The Justification for Withholding Material Medical Information From Patients:

IHQE Response to American College of Radiology Testimony to the National Mammogram Quality Assurance Advisory Board FDA Hearing
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Julie Marron
President
jmarron@inhqe.com

Tom Nerney
Executive Director
tnerney@inhqe.com
Introduction

During the 2011 FDA hearing of the National Mammography Quality Assurance Advisory Board, patient advocates had requested that the agenda include the reporting of material medical information (the impact of breast density on mammogram effectiveness and possible screening alternatives) in the patient notification report that is provided to each woman who obtains a screening mammogram. This material information is currently withheld from the patient report, while it is provided to the woman's referring physician.

This document has been developed as a draft response to the American College of Radiology's (ACR) position on withholding important medical information from the patient notification letter. Our position at the Institute for Health Quality and Ethics is that:

1. A federal statute currently requires that patients be furnished with their mammogram results directly by the imaging facility/radiologist per the Patient Notification Amendment of the Mammogram Quality Standards Reauthorization Act of 1998.
2. All material information should be provided to women in this report in terms “easily understood by a layperson” as mandated by this statute.
3. The ACR has determined that breast density is material because they recommend in the BI-RADS™ reporting system that density information be communicated to the primary care physician. There is a discrepancy in this practice as it assumes that density information is material enough to communicate to the physician, but not material enough to communicate to the patient.
4. The FDA (in its role as the government body responsible for implementing and enforcing the statute) and the ACR (as part of its responsibilities in a) accrediting mammogram facilities, b) as the developer of practice guidelines for radiologists, and c) in its role on the Advisory Board at
the FDA) have not complied with the patient notification amendment, as material information is systematically withheld from the nearly 40 million women who obtain mammograms in the US.

5. The ACR, which develops the recommended letters that provided to patients, and which accredits facilities, has the ability to immediately rectify this oversight and comply with the statute. The FDA has the ability to immediately require the ACR to rectify this oversight.

6. The FDA and the ACR should immediately comply with the existing federal statute and ensure that all material information is included in the patient notification report.

7. Failure to comply with this statute has – and is currently – denying millions of women their right to make informed medical decisions. It also results in the deaths of thousands of women each year.

There are thousands of medical professionals, researchers, and awareness advocates who have done tremendous work towards advancing the science of breast cancer, from detection to cure. We respect the work that has been done in this field and the many individuals who have dedicated their lives to this commendable pursuit.

However, there is a very real danger here for the ACR and other organizations (equipment manufacturers and prominent breast cancer awareness organizations) which have benefitted financially from years of ubiquitous mammogram screening programs. Some of the awareness campaigns and recommendations to women overstate the effectiveness of mammography overall, and completely neglect to inform women of the limited benefits of mammography in dense breast tissue.

Withholding this information from millions of women, many of whom could prevent their premature deaths and years of painful treatment for late stage cancer, calls the motivation of these organizations into question.

We do not advocate premature reliance on untested theories and medical protocols which might put more patients at risk. Our request for action on the part of the FDA and the ACR relies on existing federal law, solid peer-reviewed research, and verification in clinical settings. The continued resistance of the ACR and other organizations to providing this material medical information to women has begun to seriously undermine the faith that women have in our medical establishment.
Background

The Mammogram Quality Standards Act (MQSA) was initially enacted by Congress in 1992 to ensure that women had access to consistent and high quality mammograms for the early detection of breast cancer, one of the leading killers of women in the United States. One of the goals of the MQSA was to ensure compliance with minimum standards for mammogram facilities nationwide. To that end, the FDA was entrusted with implementation and enforcement of the program, with guidance from the National Mammogram Quality Assurance Advisory Board (NMQAAB). The American College of Radiology (ACR), which develops the practice guidelines for radiologists, was awarded nearly monopoly control over accreditation of mammogram facilities nationwide. The ACR is also well-represented on the NMAAQB at the FDA as an advisor to that government body, in addition to its role in setting standards and clinical practice guidelines for radiologists, and its role in accrediting facilities nationwide.

