

New Jersey Department of Health Breast Imaging Work Group

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New Jersey Department of Health Breast Imaging Work Group

The Breast Cancer and Breast Imaging Options Work Group was established by *P.L. 2013, c.196* requiring the New Jersey Department of Health (DOH), in conjunction with the Medical Society of New Jersey, to convene a work group to review and report on strategies to improve the dialogue between patients and health care professionals regarding risk factors for breast cancer and breast imaging options. Participants in the work group represent patient advocacy groups and health care professional organizations.

The members of the work group shall review breast imaging standards, the federal mammography quality standards act and breast imaging result protocols. The work group shall recommend strategies to improve dialogue between and health care professionals regarding breast imaging options and breast density and shall report the work group's findings and recommendations to the Governor and the Legislature pursuant to *section 2 of P.L. 1991, c.164 (C.52:14-19.1)* along with any with any legislative bills that it desires to recommend for adoption by the legislature, on an annual basis.

Background

Breast cancer is one of the most common cancers diagnosed in women in the United States, and is the second leading cause of cancer death, after lung cancer. For American women, the lifetime risk of invasive breast cancer is about 1 in 8 (12%). The American Cancer Society (ACS) estimates that in 2015 about 231,840 new cases of invasive breast cancer and 60,290 cases of carcinoma-in-situ (CIS) will be diagnosed in women, and that 40,290 women will die of the disease (1). In New Jersey alone, it was estimated that 7,310 new breast cancers would be diagnosed in 2015 and approximately 1,290 women would die of the disease (2).

The causes of breast cancer are multi-factorial; however, several risk factors are well recognized. These include age, genetic factors and family history, hormonal factors, radiation exposure and high breast tissue density (3). Breast density impacts cancer detection in two ways. First, dense breast tissue differs physiologically in ways that increase cancer risk. More important, denser tissue decreases the sensitivity of mammography to detect breast cancer (4).

Approximately 50% of women who undergo screening mammography are categorized as having “dense breasts” (40% heterogeneously dense/10% extremely dense). Supplemental imaging after a normal mammogram can increase cancer detection in these women but is associated with increases in false positive findings resulting in additional recalls and biopsies.

(table below excerpted from www.DenseBreast-info.org/Technology.aspx) (5-8)

TABLE 2. SUMMARY OF CANCER DETECTION AND RECALL RATES FOR COMMONLY AVAILABLE BREAST SCREENING TESTS

If 1,000 Women Are Screened With	Number of Women Found to Have Cancer	Type of Technology	Number of Women Called Back for More Testing
Regular 2D-mammogram alone	2-7 total	Ionizing Radiation	100
2D-mammogram plus 3D-mammogram (tomosynthesis)	Mammogram 2-7 + Tomosynthesis 1-2 = 3-9 total	Ionizing Radiation	70
Regular 2D-mammogram plus ultrasound (US)	Mammogram 2-7 + 4 = 4-11 total	Sound waves	170-230
Regular 2D-mammogram plus contrast-enhanced MRI	Mammogram 2-7 + MRI 10 or more = 12-17 or more total	Magnetic field and intravenous contrast	160-220

Courtesy of Dr. Wendie Berg

Note: On average, out of 1000 women screened with mammography, 100 will be recalled for additional testing. Of those 100 women recalled: 60 will be found to have nothing of concern; 20 will be recommended for short interval follow-up of a “probably benign” finding (specific type of mass or calcifications with < 2% risk of malignancy, for which follow-up is a safe alternative to immediate biopsy); and 20 will be recommended for biopsy, of whom 5 on average will be found to have cancer. (Reference: Rosenberg, RD, Yankaskas, BC, Abraham, LA, et al. (2006). Performance benchmarks for screening mammography. *Radiology* 241(1).

About the Work Group

The New Jersey Department of Health Breast Imaging Work Group was originally convened on February 20, 2015. Physicians, nurses, grassroots advocates, and society representatives attended the initial meeting, along with staff from the Department of Health (DOH), Radiological Society of New Jersey (RSNJ), New Jersey Association of Osteopathic Physicians and Surgeons (NJAOPS) and the Medical Society of New Jersey (MSNJ):

