover supplemental screening tests for these women (MRI is covered by most insurers if the lifetime risk is >20%), though importance of improving patient and clinician education regarding the evidence on potential benefits and harms of supplemental screening in this group.

9. Support the development of further research to develop better long-term data on the comparative effectiveness and value of supplemental screening options.

Action Steps for Payers

The following steps are designed to help payers develop policies that incentivize the use of evidencebased screening for women with dense breast tissue:

1. Collaborate with providers and other decision-makers to adopt consistent risk thresholds for assessing patients and determining appropriateness for supplemental screening.

Many existing screening guidelines and coverage policies currently use a >20% lifetime risk of breast cancer as a threshold for high risk status. This threshold is based largely on expert consensus, whereas empirically-derived risk calculators produce estimates of breast cancer risk within either 5 or 10-year horizons. There is general agreement that the 5-yr horizon used in the CTAF report is more appropriate than a lifetime risk for judgments of the potential added clinical value of supplemental screening since the risk for cancer in the shorter time horizon is most closely related to the chance that additional cancer would be detected by supplemental screening a 5-year risk horizon but recognizes that further discussion among stakeholders is warranted to help develop a consistent approach across provider groups and insurers.

2. Develop incentives to encourage the use of automated processes for risk assessment.

Determinations of breast density should be embedded in models for assessing overall breast cancer risk, and processes are needed to systematically capture this information from patients and communicate it back to patients and their clinicians at the point of examination. Payers have a role to play in incentivizing automated risk assessment processes, either through pay for performance initiatives or other quality improvement programs.

3. Incorporate Coverage with Evidence Development into new policies for supplemental screening.

Insurer coverage policies that would provide new coverage to supplemental screening strategies should encourage further evidence development whenever possible. In particular, any consideration of coverage for the newest technologies, ABUS and DBT, should recognize the need for further evidence development.

4. Ensure that medical policies for supplemental screening technologies are written clearly and transparently so that providers easily understand what modalities are covered, and how density and overall breast cancer risk are factored into coverage.

A sample coverage policy that clearly states how breast density and patient risk factor into coverage is provided below. This coverage policy is provided only as an example and may be easily modified to suit individual payers' unique policies:

Anthem Blue Cross of California:

http://www.anthem.com/medicalpolicies/policies/mp_pw_a053263.htm

Annual screening MRI of the breast using scanners equipped with breast coils with the ability to provide needle localization for biopsy is considered **medically necessary** in the following clinical situations:

- Individuals with a BRCA1 or BRCA2 mutation; or
- Individuals who are a first-degree relative of a BRCA1 or BRCA2 mutation carrier, but have not been tested for BRCA1 or BRCA2 mutation; **or**
- Individuals with a lifetime risk for breast cancer that is 20–25% or greater, as defined by BRCAPRO or other models (e.g., BOADICEA, Gail, Claus, Tyrer-Cuzick) that are largely dependent on family history; or
- Individuals who have had radiation therapy to the chest between the ages of 10 and 30 years old; **or**
- Individuals who have Li-Fraumeni syndrome (mutations of the p53 gene), Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome (mutations of PTEN gene), or have a first-degree relative with a history of one of these syndromes; **or**
- Individuals with both a personal history of breast cancer and dense breasts by mammography; or
- Individuals considered at high familial risk with any of the following family history:
 - o Two or more first degree relatives with breast cancer; **or**
 - One first degree relative and two or more second degree or third degree relatives with breast cancer; **or**
 - One first degree relative with breast cancer before the age of 45 years and one other relative with breast cancer; **or**
 - One first degree relative with breast cancer and one or more relatives with ovarian cancer; **or**
 - Two second degree or third degree relatives with breast cancer and one or more with ovarian cancer; **or**
 - One second degree or third degree relative with breast cancer and two or more with ovarian cancer; **or**
 - \circ $\;$ Three or more second degree or third degree relatives with breast cancer; ${\it or}$
 - o One first degree relative with bilateral breast cancer; or
 - Breast cancer in a male relative.

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APPENDIX

Appendix A: Kaiser Permanente letter to patients with normal mammogram result

(Provided with permission, October 18, 2013)

DENSE BREAST – CATEGORY 1/2

Dear <Name>

I am writing with good news about your recent mammogram from *(DATE)*. I am pleased to send you written confirmation that your test shows no signs of breast cancer. Although your examination is normal, your mammogram shows that your breast tissue is dense. This is a common finding and not unusual. Recently the State of California passed a law requiring that women whose mammograms show dense breast tissue be informed of that in writing. Included below is the language required by the California State Law for your reference. Additional imaging is not routinely recommended. If you have questions about breast density, we can discuss this further at your next visit.

Breast cancer is the most common form of cancer among women, and at Kaiser Permanente, we are rated among the very best in the nation in breast cancer screening and early detection. I recommend regular mammography screening based on age and personal risk factors. By visiting my home page at *(DOCTOR'S URL – kp.org/mydoctor/mdname)*, you will be able to review when you are due for your next mammogram. You can also learn more about dense breast tissue by entering "breast density" in the search section. In addition, through my home page you can email me with questions about your health or health care, schedule a routine appointment, order prescription refills and view most laboratory results.

At Kaiser Permanente, we have a wide range of resources designed specifically for women. We recently added a free Kaiser Permanente Preventive Care App, which is now available on the App Store, and will be available on the Android Market beginning in June. I encourage you to download this app and continue to learn about ways to improve and maintain your health.