In 1998, the patient notification amendment was enacted as part of the Mammogram Quality Standards Reauthorization Act to address a breakdown of communications among the facility, the referring physician, and the patient, who often did not receive results of her screening mammogram. This statute requires the facility to provide notification of the mammogram results directly to patients in terms “easily understood by a layperson,” in addition to providing results to the referring physician. As a result of this statute, the onus of communicating results to patients was clearly placed on the radiologist and imaging facility. Since that time, the ACR has developed sample notification letters to patients and made them available to radiologists and mammogram facilities, ensured that these letters are provided to patients according to the statute as part of its accreditation activities, and has also advised the FDA in its role on the NMQAAB.

Sample notification letters that are provided to each patient for whom there is no evidence of cancer includes the following language: “We are happy to report that the results of your mammogram are normal.” This “normal” result is often in bold, and the letter often includes a very general disclaimer that a mammogram does not detect all cancers. What is presently at issue is the relative ineffectiveness of the mammogram for a large number of women, and material medical information which is systematically withheld from these women in the mammogram reports. For more than 40% of women – those with dense breast tissue – the effectiveness of mammograms is seriously compromised. There are readily available screening modalities which could be used to significantly increase the detection of cancer
in these women. This information has been well documented for years, but has not been provided to women patients, and is often not understood by the patient’s referring physician.

Patient advocates have attempted to ensure that this information is provided in the patient notification report, but they have met with resistance from the ACR, the organization which has been tasked with oversight of the majority of the MQSA provisions. Through its lobbying activities, the ACR has consistently attempted to derail legislation at the state level which would require full notification in the patient report. The ACR and its sister organization, the Society for Breast Imaging (SBI), have also consistently denied advocate requests to include this information in the patient notification report at the national level.

The NMQAAB held its annual hearing at the FDA on November 4, 2011, during which this issue was discussed. The attached letter from the ACR outlines that organization’s justification for refusing to provide this information in the patient results. IHQE responses are included within the document in blue font.

ACR Testimony and IHQE Responses

A Statement to the NMQAAC by the American College of Radiology on Reporting Breast Density in Mammography Reports and Patient Lay Summaries

The American College of Radiology, representing 34,000 radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates this opportunity to comment on “reporting breast density in mammography reports and patient lay summaries.” For decades, the American College of Radiology (ACR) has been a vigorous advocate of quality breast imaging. Before there was a federal mandate for breast imaging accreditation, the College established a voluntary mammography accreditation program promoting standards for quality assurance and quality control. The ACR supported the Mammography Quality Standards Act (MQSA) legislation when it was initially enacted, and was pleased that the rules and FDA guidance for MQSA incorporated much of the ACR’s work. ACR has supported subsequent reauthorizations of MQSA, and the requirement for patient notification through lay summary letters. In addition, the ACR has developed voluntary accreditation programs for other breast imaging modalities that are not covered by the MQSA. The ACR supports the breast cancer screening guidelines promulgated by the American Cancer Society, and has
invested considerable effort to encourage women and their health care providers to utilize screening to save lives.

The ACR recognizes that breast density has an impact on mammographic screening. The ACR’s BI-RADS lexicon describes four categories of breast parenchymal density and instructs radiologists to include this density information in the medical report. It is well known that greater breast density results in lower sensitivity for mammography. By including this information in the medical report, the referring health care provider is given a general idea of the likelihood that cancer will be detected or missed based on the parenchymal pattern. The ACR supports the FDA mandate that information on breast parenchymal density be included in the mammography report. However, it is less clear how the typical patient would interpret or understand the same information if included in a lay summary.

**IHQE Response:**

The statement "It is well known that greater breast density results in lower sensitivity for mammography" may be true among radiologists, but this knowledge has not been disseminated among the nearly 40 million women who obtain screening mammograms. This information is certainly not well known among the more than 15 million women with dense breast tissue, for whom mammograms are significantly less effective. It is also not well communicated to the many referring physicians who recommend that their patients receive screening mammograms. A Harris Interactive survey conducted in 2010 revealed that only about 5% of women know their breast density, and only 1 in 10 referring physicians discussed density or its implications on mammogram effectiveness with patients.

