

The Evidence Behind Screening Recommendations for Breast Cancer

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May 21, 2010



“ . . . If we did not respect the evidence, we would have very little leverage in our quest for the truth.”

Carl Sagan

THE DEVELOPMENT OF EVIDENCE FOR BREAST CANCER SCREENING GUIDELINES

What is evidence?

“...the available body of facts or information indicating whether a belief or proposition is true or valid.”

- Evidence-based practice integrates:
 - Data or scientific evidence
 - Professional experience
 - Input from community members and other stakeholders

Source: Brownson RC, Baker EA, Leet TL, Gillespie KN. *Evidence-Based Public Health*. New York: Oxford University Press; 2003

Why use evidence-based practices?

- Resources are limited.
 - We should apply practices that have been shown -- in well-designed studies -- to be effective.
- Applying the best available evidence, moderated by patient circumstances and preferences, can:
 - Increase the quality of clinical judgments;
 - Inform patient's decisions;
 - Facilitate delivery of more cost-effective care;
 - Improve medical and health outcomes.

Source: Cochrane A. Effectiveness and Efficiency: Random Reflections on Health Services. London, Nuffield Provincial Hospitals Trust) and Cochrane Collaboration (2003) <http://www.cochrane.org/cochrane/archieco.htm>

How do we develop an evidence base?

- Knowledge synthesis
 - Single studies
 - Peer review
 - Systematic review and meta-analysis
 - Expert evaluation and assessment of clinical/public health relevance

Steps in Developing a Systematic Review

- Develop an analytic framework
- Systematic search of relevant literature
- Dual review of abstracts and full text articles
- Data abstraction for evidence tables
- Dual rating of quality of each article
- Dual “grading” of strength of evidence
- Resolve disagreements by consensus
- Vet findings with independent panel of experts

Source: Holden DJ, Harris R, Porterfield DS, et al. Enhancing the Use and Quality of Colorectal Cancer Screening. RTI International–University of North Carolina Evidence-based Practice Center, Contract No. 290-2007-10056-I. Rockville, MD: Agency for Healthcare Research and Quality. February 2010

Systematically-reviewed Breast Cancer Screening Procedures

- Breast Self Exam
- Clinical Breast Exam
- Film Mammography
- Digital Mammography
- **MRI**
 - For high risk women

4 Main Sources of Breast Cancer Screening Guidelines

- National Institute for Health (NIH) Consensus Conference
 - 1997 about age for starting mammography
- American Cancer Society (ACS)
 - 2003 about BSE, CBE and mammography
 - 2009 about MRI for high risk women
- Cochrane Collaborative
 - 2008 about BSE, CBE and mammography
- US Preventive Services Task Force (USPSTF)
 - 2002 and 2009 about BSE, CBE and mammography

**USPSTF: ONE IMPORTANT INTERPRETATION
OF THE EVIDENCE**

How the USPSTF “Grades” Evidence

Grade Definition	Suggestions for Practice
A The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Three Levels of Certainty Regarding Net Benefit High, Moderate and Low

Level of Certainty	Description
High	<p>The available evidence usually includes <i>consistent results</i> from <i>well-designed, well-conducted studies</i> in <i>representative primary care populations</i>.</p> <p>These studies assess the effects of the preventive service on health outcomes. <i>This conclusion is therefore unlikely to be strongly affected by the results of future studies.</i></p>

Levels of Certainty Regarding Net Benefit

Level of Certainty	Description
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes but <i>confidence in the estimate is constrained</i> by such factors as:</p> <ul style="list-style-type: none">•The number, size, or quality of individual studies•Inconsistency of findings across individual studies.•Limited generalizability of findings to routine primary care practice.•Lack of coherence in the chain of evidence. <p><i>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</i></p>

Levels of Certainty Regarding Net Benefit

Level of Certainty	Description
Low	<p>The <i>available evidence is insufficient</i> to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none">•The limited number or size of studies.•Important flaws in study design or methods•Inconsistency of findings across individual studies.•Gaps in the chain of evidence.•Findings not generalizable to routine primary care practice.•Lack of information on important health outcomes. <p>More information may allow estimation of effects on health outcomes.</p>

