

BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM



43,791 women remained
uninsured after Medicaid
Expansion and the ACA and
eligible for Mammograms

FUNDING ONLY PROVIDED
FOR 47% OF WOMEN
ELIGIBLE FOR THE
PROGRAM





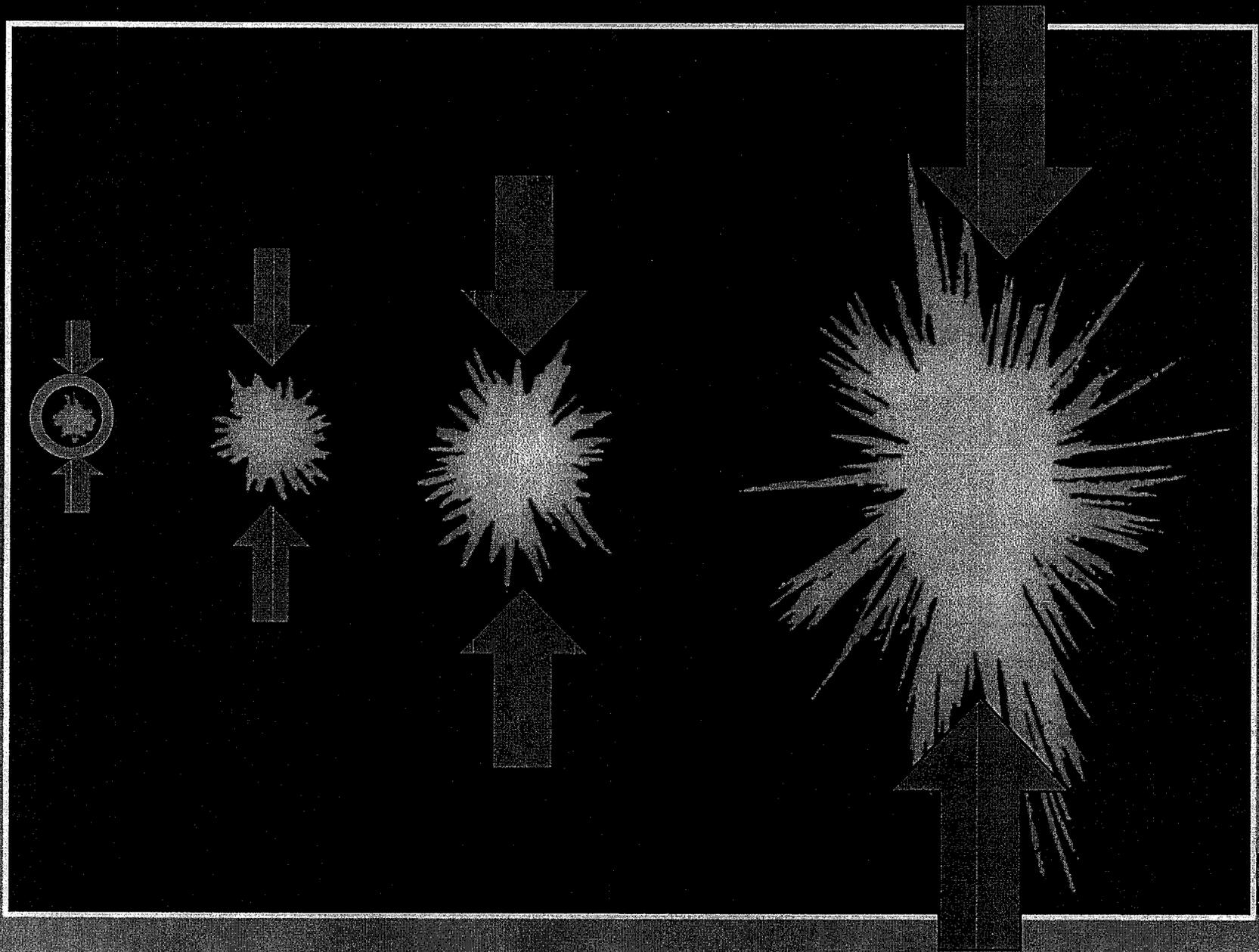
BREAST CANCER IN THE UNITED STATES: 2014