There is no "FDA mandate that information on breast density be included in the mammography report" that is provided to referring physicians. The ACR includes this information in the report to the physician because it is material information which is highly relevant to the interpretation of the report. Unfortunately, most referring physicians are not well versed in the ACR BI-RADS terminology, and, as noted in the Harris survey, few discuss the issue of density, its impact on mammogram effectiveness, or alternatives, with patients. The ACR claim that “By including this information in the medical report, the referring health care provider is given a general idea of the likelihood that cancer will be detected or missed based on the parenchymal pattern” is verifiably false. While a small number of referring physicians may be aware of this linkage and the implications, the vast majority are not.

Providing this information to a referring physician while failing to disclose this information to the patient violates both the letter and the spirit of the patient notification statute. It also prevents the dialogue which should occur between a women and her physician regarding her personal preferences for
additional screening, as most women are not aware that additional screening may be warranted or available.

The ACR also fails to mention in its Statement that it has, in fact, promulgated two different standards for reporting mammography. One is the BI-RADS report that they refer to in their Statement, but there is a parallel reporting guideline, contained in the ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography (2008 Res.24-eff January 1, 2009). This guideline is similar in every respect to the BI-RADS guideline, except that it omits all mention of breast tissue density in the performance of the screening mammogram, including in the report to the referring physician.

The ACR has vigorously lobbied against inclusion of the density information on patient reports when state legislation has been introduced across the country. The ACR has also repeatedly declined to provide density information to patients as evidenced in letters from the ACR and Society of Breast Imaging (SBI) as recently as December 2010.

...we urge that FDA consider the benefits, possible harms and unintended consequences of reporting mammographic breast density to women. In particular, we would urge consideration of the following:

The assessment of breast density is not reliably reproducible. When the same mammogram is interpreted by different radiologists or by the same radiologist on different occasions, differing density is often reported. If these variations are reported to each woman screened on each occasion, it might result in confusion or an impression of the lack of reliability of mammography.

“ACR, of course, recognizes that breast density has an impact on mammographic screening. It’s very well known that greater breast density results in lower sensitivity for mammography. We all know that. It’s obvious.

For that reason the ACR has included in its BI-RADS lexicon descriptions of breast density, and there are four levels of breast density, and it asks physicians to include those in their reports.”

- Dr. Barbara Monsees, speaking on behalf of the ACR and SBI at the NMQAAB
IHQE Response:

1. **Mammography is not reliable for women with dense breast tissue, who account for approximately 40% of all women.** The primary purpose of providing this information to these women is to *inform them of the lack of reliability*.

2. The comment that variations in density reported to women might result in “confusion or an impression of the lack of reliability of mammography” is condescending towards women and disingenuous. Is the ACR’s position that individual women do not have the right to know about the limitations of mammography with respect to their own breasts, and that women are incapable of grasping the concept of breast density? The idea that density occurs along a continuum and that higher density means a mammogram is less effective is simply not that difficult to comprehend.

Most of the confusion upon disclosure of this information will likely stem from concerns that critical information has been withheld for so long by the medical community at the expense of thousands of lives.

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**Breast Tissue Density**

For clinical purposes, the American College of Radiology measures breast tissue density on a mammogram along a four point BI-RADS™ (4th ed.) scale for breast density:

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<tr>
<td>Predominantly Fatty Tissue</td>
<td>Predominantly Fatty Tissue</td>
<td>Scattered Fibroglandular Densities</td>
<td>Heterogeneously Dense</td>
<td>Extremely Dense</td>
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<tr>
<td>Having no areas of tissue that obscure cancer.</td>
<td>Having at least one area of tissue that can obscure cancer.</td>
<td>Tissue may obscure cancer in 50-75% of the breast.</td>
<td>Tissue may obscure cancer in &gt;75% of the breast.</td>
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High density is typically characterized as BI-RADS categories 3 and 4. While the mammogram is not 100% effective for any women, the greater the density, the greater the chances of missing a cancer.