NJ Department of Health - Breast Imaging Work Group Members

Work Group Members	Organization
Representatives of Health Care Organizations	
Dr. William Diehl	Summit Medical Group
Dr. Michelina DeSanti	Hackettstown Regional Medical Center
Dr. Lauren Levy	Valley Hospital Radiology Assoc.
Ms. Lois Greene, DHA, MBA, BSN, RN	University Hospital
Dr. Roger Yang	Somerset Medical Center
Dr. Sharon Mass	Morristown OB and Gyn
Dr. Mitchell Miller	Radiological Society of New Jersey
Representatives of Patient Advocacy Groups	
Ms. Susan Bedell	American Cancer Society
Ms. Jessica Morton	Patient Advocate
Ms. Laurie Scofield	Dense Breast NJ
Healthcare Providers	
Dr. Susan McManus	St. Peters University Hospital
Dr. Nichole Saphier	Memorial Sloan Kettering Monmouth
Dr. Linda Sanders	Barnabas Health
Dr. Lisa Weinstock	Woman's Digital Imaging
Dr. Arnold Baskies	Virtua Medical Group
Dr. Lisa Marie Sheppard	PINK Breast Center
State of New Jersey	
Mr. Scott Owens, MSA	Department of Health

Group Dynamics

Initially, two sub-groups were created: Radiology, chaired by Mitchell Miller, MD and Education, chaired by Sharon Mass, MD. Subsequent meetings were held on April 30, 2015 and June 22, 2015.

The work group has focused on reviewing the law and its implications, evaluating educational resources, existing and needed, and making clinical recommendations regarding screening and management for women with dense breasts.

Breast Density Legislation and its Impact in New Jersey

As of December 2016, 27 states have enacted legislation regarding notification of breast density. Similar Federal bills are pending. These provisions vary greatly. The intent of the laws is to raise patient awareness about the impact of breast density on mammographic screening so that patients can make informed decisions, in conjunction with their physicians, about individualized screening approaches. New Jersey became the 14th such state and the legislation, P.L. 2013, Chapter 196.

The NJ law requires insurers to cover breast evaluations and other additional medically-necessary testing under certain circumstances. Specifically, it requires patient reporting in the form of a lay letter informing the patient: “Your mammogram may show that you have dense breast tissue... .” (C.26:2-184.3). It also includes a provision for insurance coverage for supplemental screening for women with “extremely dense” breasts and others deemed medically necessary, subject to utilization review. Furthermore, the law mandated the formation of a Department of Health work group to review and report on strategies to improve the dialogue between patients and health care professionals regarding risk factors for breast cancer, particularly with regard to breast density and breast imaging options (9).

A recent article looking at some of the financial implications of the law indicate a significant financial cost as a result of reimbursement for screening ultrasound (10), though there were important deficiencies in that analysis which inflate the costs and reduce the expected benefits (11) of adding screening ultrasound to mammography in women with dense breasts.

An additional controversy raised by dense breast notification legislation is “who” should discuss results with patients, the ordering physician or the radiologist. Many primary care physicians are unaware of the legislation or are uncomfortable with discussing breast density with their patients (12, 13).

There is no national consensus on the approach to recommending any alternate or additional screening for women with dense breasts solely on the basis of breast density. Some physicians and advocates support the use of supplemental whole-breast screening ultrasound in some or all women with heterogeneous and/or extremely dense breasts. These issues and controversies were explored and debated during the New Jersey legislative process and subsequent work group discussions.

Clinical Management

There are currently no standard/uniform recommendations for management of women with heterogeneously or extremely dense breasts (or for mammography in general). A national organizational statement would be helpful if national organizations (such as the American College of Radiology, American College of Obstetricians and Gynecologists, American Association of Osteopathic Physicians, Society of Breast Imaging) develop guidelines on the proper management of patients with dense breasts on mammography so that all practitioners would have an available reference to help them manage such patients.

The benefit of such a system is that it would standardize management and lessen the confusion that has existed in managing these patients. Based on current evidence, use of Digital Breast Tomosynthesis (DBT) for screening mammography increases cancer detection at all levels of breast density while decreasing the risk of recall for additional imaging and biopsy (14). Though data is still emerging, a majority of work group members believe that when available, women with dense breasts should be made aware of this option.

A majority of work group members believe that evaluating other risk factors for breast cancer and providing that information to the radiologist would assist in individualizing patient screening options; alternatively, breast centers could obtain an appropriate history and include a calculated lifetime risk in their official mammogram reports (including which model used). The current national guidelines from both the National Comprehensive Cancer Network and the American Cancer Society include annual MRI in addition to mammography for women at high risk of breast cancer, independent of breast density (15).

A majority of work group members can support the use of the algorithm outlined at DenseBreast-Info.org for screening of women with “dense” breasts (8). Based on this algorithm (below), the work group can agree that appropriate additional/supplemental imaging could include whole-breast screening ultrasound for women with “extremely” dense breasts, MRI for women with “heterogeneously” or “extremely” dense breasts *and* intermediate risk (lifetime 15%), MRI for a woman with any level of density and lifetime risk of 20% or greater.