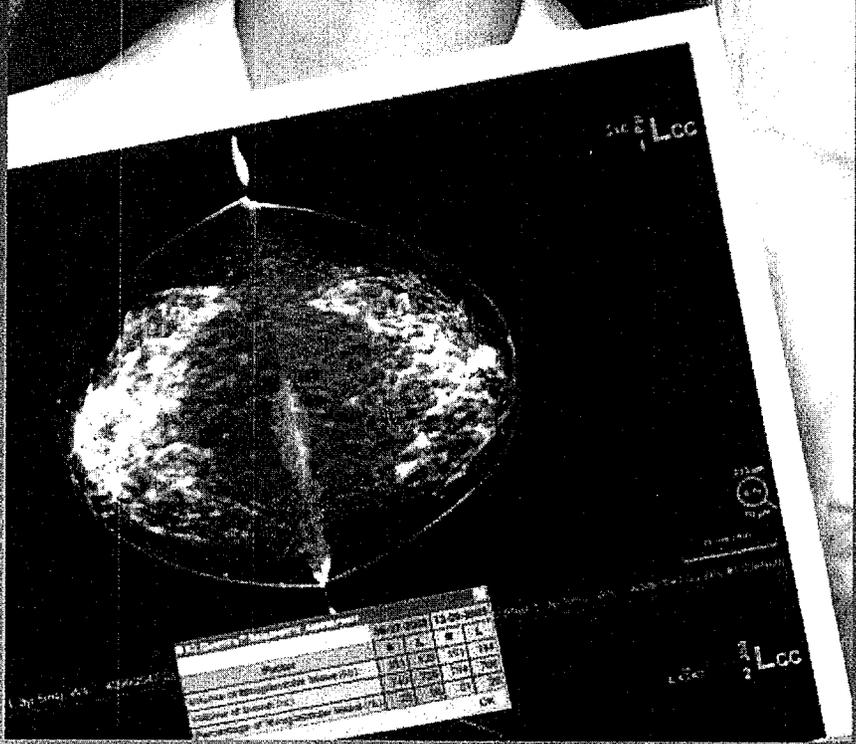
- **Most common cancer in women:
one woman in 8 by age 95 (20% <50)**
 - **5 to 10% is hereditary breast cancer
(these linked to ovarian cancer too)**

**SO- WHAT IS A MAMMOGRAM,
AND WHAT DOES BREAST
CANCER LOOK LIKE ON A
MAMMOGRAM?**



INVASIVE CANCER GROWTH





When breast cancer is detected before it has spread to the lymph nodes, the five year survival rate is

98%



MAMMOGRAPHY: THE GOOD, THE PRETTY GOOD, & THE NOT SO GOOD

- Prompt annual mammography has shown the ability to reduce the mortality rate from breast cancer in a population by 15% to 50%.
- As many as 20% of breast cancers will be missed by 2D mammography.
- Approximately 10% of women are recalled for additional workup and a significant portion prove to have no abnormality, resulting in unnecessary anxiety and cost.





NEW TOOLS IN MAMMOGRAPHY

- **Full Field Digital Mammography (“2-D”)**



NOW WE CAN “SLICE AND DICE”!

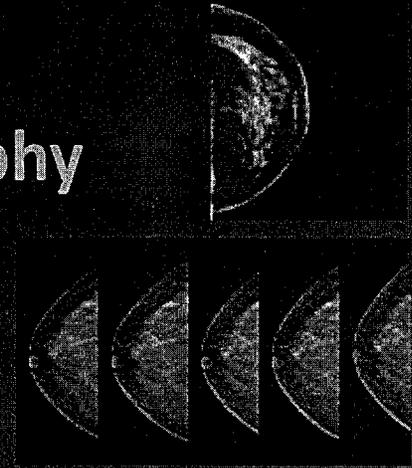
mammography now has three imaging modes available:

- Conventional 2D digital mammography

1. 3D Tomosynthesis imaging

- “Combo-mode” ... the method of choice right now

Note: A tomosynthesis screening exam consists of a digital mammogram and tomosynthesis image set.



Why Is Combo-mode Important?

For Radiologists

- Facilitates comparison to priors and images from other facilities
- Easier transition with the 2D image as a reference
- Co-registration of 2D and Tomo images under the same compression



The Value of 2D Plus Breast Tomosynthesis

Tomosynthesis Imaging vs. 2D Alone

- Breast cancer screening with tomosynthesis finds many more cancers than conventional 2D mammography¹
- Tomosynthesis gives radiologists the confidence to significantly reduce recall rates²
- **Masses, distortions and asymmetric densities are better visualized with breast tomosynthesis³**
- Skaane P, Gullien R, Eben EB, et. al. Reading time of FFDM and tomosynthesis in a population-based screening program. Radiological Society of North America annual meeting. Chicago, IL, 2011.
- FDA PMA submission P080003
- Bernardi D, Ciatto S, Pellegrini M, et. al. Prospective study of breast tomosynthesis as a triage to assessment in screening. Breast Cancer Res Treat. 2012 Jan 22 [Epub ahead of print].