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**What is “Breast Tissue Density?”**

Breast tissue density refers to the amount of fatty tissue in the breast vs. the amount of “fibroglandular” tissue. The mammogram, which is simply an x-ray of the breast, is reasonably suited to detect most (but not all) cancers in fatty breasts, because the fatty tissue appears dark, and cancers appear white. Fibroglandular tissue, however, also appears white on an x-ray, which means that it can more easily hide a cancer. The more dense tissue, the less effective a mammogram is at distinguishing a cancer from the surrounding tissue. Density occurs along a continuum, and for the purposes of communicating density, the ACR developed its BI-RADS density scale, which categorizes density along the continuum into one of four
quadrants. Tissue with the least density, "predominantly fatty tissue" is categorized as a "1," and the breast tissue with the highest density is categorized as a "4."

Studies of density on both mammographic effectiveness and breast cancer risk generally categorize density as "high" using BI-RADS density 3 and 4 and "not high" for categories 1 and 2. High density has been found to affect overall sensitivity of the mammogram by 25% to 40%, with even further degradation of sensitivity at higher density levels, although a small cancer can be obscured by even a small amount of fibroglandular tissue.

Breast tissue density is a significant issue. One study reported 55% of women age 40 to 50, and 33% of women over the age of 50 have high breast tissue density. The overall percentage of women with high breast tissue density in a general screening population was found to be in excess of 40%. Given the sensitivity and risk implications of high breast tissue density, the high percentage of women for whom mammograms are not effective makes this an important public health issue.

Like many of the skills in medicine, the "subjectivity" of visual assessment of breast tissue density can be minimized through training. More importantly, because density occurs along a continuum, any disparity in a density reading will typically occur on the margins as noted by Dr. Monticciolo, a radiologist speaking at the FDA hearing, “I don't think it's the extremes that get confused, but I think it's hard subjectively to decide between 49 percent and 51 percent (categorizing density as a “2” on the BI-RADS scale or a “3”). So what we see is variability around that. And that's the biggest issue.”

In addition to providing training to increase consistency for those assessing density, there are also two FDA approved, commercially available density assessment products that automatically assess breast tissue density.

The assignment of density categories has been used by the ACR for years. While it can be improved, it is a reasonably reliable method of determining the relative effectiveness of a mammogram, and this categorization has been utilized in peer-reviewed medical research for twenty years without comment or question. The idea that density occurs along a continuum and that higher density means lower sensitivity is simply not that difficult to comprehend.
• For women with fatty breasts, the reporting of this information may convey a false sense of security about negative mammography results. Even women with fatty breasts may have breast cancer undetected by mammography and may present with a palpable finding. High risk women should not be complacent and forego recommended screening MRI because they have fatty breasts.

IHQE Response:

Mammograms are most effective for women with fatty breast tissue. Mammograms are not as effective for women with dense breast tissue, most of whom have a false sense of security based on the false and misleading negative mammogram report that is routinely provided to them.

The current patient notification letter provided to women when no cancer is detected states, “We are pleased to inform you that the results of your recent mammography examination are normal/benign.” This letter is provided even to women with dense breast tissue, for whom a mammogram is not effective. Women understand that a screening test will not detect all cancers. However, they do expect that their results are provided with a reasonable degree of certainty. More than half of breast cancers can be missed on mammography in women with dense breasts, and there are other technologies that can detect the missed cancers. Providing a “normal” mammogram result to a woman with dense breast tissue is false and misleading.

Because density information is not included in the patient notification letter, approximately 15 million women who have dense breast tissue receive false and misleading reports. These women are significantly more likely to receive a normal report when a cancer is present (a “false negative” finding) than women with tissue that is predominantly fatty. The Institute for Health Quality and Ethics has estimated that between 40,000 and 50,000 women each year receive false negative mammogram reports, meaning that their cancer remains undetected while it is small and most treatable. The vast majority of these women are women with dense breast tissue.

The ACR professes concern for women with “fatty tissue” (the group of women for whom mammograms are most effective) while dismissing the false sense of security that is provided every day to the 40% of women who are most at risk for having a cancer missed by a mammogram.
• The significance of breast density as a risk factor for breast cancer is highly controversial. Moreover, there is no consensus that density per se confers sufficient risk to warrant supplemental screening. For women with dense breasts, receipt of breast density information may create undue anxiety about their risk and worry that mammography may have missed a breast cancer.

