

Introduction to Breast Density



The Institute

basil hetzel institute for translational health research



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Breast Biology & Cancer Unit

Ethical and Legal Considerations in Breast Density Workshop 2018



In this presentation

- My interest in breast density
- What breast density is, how it's measured, how common it is
- Why does breast density matter?
- Patient advocates changing policy
- Breast density policy around the world
- Australian breast density policy

My interest in breast density

- I am a breast biologist interested in understanding the biological mechanisms that link breast density to increased breast cancer risk as a step towards preventing breast cancer in the future
- My breast density research is funded by The Hospital Research Foundation, Australian Breast Cancer Research and the National Breast Cancer Foundation

InforMD (INformation FORum on Mammographic Density)



Wendy Ingman
University of Adelaide



Jennifer Stone
University of WA



John Hopper
University of Melbourne



Gail Ward
Screening Expert



Rik Thompson
Queensland Uni Technology



Kara Britt
Peter Mac Cancer Centre



Honor Hugo
Queensland Uni Technology



Gerda Evans
Breast Cancer Community Advisor

My interest in breast density

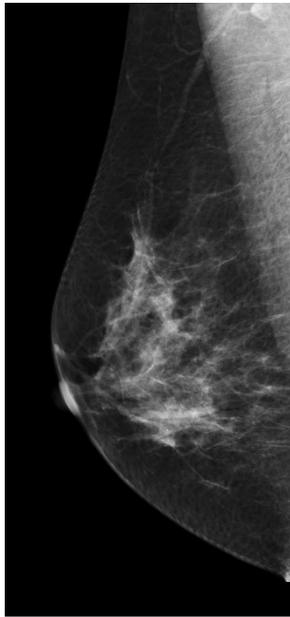
- InforMD ran a breast density public awareness campaign reaching 7 million Australians, and launched the website www.informd.org.au on 4th October 2016
- Communication between InforMD and Health Minister Greg Hunt in 2017 led to the current review of national breast density policy
- InforMD has been advocating for the establishment of a panel of experts (including users of screening services and patients) tasked with development of evidence- and/or consensus-based Australian clinical guidelines for breast density management and notification
- I am a member of a Clinical Oncology Society of Australia working group developing a fact sheet on breast density for health care professionals
- I am a member of the Pink Hope Expert Advisory Committee

Breast density on a mammogram

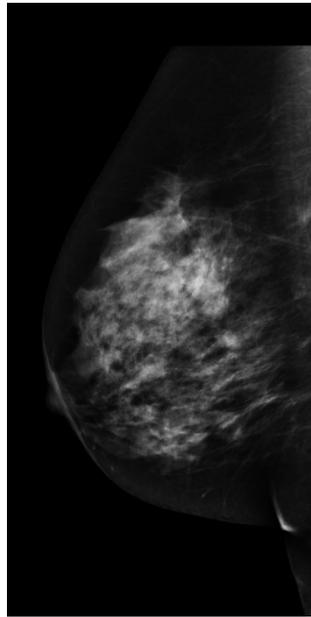
- BI-RADS 5th edition, American College of Radiologists
- Subjective measure by the radiologist