AND OTHER RECENT STUDIES:



**What is the scientific
evidence that tomosynthesis
works?**





2-D CONVENTIONAL DIGITAL MAMMOGRAPHY vs 2-D PLUS 3-D TOMOSYNTHESIS

● 12,631 Screening Studies

➔ **2-D Digital Mammo alone:**

➔ **2-D + 3-D Tomosynthesis:** 8.1/1000 defect rate

➔ **Difference: 25% increase in cancer detection rate with tomosynthesis (25 more cancers)**

➔ **False Positive rate: Decreased by 15% (61/1000 vs. 53/1000) with tomosynthesis**

Skaane P, Bandos AI, Guillien R, et al. Comparison of digital mammography alone with digital mammography plus tomosynthesis in a population-based screening program. Radiology 2013, vol. 267: pp. 47-56.

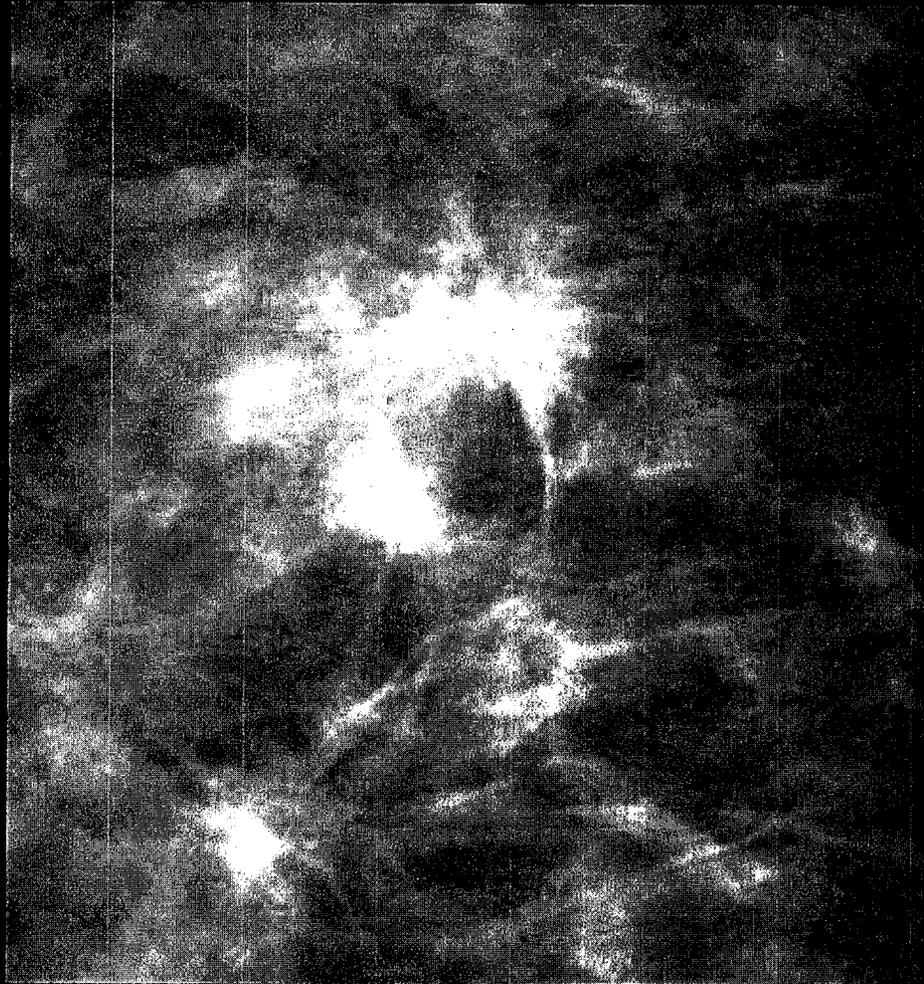


2-D CONVENTIONAL DIGITAL MAMMOGRAPHY vs 2-D PLUS 3-D TOMOSYNTHESIS

- **Multi-center study: 454,850 examinations**
 - ➔ **2-D Digital Mammo alone:**
invasive
 - ➔ **2-D + 3-D Tomosynthesis:** 5.4/1000 detect rate
(4.1 invasive cancer/1000)
 - ➔ **Difference: 29% increase in cancer detection rate with tomo**
 - ➔ **Recall rate: Decreased by 15% (107/1000 vs. 91/1000) with tomosynthesis**

Friedewald SM, Rafferty EA, Rose SL, et al. Breast Cancer Screening using Tomosynthesis in Combination with Digital Mammography. JAMA, June 25, 2014; Vol. 311 (24): 2499-2507.

Digital Mammo (2D)



Tomo Slice (3D)



**NOW WE CAN SAVE LIVES
LIKE NEVER BEFORE,**

**AND - WE CAN CALL LESS
PATIENTS BACK TO DO SO!**

(A REAL WIN-WIN SITUATION!)