IHQE Response:

1. The ACR claims that “For women with dense breasts, receipt of breast density information may create undue anxiety about their risk and worry that mammography may have missed a breast cancer.” This statement confuses causal risk, the independent risk for cancer, with masking risk, or the decreased sensitivity of mammography in women with dense breasts. For women with dense breast tissue, the risk that a mammogram may have missed a breast cancer is very real. As referenced above, mammograms only detect an average of between 27% and 59% of cancers in women with dense breast tissue, and the rate is even lower for women with the highest densities. It is not “undue anxiety” for a woman to worry about missing a cancer when almost half of breast cancers are missed by mammography in women with dense breasts.

2. Furthermore, breast density as a significant risk factor for cancer is not regarded as controversial. The ACR and SBI’s own recommendations, published in 2010, reference peer reviewed studies demonstrating that density is one of the highest risk factors for breast cancer:

   “With the release of the first results of the ACRIN® trial, more attention is being paid to the use of supplemental screening with ultrasound, particularly in women with dense breasts. Breast density in and of itself has been shown by several studies to be an independent risk factor for the development of breast cancer, with the relative risk for women with the most dense breasts 2 to 6 times that of women with the least dense breasts [76, 77, 78].”

   The “controversy” the ACR references in its testimony is a single opinion article.

3. Finally, it is not the task of the physician to reduce anxiety by withholding important medical information. Opinion 8.082 of the American Medical Association ethical guidelines states, “Withholding medical information from patients without their knowledge or consent is ethically unacceptable.” Opinion 8.082 makes no exception for instances in which “anxiety” may
The inclusion of breast density information in the lay summary could result in demands for additional non-mammographic screening. Both ultrasound and MRI have been studied as supplemental screening techniques, primarily in higher risk women, and both can detect malignancies that are mammographically occult. Breast MRI is more sensitive than either mammography or ultrasound and can detect malignancies not found when both screening mammography and screening ultrasound are combined. Importantly, both additional techniques result in additional false positive examinations and increase the number of benign breast biopsies.

IHQE Response:

The inclusion of density information in the patient notification letter should increase demand for adjuvant or alternative screening for women with dense breast tissue, for whom a mammogram alone is not effective.

While the ACR has been aggressively promoting MRI as an adjuvant screening technology for the 5% of women at “high risk” of breast cancer, they have advocated withholding material medical information from the 40% of women with dense breast tissue, and have conspicuously avoided the recommendations of their own ACRIN 6666 trial. (A study funded and administered by the ACR, the federal government, and Avon Corporation, through the American College of Radiology Imaging Network (ACRIN), which increased cancer detection by 55% for women with high density breast tissue who had negative mammograms using whole breast ultrasound.) Early results were published in 2008 because "there is a potential benefit from early detection of small, node-negative breast cancers seen only on ultrasound, we are announcing these results at this time so that women can consider these results when deciding whether or not to have ultrasound screening in addition to mammography."

There have been many other studies that have uniformly shown the value of adding supplementary whole breast ultrasound to screening mammography in women with dense breast tissue. Adjuvant ultrasound is one screening modality that is readily available, and there are approved technologies which
can increase effectiveness beyond the results of the ACRIN trial using Whole Breast Ultrasound or Automated Whole Breast Ultrasound (AWBU). Two trials conducted in Connecticut using automated whole breast ultrasound doubled the cancer detection in women with dense tissue who had negative mammogram results.

Any discussion that raises “false positives” or “benign biopsies” is primarily about cost. While we commend the ACR’s interest in the cost of care, the IHQE believes that discussions of the “value” of any given procedure or study need to occur in an open, public forum where all parties, especially patients, are informed and allowed to participate. The refusal of the ACR to follow the mandate of the 1998 patient notification amendment, and its continuing opposition to legislation in the various states that would require patient density notification, constitutes an unauthorized rationing of care that is totally without authority.

- The false-positives due to mammography screening have been categorized as “harms” and have been the subject of heavy criticism of screening because of incurred anxiety and costs. The ACR recommends additional research on the benefits and harms of adding another screening technique based on breast density.