Findings and Recommendations from the Work Group

Though the work group was unable to come to consensus on all issues (see below) there were numerous recommendations that the majority of members could agree upon:

- “Dense” (heterogeneously dense/extremely dense) breast tissue decreases the sensitivity of a mammogram.
- “Dense” (heterogeneously dense/extremely dense) breast tissue increases the relative risk of breast cancer.

Patients have the right to know their level of density and a majority of work group members feel that patients should be informed of their own specific level of density. While not mandated by law, this information could be included in the lay reports and radiologists could be provided with language that represents “best practices.”

Legislation

- The current legislation (P.L. 2013, Chapter 196) has resulted in a great deal of confusion for both patients and physicians.
- At this point the work group does not recommend further NJ *legislative* action regarding breast density.

Education

- Patient education about the facts and implications of breast density in the state of NJ appear to be lacking.
- Physician knowledge and education about the facts and implications of breast density in the state of NJ seem to be lacking.
- Patients and physicians would benefit from educational campaigns supporting the following educational resources:
 - www.DenseBreast-info.org A collaborative website created by DenseBreast-info in conjunction with Dr. Wendie Berg.
 - www.acog.org/-/media/Sections/NJ/DiscussingBreastDensity.pdf - NJ American College of Obstetrics and Gynecology (NJ ACOG) Discussing Breast Density Toolkit.
 - www.breastdensity.info/docs/BreastDensitybro_ACR_SBI_F.pdf - American College of Radiology (ACR) brochure.
 - www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-039989.pdf - American Cancer Society (ACS) brochure.

Billing and Coding Discussion

There is need for clarification of coding and billing for imaging in women with “dense breasts.” A majority of work group members strongly believe that digital breast tomosynthesis (DBT) should be covered by insurance as a screening modality for the general population.

Further, the Department of Banking and Insurance (DOBI) should encourage insurance companies to expand coverage of screening mammography to include coverage for DBT for all women, or at a minimum for women with heterogeneous density (coverage is already mandated for extremely dense breasts).

- The Committee believes that this modality should not be considered “experimental.” There was fairly uniform agreement that DBT does have a role in managing patients with dense breasts given its improved sensitivity when compared to standard mammography.
- At the time that we completed this report, many insurers were not reimbursing DBT. At least one insurance carrier had labelled DBT an experimental procedure.
- Since the working group submitted the initial report for review in 2015, some state legislatures have passed legislation mandating reimbursement for DBT.

- Legislation is pending in the New Jersey Legislature which requires insurers to provide coverage for DBT for screening and diagnostic purposes related to breast cancer.

