The Physical Basis of the Imminent Changes in Breast Screening

Who Am I?
- Kevin Kelly MD
- Breast Radiologist: >30 years
- Clinical Researcher in Breast US: >20 years
- Past Dir. Huntington-Hill Breast Ctr., Pasadena, CA
- Founder, Inventor & Board Chairman SonoCiné
- Science and Medicine of Breast Cancer Detection

Breast Density
- Dark fatty tissue
- White glandular tissue
- Dense means more WHITE than DARK
- Cancer WHITE on Mammograms

The Breast Cancer Problem
- ~192,370 Invasive Cancers
- ~40,170 Deaths (110/Day)
- ~40,800 Deaths in 2000

Facts
- 70% of Cancers in Dense Breasts
- 40% of Women have Dense Breasts
- ~ 50% of these Cancers NOT VISIBLE ON MAMMOGRAM
- The Others found too Large

Mammography is Inadequate in 40% of Women (70% of Breast Cancer)
Secondary Screening by US, MRI or MBI
Can find Invasive Breast Cancer at an average diameter of ~1.0 cm

MRI & MBI compared to AWBU

| MRI | $2000 comp $300 |
| MBI | $700 comp $300 |
|     | IV injection     |
|     | Double the time to do |
|     | Uncertain risk of Gd** for 20 – 40 M Women w/ Annual Injections |

Screen Women with Ultrasound

Large Clinical Trials

- ACRIN 6666 (2809 Patients) - Handheld US by Radiologist
  - 60% more breast cancers detected (12/32)
  - 20 minutes of radiologist time
- AWBU – SonoCiné (4419 Patients, 6425 tests) - Automated
  - 100% more breast cancers detected (23 of 46)
  - 67% ↑ over ACRIN
  - 200% more IBC ≤ 1cm (14 of 21)
  - 67% ↑ over ACRIN
  - 6 minutes of radiologist time – feasible for population screening

Why Find Cancers Small?

- Size Matters
- Average Cancer found by SonoCiné – 1cm
- Mammo-found Cancer in Dense Breasts – 5 times as large (volume)
- Mammo-missed Cancer in Dense Breasts – 18 times as large (volume)

Price of Breast Cancer

<table>
<thead>
<tr>
<th>Cancer &gt; 1.5 cm</th>
<th>Cancer ≤ 1.0 cm</th>
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<tbody>
<tr>
<td>Surgery</td>
<td>$ 5,000</td>
</tr>
<tr>
<td>Radiation</td>
<td>$ 20 to 40,000</td>
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<tr>
<td>Chemotherapy</td>
<td>$ 40 to 100,000</td>
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<tr>
<td>Follow up</td>
<td>$ 6,000</td>
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<tr>
<td>Total</td>
<td>$ 60 to 150,000</td>
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- Total Direct Medical Costs Savings in U.S. ~ $15 Billion
- Indirect Costs Savings (Work & Family) – Many Billions
- Lives Saved Annually ~ 30,000
Why Does AWBU Do So Well?

- Designed to Maximize Detection of Small Cancers
- Utilizes Motion to Increase Detection
- Standardized and Methodical
- Optimizes Viewing Conditions

2-D Automated Whole Breast US

- Compatible with any High-end Ultrasound Machine
- Room & US Available for Other Uses, when no AWBU
- Images the Radiologist Knows – No Learning
- Inter-image Distance of 800μ (½ sec to see 5 mm Ca)
- Complete Coverage of Both Breasts Once
- Rapid Examination Time (~15 – 20 minutes)
- Sonographer-Controlled Probe Pressure & Angle
- Same as Handheld Scan with Greater Image Density
- Small Field of View, No Eye Movement during Review
- Readable without Patient Present (No Distractions)
- Further Image Optimization with ‘Auto-normalize’
- Control of Image Size, Speed, Brightness & Contrast
- Read in 2-D mode as Ciné Loop in 5 – 7 minutes
- Storage of all images: PACS, Network and/or CD
1957
15,000 women dying of cervical cancer.
1st national call for screening

2011
≤ 4,000 dying
with DOUBLE the female population
87% ↓ deaths based on present population

Dr. George Papanicolaou
1st Pap Smear Lecture 1923
Definative Article 1928

1928 to 1957
~500,000 women died
before national implementation of the Pap Smear.

What’s Happened between Then & Now?

Automated Whole Breast Ultrasound
– The community is aware of the need

Grassroots Legislative Efforts to Require Density Information Reporting

Connecticut: Public Act 09-41 passed June, 2009 - became law October 1, 2009
New York: S-8488 introduced to NY State Senate killed in committee
California: Senators Manning & Semintas have sponsored bill. Bill passed Senate 15 to 0. Passed multiple Assembly Committees. May be law by 1/2012
Massachusetts: Representative Kathi Anne Reinstein will introduce State bill in 2011 session
Kansas: Representative Pat Callison met with Dr. Marc Incoard and Dr. Nancy Cappello in Oct, 2010. Representative Callison is working with Lieutenant Governor Jeff Colyer to discuss, draft breast Density Inform legislation
New Hampshire: Representative Karen Hutchinso will be sponsoring a Breast Density Inform bill in the NH assembly

If something so simple as 2D-AWBU can have such a profound effect on breast cancer, why aren’t we already doing it everywhere?