IHQE Response:

*In all cases, a false negative mammogram report delays the diagnosis of the cancer, causes more severe health outcomes for the patient, and often results in death.*

A false positive finding simply means that additional testing is required to determine if a mass is cancerous, and may include additional imaging or a biopsy for which the ultimate finding is good news for the patient.

Here, the ACR appears to be claiming that additional testing for what is happily a non-cancerous result is more serious than 40,000 to 50,000 false negatives each year that delay the diagnosis of cancer and, *in all cases*, impact the patient’s health and possibly result in death.
It should be the decision of the patient to determine if she would like to pursue additional screening based on her personal preferences and history, and with input from her physician. Some women may agree with the ACR’s opinion and choose to forego additional screening because they believe the additional cost and additional time and procedures outweigh the benefit for them personally. On the other hand, many women would elect to participate in adjuvant screening to ensure a reasonable degree of certainty in their “normal” result.

It is not the right of the American College of Radiology to make this determination for the patient, which it has done by systematically withholding this material medical information from millions of women. For a woman to provide informed consent – either to have or to forego additional screening - she must be provided all relevant information.

The ACR is concerned that unless supplemental screening were reimbursed by payors, that there would be an unfortunate disparity between women who can afford to pay for the additional screening exam and those who cannot.

IHQE Response:

This assertion is very troubling, as it appears to indicate a willingness to substitute third party payor policy for clinical judgment. We believe that the physician’s advice to the patient should reflect the best clinical evidence, not the willingness of a healthcare insurance company to pay for a particular procedure. We believe that a woman should be afforded the choice in her healthcare decisions, regardless of the status of third-party payor concerns. There are many procedures and medications which are beneficial to women, and to which they are provided access, which are not covered by third party payors. Withholding information on the benefit of these procedures from the patient and denying her the ability to exercise choice because of some predetermined judgment that she can’t afford it, or that society can’t afford to pick up the tab, is very concerning.

This justification for withholding material medical information is even more troubling insofar as it violates the principle of informed consent and denies the patient her right to make informed medical decisions. This justification appears to violate both the ethical obligations of physicians and the legal
requirements which exist in statutes and case law in all fifty states. The American Medical Association describes informed consent as a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo (or forego) a specific medical intervention. In order to ensure that the patient is acting with informed consent, the physician should disclose the risks and benefits of a proposed treatment or procedure; alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance); the risks and benefits of the alternative treatment or procedure; and the risks and benefits of not receiving or undergoing a treatment or procedure.

Many women face these kinds of decisions on a daily basis – particularly those who do not have medical insurance. Radiology has been exceptionally resilient under these conditions, particularly with mammography, by helping to find other resources to pay for mammography and other procedures that may be required for breast patients.

While the ACR has lobbied extensively to ensure reimbursement for mammogram and MRI screenings, the organization has not lobbied for supplementary ultrasound screening where it might be indicated, despite the wealth of research and information generated by many of the organization’s most talented researchers and clinicians. Women cannot advocate for needed services on their own behalf if they are provided false and misleading information regarding their own bodies, the relative effectiveness of mammography, and potential alternatives that are available.

To withhold important health information from women because a procedure that might be involved may not be reimbursed would completely change the way medicine is delivered in the United States, making the physician a de facto agent of the third party payor system, rather than an advocate for the patient’s care.

The ACR recommends that the FDA proceed with some caution in considering the mandate to include breast parenchymal density information in the lay summary. It might be valuable to review the experience in the State of Connecticut, where a law requiring this communication has been in place long enough to gather and evaluate its outcomes. As always, the ACR is happy to provide the FDA with additional information on this topic.
IHQE Response:

We agree. It is valuable to review the Connecticut results, which again confirm the outcome of previous studies. In Connecticut the data demonstrated that mammography missed half the cancers in women with dense breast tissue, and that ultrasound could find those cancers.  

The issue of mammography effectiveness and sensitivity for women with dense breast tissue is not a new one. Concern about density and mammogram effectiveness has driven the development of digital mammography, digital breast tomosynthesis, and magnetic breast imaging. It has spurred research into the use of ultrasound screening and the development of automated whole breast ultrasound technology.