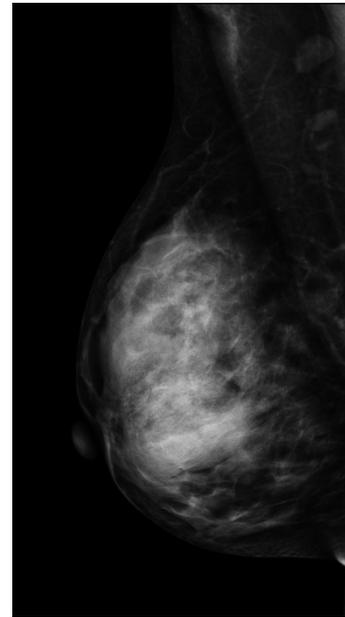
“a”
Mostly fatty



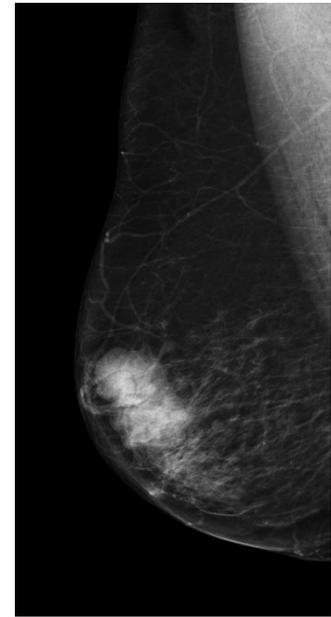
“b”
Scattered
density



“c”
Heterogeneously
dense



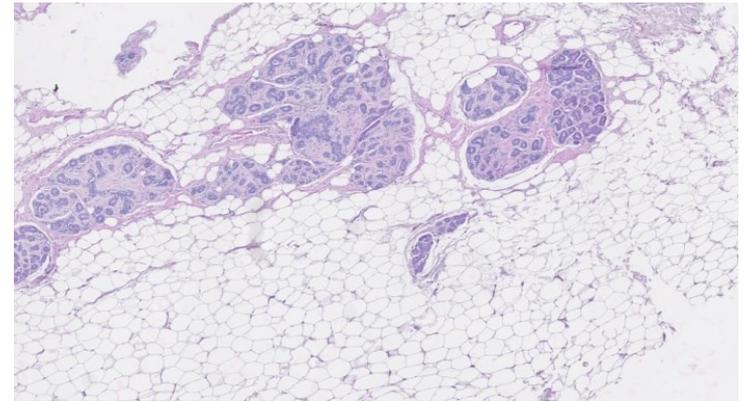
“d”
Extremely dense



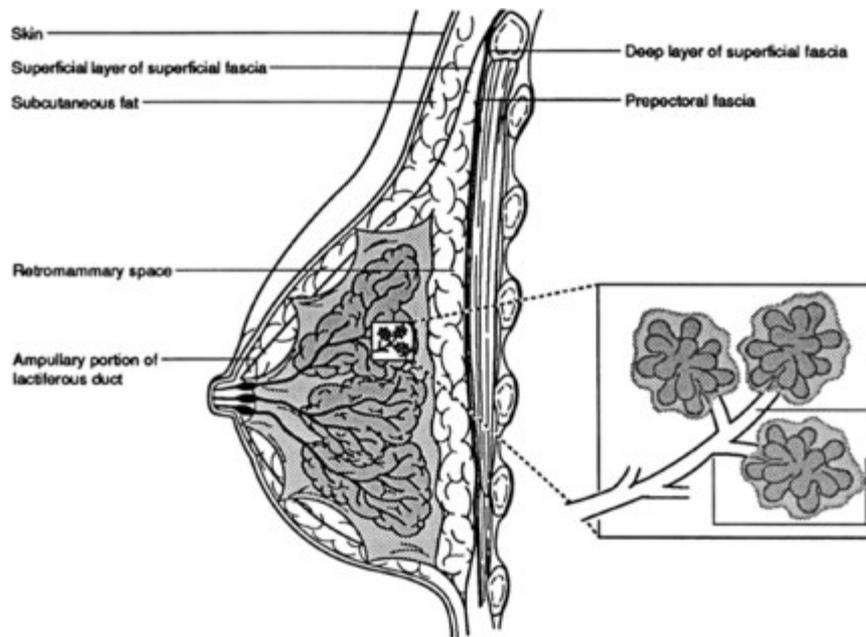
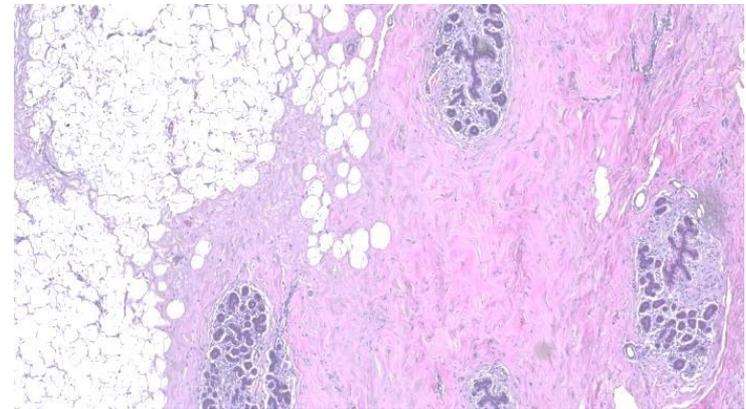
Breast cancer

What is breast density?