Thank you for taking the time to get your recent mammogram.

Sincerely,

Ordering Clinician NAME

The following notice is in accordance with California State law.

Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to inform your conversations with your doctor. Together, you can decide which screening options are right for you. A report of your results was sent to your physician.

Appendix B: Kaiser Permanente FAQ for patients

(Provided with permission, October 28, 2013)

ASK THE DOCTOR: BREAST DENSITY ON YOUR MAMMOGRAM

Dr. Susan Kutner, MD, Chair, Breast Care Task Force Kaiser Permanente Northern California

What does it mean to have dense breasts?

Breasts are a mix of different types of tissue that show differently on a mammogram. Breast density looks "white," and relates to how much fibrous and glandular tissue your breast has. The "black" area is mostly fatty tissue. Dense breasts have more fibrous or glandular tissue and less fat.

Why am I learning about this now?

California law now requires that all women who have dense breasts be notified. Breast density is not a new discovery. It has always been one of the things that we look at when reading a mammogram.

Who has dense breasts?

Many women have dense breasts. Breast density is normal. It will change over a woman's lifetime as hormone levels change. Most women in their 40s have dense breasts. By the age of 60, only one-third of women have dense breasts. Estrogen exposure, such as hormone replacement therapy, will increase your breast density. Breast density also runs in families. If your mother had dense breasts, you may have them too.

What does this mean for me?

Breast density makes it harder to interpret a mammogram. So if you have dense breasts, please talk to us about your screening options. Mammography is still the only screening test that has been proven to save lives by finding breast cancer early.

How often should I have a mammogram?

We recommend that most women age 40 to 75 get mammograms every 1 to 2 years.

What about other risk factors for breast cancer?

- Breast cancer gene
- Two or more first degree relatives (mother, sister, daughter) with breast cancer before age 50
- Male breast cancer in the family
- Chest radiation as cancer treatment before age 30

Do I need more tests?

If you need more tests, we will contact you directly to set this up at your earliest convenience.

This information is not intended to diagnose health problems or to take the place of medical advice or care you receive from your physician or other medical professional. If you have persistent health problems, or if you have additional questions, please consult with your doctor. If you have questions or need more information about your medication, please speak to your pharmacist.

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For more information on Breast Health, including screening guidelines go to kpdoc.org/ breastdensity

Appendix C: Hill Medical Corporation FAQ for patients <u>http://www.hillmedical.com/breast-density-law.php</u>

BREAST DENSITY LAW TAKES EFFECT

A new California law has been passed that is designed to improve breast cancer detection and prevention by educating patients about dense breast tissue and how it could conceal possible abnormalities during mammographic procedures.

Starting April 1, 2013, The Huntington-Hill Breast Center, Inc. and The Hill Imaging Center, Inc. are mandated by the State of California to notify patients via written form if on their screening mammography their breast density tissue was categorized either heterogeneously dense or extremely dense breasts. These categories are based on the Breast Imaging Reporting and Data System established by the American College of Radiology.

Patients that are classified with either of these two categories of dense breasts can expect to receive the following written notice:

"Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to inform your conversations with your doctor. Together, you can decide which screening options are right for you. A report of your results was sent to your physician."

Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. However, it is important for The Huntington-Hill Breast Center, Inc. and The Hill Imaging Center, Inc. patients to understand that dense tissue is not the only factor when labeling a woman at high risk of breast cancer.

In addition to the written report, the new law requires our physicians to inform women who have dense breast tissue that additional screening options are available, including breast ultrasound and breast MRI, both of which we offer at our facilities.

What is breast density?

Breasts are made up of a mixture of fibrous and glandular tissue and fatty tissue. Your breasts are considered dense if you have a lot of fibrous or glandular tissue but not much fat. Density may decrease with age, but there is little, if any, change in most women.

How do I know if I have dense breasts?

Breast density is determined by the radiologist who reads your mammogram. There are four categories of mammographic density. The radiologist assigns each mammogram to one of the categories. Your doctor should be able to tell you whether you have dense breasts based on where you fall on the density scale.

Why is breast density important?

Having dense breast tissue may increase your risk of getting breast cancer. Dense breasts also make it more difficult for doctors to spot cancer on mammograms. Dense tissue appears white on a mammogram. Lumps, both benign and cancerous, may also appear white. So, mammograms can be less accurate in women with dense breasts.

If I have dense breasts, do I still need a mammogram?

Yes. A mammogram is the only medical imaging screening test proven to reduce breast cancer deaths. Many cancers are seen on mammograms even if you have dense breast tissue.

Are there any tests that are better than a mammogram for dense breasts?

In breasts that are dense, cancer can be hard to see on a mammogram. Studies have shown that ultrasound and magnetic resonance imaging (MRI) can help find breast cancers that can't be seen on a mammogram. However, both MRI and ultrasound, show more findings that are not cancer, which can result in added testing and unnecessary biopsies. Also, the cost of ultrasound and MRI may not be covered by insurance.

What should I do if I have dense breasts? What if I don't?

If you have dense breasts, please talk to your doctor. Together, you can decide which, if any, additional screening exams are right for you. However, it is important for The Huntington-Hill Breast Center, Inc. and The Hill Imaging Center, Inc. patients to understand that dense tissue is not the only factor when labeling a woman at high risk of breast cancer.

If your breasts are not dense, other factors may still place you at increased risk for breast cancer — including a family history of the disease, previous chest radiation treatment for cancer and previous breast biopsies that show you are high risk. Talk to your doctor and discuss your history.