A simple and clear explanation of the implications of breast tissue density is relatively easy to draft for inclusion in the patient lay letter and should have been included years ago. Such a course would certainly be preferable to leaving women with dense breast tissue with the mistaken impression that their results are normal, when the mammogram misses an average of 50% to 75% of cancers in this population.

We hope that the ACR’s recommendation to wait for more data from the State of Connecticut is not another reason to delay proper notification. Women advocates and state legislators enacted the Connecticut legislation because the FDA and the ACR failed to adequately implement the patient notification amendment. It is time for the ACR to cease its lobbying against density notification and give meaning to the language it used with the SBI in their joint recommendations for imaging women with occult breast cancer, "It has been demonstrated that the sensitivity of mammography is lower in women with dense breasts, and regardless of whether women with dense breasts are at increased risk or not, it has been shown that the use of supplemental ultrasound screening will result in the detection of otherwise occult cancers."

The studies from Connecticut have reinforced the prior research regarding adjuvant ultrasound screening for women with dense breast tissue, increasing the number of cancers detected in these women at a rate of 3.2 per 1,000 for women with dense breast tissue who received negative mammograms. This legislation has resulted in a doubling of early cancer detection in a large group of women at high risk. We believe that providing material information on breast density in the patient report and properly advising patients of their alternatives could result in significant progress
in the efforts directed at decreasing breast cancer mortality, potentially reducing the 40,000 deaths per year by 25%.

Our healthcare system is predicated upon the principle of informed consent. No woman can be considered to consent to treatment – or to consent to forego treatment – without access to all material information. Whether or not a woman participates in additional screening is a decision that should be made by the individual woman, based upon all material information, and not by the American College of Radiology. The most expedient way to reasonably ensure that women are informed of their individual breast tissue density and the relative effectiveness of a screening mammogram is to include this information in the patient notification letter.

In its statement to the NMQAAB, the ACR consistently admits the negative impact of increasing tissue density on the sensitivity of the screening mammogram. The ACR also acknowledges that other imaging modalities have proven to be clinically effective in imaging cancers that are mammographically occult in women with dense tissue. Despite this, the ACR has consistently opposed patient notification of density under MQSA regulations, and has lobbied against legislative notification mandates in the various states. This policy dissonance infers that the ACR has adopted the organizational position that it and its membership are willing to accept the medical legal risk associated with:

1. delayed diagnosis of a life-threatening cancer;
2. that is the proximate result of the failure to notify the patient of the sensitivity risk; and
3. further failure to notify the patient of her ability to mitigate that risk through the use of supplementary imaging.

While this may be an unintended consequence of the ACR’s actions, it is very real nonetheless, and is completely avoidable.

The burden of patient notification is statutorily placed on the imaging facility, which is subject to MQSA regulation and accreditation, as well as the patient notification amendment enacted in 1998. The ACR has the ability and the authority to make the necessary changes immediately.

The FDA is accountable for ensuring that the necessary changes are made without further delay, and before more lives are lost unnecessarily to breast cancer.
The Institute for Health Quality and Ethics is a non-profit organization dedicated to protecting the rights of all people to make fully informed medical decisions. We seek to promote a system of quality healthcare which supports the dignity and rights of each individual based on personal choice and ethical considerations.

The Institute is not affiliated with any political party or religious persuasion. We invite meaningful discussion of the issues and value different perspectives, and we welcome your thoughts and feedback.

The Institute for Health Quality and Ethics
75 Sprague Hill Road
Chepachet, RI 02814
www.inhqe.com
401-588-2450

For additional information, please contact:

Julie Marron
President
jmarron@inhqe.com
401-282-8115

Tom Nerney
Executive Director
tnerney@inhqe.com
401-207-3616
References


11. Much has been made about the rate of false positives, and that issue was addressed earlier in this document. However, the high false-positive biopsy rate in these studies was a function of the workflow method, however, and not the technology method. Unlike mammography, there were few callbacks, and biopsy decisions were made at the initial exam. In other words, there was a lower false positive rate on the callbacks but a higher false positive rate on the biopsies. Other studies have demonstrated the same doubling in detection rates, with a lower false positive biopsy rate by adjusting the workflow parameters.