Low density



High density

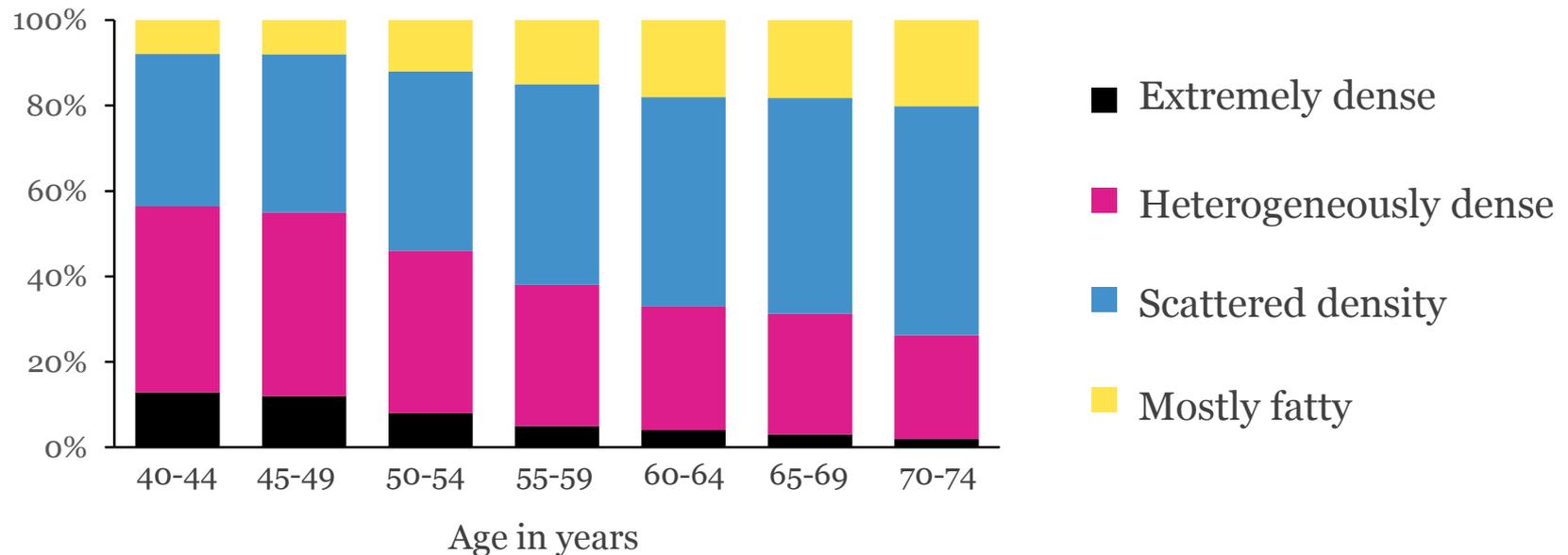


How density is measured

- There is no single agreed upon method for measuring breast density
- BI-RADS is most common but it is subjective, 12% to 19% of all women screened would potentially be advised differently (dense or non-dense) at next screen (Melnikow et al, USPSTF 2016)
- Semi-automated (eg Cumulus)
- Automated (eg Volpara, Quantra)

How common are different breast density categories?

- Almost 8% of women aged 40-74 have extremely dense breasts
- Frequency of extremely dense breasts decreases with age
- Having children and going through menopause reduce density
- Frequency of extremely dense breasts decreases with BMI



Sprague et al, 2014

What causes high density?