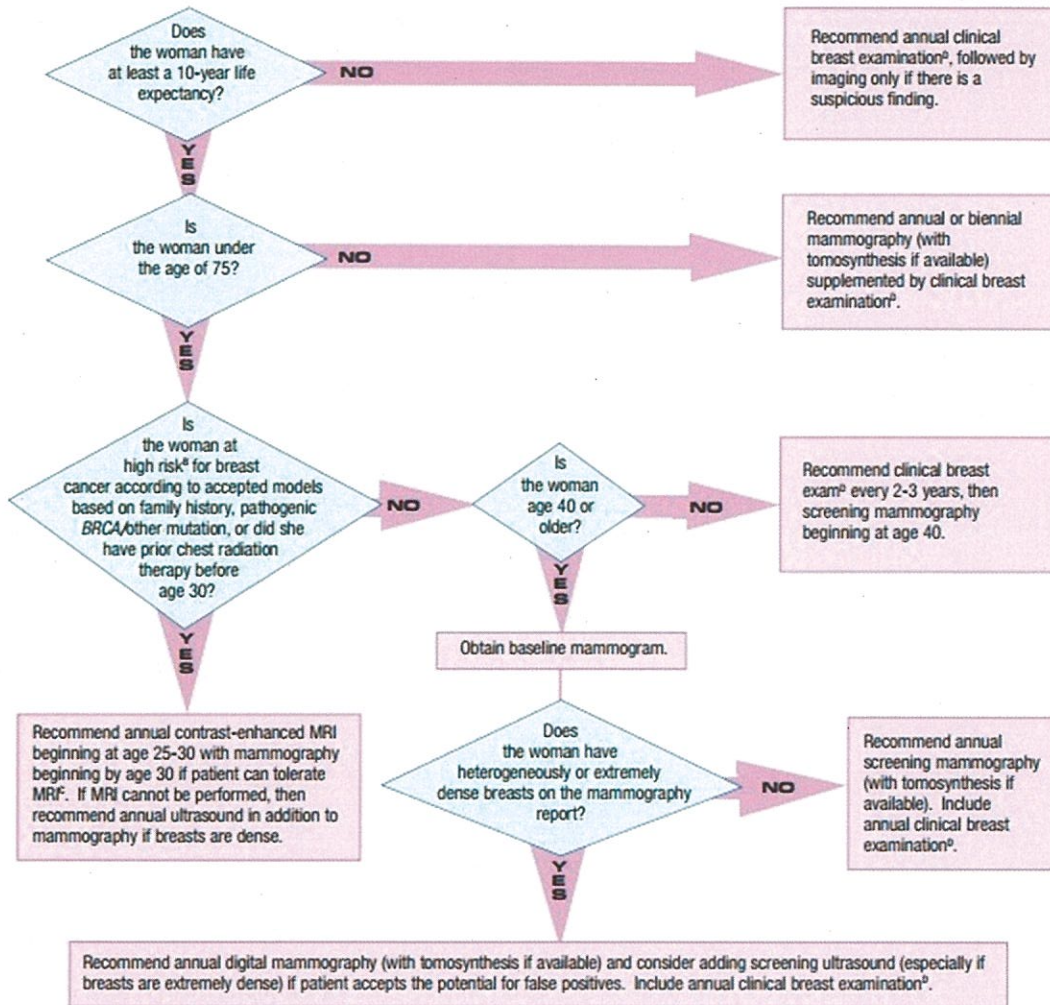
Areas of Ongoing Conflict/Disagreement

- The work group members could not come to consensus regarding the recommendation for whole-breast screening ultrasound in *all* women with “dense breasts” but no other risk factors for breast cancer.
- The work group members could not come to consensus regarding the support for management based on Annals of Internal Medicine article (16) that women with certain levels of density *and* other risk factors be offered supplemental whole-breast screening ultrasound.
- The work group members could not come to consensus regarding *who* should be providing the information and recommendations for follow up to patients (*i.e.*, ordering physicians or radiologists).

Suggestion for Future Activities and Strategic Planning

The NJ DOH Breast Imaging Work Group should reconvene during 2017 to develop a list of specific actionable items, including time lines, responsible parties, and determining resources for the recommendations listed below:

- Plan for the dissemination of DenseBreast-Info.com Screening Decision Support Tool and other educational resources as they emerge to ordering physicians and radiologists in NJ and encourage radiologists to reference the DenseBreast-Info website in the patient lay letter.
- Develop an objective survey about physician knowledge of breast density in NJ to be submitted to NJ-ACOG and RSNJ for consideration of distribution to their members. Survey findings will be reported back to the work group subcommittee to assess needs and compile recommendations for additional educational resources if any.
- Develop an action plan for the work group subcommittee to collaborate and encourage insurance companies to cover DBT as an option for screening mammography in women in New Jersey.



^A See also DenseBreast-info.org (Technology tab Table: Summary of Cancer Detection Rates for Commonly Available Breast Screening Tests).

^B See DenseBreast-info.org (Health Care Provider tab / Risk Models).

^C Contrast-enhanced MRI is not recommended in women who are pregnant, have a pacemaker, have a non-MRI compatible metallic implant near vital structures, or who have decreased renal function.

^D No longer recommended by the American Cancer Society, but may be helpful on individual level.

All individuals should know how their breasts normally look and feel and report any change promptly to their health care provider. Technology can be used in many combinations for breast cancer detection and not every technology is available at every site.

Note: This flow chart was developed as an educational tool and reflects the consensus opinion of our medical reviewers based on the best available scientific evidence. The proposed strategy is relatively aggressive, designed to optimize cancer detection. Other guidelines may recommend a later start or different screening frequency. This is not intended to be a substitute for medical advice from a physician or to create a standard of care for health care providers.

Rev. 10/15

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- 2) <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspsc-044552.pdf>, accessed 1/5/17.
- 3) <http://www.nci.nih.gov>, accessed 1/5/17.
- 4) (Carney PA, Miglioretto DL, Yankaskas BC, et al. Individual and combined effects of age, breast density and hormone replacement therapy use on the accuracy of screening mammography. *Ann Intern Med.* 2003;138(3):168-175.
- 5) Hooley RJ, Greenberg KL, Stackhouse RM, Geisel JL, Butler RS, Philpotts LE. Screening ultrasound in patients with mammographically dense breasts: initial experience with Connecticut public Act 09-41. *Radiology* 2012; 265:59-69.
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- 10) Sobotka J, Hinrichs C. Breast density legislation: Discussion of patient utilization and subsequent direct financial ramifications for insurance providers. *JACR.* 2015;12 (10):1011-5.
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- 15) Saslow D, Boetes C, Burke W, et al. American Cancer Society Guidelines for breast screening with MRI as an adjunct to mammography.
- 16) Kerlikowske K, Zhu W, Tosteson AN, et.al. Identifying women with dense breasts at high risk for interval cancer – A cohort study. *Ann Intern Med.* 2015; 162:673-681.