- Density is established during puberty, when the breasts develop
- Genetic factors affect breast density
- Ovarian hormones affect density, however the drivers of density are more complex
- Combined hormone replacement therapy increases density
- Tamoxifen treatment reduces density
- The current understanding of breast density is that all BI-RADS categories of density are considered normal
- Many women have extremely dense breasts and do not develop breast cancer

Why does breast density matter?

A RISK FACTOR FOR BREAST CANCER

- Women with extremely high “d” breast density have a 4-6 times increased risk of developing breast cancer compared to women with “a” low density, with the same age and BMI (McCormack 2006).
- However, this compares the two extremes of density.
- Compared to average or scattered “b” density, women with extremely dense “d” breasts have double the risk of breast cancer, women with heterogeneously dense “c” breasts have an increase risk of 20-40% (Sickles 2010, Engmann et al 2017).
- The InforMD alliance suggests it is important that breast density be considered together with other risk factors (such as age, family history, and body mass index).

Why does breast density matter?

AFFECTS THE SENSITIVITY OF A MAMMOGRAM

- Abnormal areas on the mammogram become more difficult to see in areas of dense breast tissue
- Sensitivity of mammogram to detect breast cancer (Kerlikowske et al 2018):
 - 92% for “a” mostly fatty
 - 90% for “b” scattered density
 - 76% for “c” heterogeneously dense
 - 61% for “d” extremely dense

Nancy's story



- Nancy Cappello received a breast cancer diagnosis in 2004, 6 weeks after a “normal” mammogram.
- In 2009, Connecticut became the first state in the U.S.A. to legislate breast density notification.
- State legislation is strongly opposed by the American Society of Obstetricians and Gynecologists.



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

A correction was published in January 2016 for this title. [Click here to view the correction.](#)

COMMITTEE OPINION

Number 625 • March 2015

(Reaffirmed 2017)

Committee on Gynecologic Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Management of Women With Dense Breasts Diagnosed by Mammography

- “The assessment of breast density is subjective and based on the opinion of the radiologist.”
- “Current published evidence does not demonstrate meaningful outcome benefits (eg reduction in breast cancer mortality) with supplemental tests (eg ultrasonography and MRI) to screening mammography or with alternative screening modalities (eg breast tomosynthesis or thermography) in women with dense breasts...”

Patient advocates changing policy

- In 2017, Nebraska state legislators voted unanimously in favour breast density notification law after death of patient advocate.



Cheri Rauth diagnosed with stage 4 breast cancer after 15 years of normal mammograms



Iowa state Governor Branstad signs “Patty's Law” in 2017

Colorado votes in 2017:



Sen. Angela Williams  @C... · 3d 
To withhold medical information from patients without their knowledge is ethically unacceptable
[#SB142](#) [#coleg](#) [#copolitics](#)
[#womenshealth](#)

Wisconsin votes in 2017:



Gail Zeamer @GailZeamer · 16h 
Replying to [@densebreastscdn](#) and [@JoAnnPushkin](#)
Thank you! We will not let this happen to any other woman. No more missed tumors. Enough is enough! [#onwisconsin](#) [#notification](#)

- Last week, Illinois became the 35th state to require some level of breast density notification after a mammogram.

State legislation varies widely

State	Receives letter	Notification text	Supplementary screening
New York	Density (C) and (D)	“Your mammogram shows that your breast tissue is dense. ”	Yes
Connecticut	Density (C) and (D)	“ If your mammogram demonstrates that you have dense breast tissue...”	Yes
New Jersey	ALL women	“Your mammogram may show that you have dense tissue...”	No

www.Dense-breast.info

Changing national policy in the U.S.A.

- Breast Density and Mammography Reporting Act of 2017 introduced in Congress with bipartisan support.
- To create a national standard for the written report language and establish best practices for communicating with patients.
- Requires the U.S. Secretary of Health and Human Services to undertake an evidence-based process that includes a review of current scientific knowledge, technological advances, and guidance from medical experts to develop specific language regarding dense breast tissue for mammography written reports.

**ACS CAN Supports the Breast Density and
Mammography Reporting Act of 2017**
(H.R. 4122/S. 2006)



Changing national policy in the U.S.A.



The screenshot shows the Reginfo.gov website header with the following elements:

- Logo of the Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President.
- U.S. General Services Administration (GSA) logo.
- Search options: Agenda, Reg Review, ICR.
- Navigation menu: Home, Unified Agenda, Regulatory Review, Information Collection Review, FAQs / Resources, Contact Us.

The main content area displays the following information:

- View Rule**
- [View EO 12866 Meetings](#) | [Printer-Friendly Version](#) | [Download RIN Data in XML](#)
- HHS/FDA** | **RIN: 0910-AH04** | **Publication ID: Fall 2017**
- Title:** Mammography Quality Standards Act; Regulatory Amendments
- Abstract:**
FDA is proposing to amend its regulations governing mammography. The amendments would update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA). FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published in 1997 and to address breast density reporting to patient and healthcare providers.

- The Food and Drug Administration is proposing to amend the Mammography Quality Standards Act (1992), to address breast density reporting to patient and healthcare providers.
- The American College of Radiologists “supports an FDA mandate that information on breast parenchymal density be included in the mammography report” (November 2017)

International breast density policy

- United Kingdom (patient advocates: Breast Density Matters U.K.)
- Canada (patient and HCP advocates: Dense Breasts Canada)
- Ireland (patient advocates: Being Dense)
- France, Austria (supplementary ultrasound provided for dense breasts)
- The European guidelines for organised population breast screening programs do not endorse supplementary screening
- Switzerland (Swiss Medical Board recommend phasing out mammographic screening)
- Union for International Cancer Control is considering developing a position on breast density



RANZCR position statement

Approved by: Faculty of Clinical Radiology Council

Date of approval: 30 September 2016

<http://www.ranzcr.edu.au/documents-download/document-library-2/document-library-4/4227-2016-position-statement-on-breast-density>

“There are currently no randomised controlled trial data that show supplemental screening using technologies such as ultrasound, MRI or tomosynthesis saves lives.”

“The potential harms associated with supplemental screening include unnecessary and invasive tests, additional false positive examinations, a higher rate of benign breast biopsies, associated psychological distress and financial costs to both the woman and the health system.”

“At this time, mammography providers, including BreastScreen Australia, do not routinely provide women with information about breast density.”

BreastScreen position statement

Approved by: Cancer Australia, Cancer Council Australia, The Royal Australian and New Zealand College of Radiologists and Breast Surgeons of Australia and New Zealand

Date of approval: 30 September 2016

<http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/br-policy-breast-density>

“When the same mammogram is interpreted by different radiologists or by the same radiologist on different occasions, differing density may be reported (inter and intra-observer variability).”

“The Standing Committee on Screening recommends that, until such time that more evidence is available on how breast density should be assessed and managed, BreastScreen Australia should not routinely record breast density or provide supplemental screening for women with dense breasts.”

Why screening programs do not report density to women

- More scientific evidence is needed to guide decision-making around how to measure breast density.
- It is unclear what women with high breast density, and their doctors, should do to manage their breast cancer screening and breast cancer risk once they have been notified.
- More evidence is required to tailor screening programs to benefit the individual woman. Tailored screening might include more intensive screening of women with higher breast cancer risk, and reduced frequency of screening of women with lower breast cancer risk.
- The program aims to avoid unnecessary harms. Potential harms of breast density notification might include unnecessary anxiety, costly supplementary testing for some women potentially leading to false positives, and finding a slow-growing cancer which would not be harmful during a woman's lifetime (leading to unnecessary treatment).

Take home messages

- Breast density is the white and bright on a mammogram
- 43% of women aged 40-74 have dense breasts (BI-RADs category “c” or “d”), almost 8% of women have extremely dense “d” breasts
- Women with dense breasts have an increased breast cancer risk, however most women with dense breasts do not develop breast cancer
- Mammography is less effective at detecting breast cancer in women with dense breasts
- The current BreastScreen Australia policy is not to record or report breast density
- Whether or not to notify women about their breast density is a complex issue and different jurisdictions deal with this differently