Determining Your Risk

- Risk is unique to an individual
- Most guidelines apply to average risk individuals
- You can learn more about your risk compared to other women using the Breast Cancer Risk Assessment Tool (BCRA)
- BCRA is an interactive tool designed by scientists at the National Cancer Institute and the National Surgical Adjuvant Breast and Bowel Project
- Find it here:

<http://www.cancer.gov/bcrisktool/Default.aspx>

USPSTF Recommendations for Breast Cancer Screening, 2009

- Recommends biennial screening mammography for women aged 50 to 74.
 - Grade: [B recommendation](#)
- Before the age of 50, biennial screening mammography should be an individual decision that takes into account patient context and values regarding specific benefits and harms.
 - Grade: [C recommendation](#)
- Recommends against teaching BSE.
 - Grade: [D recommendation](#)
- Concludes the current evidence is insufficient to assess the additional benefits and harms of:
 - Screening mammography in women 75 years or older;
 - CBE beyond screening mammography in women 40 years or older;
 - Digital mammography or MRI instead of film mammography.
 - Grade: [I statement](#)

COMPARISON OF EVIDENCE-BASED SCREENING RECOMMENDATIONS

Mammograms: How Much Agreement Over Time? Across Guideline Groups?

Year	Organization	Recommendation
1997	NIH	Start at age 50. “Universal screening not warranted” for women 40-49.
2002	USPSTF	Start at age 40. Screen every 1-2 years.
2003	ACS	Start at age 40. Screen every 1-2 years.
2009	USPSTF	<ul style="list-style-type: none">• Recommend to women 40-49 if warranted on basis of patient context and values regarding benefits and harms.• All women 50-74 should be screened every 1-2 years.• For women 75+ insufficient evidence.

Mammography Screening: Uncertain Evidence for Younger Women

- Fairly consistent message for women 50-74 years
 - Have a mammogram (at least) every 2 years
- Inconsistent message for younger women
- Why do recommendations vary by age?
 - Breast cancer incidence increases with age.
 - Women 60 years and older account for more than half of all new cases.
 - Greater recognition (some new data) on the potential harms associated with screening younger women

What is the harm in screening younger women?

- Since 1992, knowledge has increased about the burden of false positive screening tests
 - The burden falls most heavily on younger women.
- Specific harms of false positive mammography are
 - Psychological
 - Unnecessary imaging/biopsies

BSE Guidelines: How Much Agreement Over Time? Across Guideline Groups?

Year	Organization	BSE Recommendation
2002	USPSTF	Evidence is lacking. The balance of benefits and harms cannot be determined.
2003	ACS	Evidence is lacking and mostly inferential. ACS no longer recommends monthly BSE; however women should be informed of potential benefits, limitations, and harms . Women should receive instruction if they choose to do BSE.
2007	Cochrane	Not recommended. "Data do not suggest beneficial effect, but do suggest increased harm (i.e., increase in detection and biopsy of benign lesions.)"
2009	USPSTF	Teaching BSE not recommended

BSE Screening Recommendations: Summary

- The research evidence, which has been accumulating and fairly consistent since 1992, contradicts widely held beliefs.
 - To date, research evidence has not shown BSE to be a beneficial screening procedure.
- Harms may outweigh benefits.
 - If BSE is taught, potential risks should be taught, as well as presumed benefits.

Advocacy and Health Care Agencies Struggle to Reconcile Evidence and Beliefs

“There is no evidence on the effect of screening through BSE. However, the practice of BSE has been seen to empower women, taking responsibility for their own health.

Therefore, BSE is recommend for raising awareness among women at risk rather than as a screening method.”¹

¹World Health Organization

<http://www.who.int/cancer/detection/breastcancer/en/print.html>

Advocacy and Health Care Agencies Struggle to Reconcile Evidence and Beliefs

“We cannot afford to waste our limited resources on a public health intervention that has not been shown effective, particularly when there is evidence that the intervention may be causing harm...NBCC is not recommending that women stop practicing BSE. The decision of whether or not to practice BSE must be made individually. However, if a woman wishes to be taught BSE, she must be informed of the potential risks and benefits.

Because BSE has been aggressively promoted for so many years, NBCC recognizes that the above recommendations may be difficult to accept. **However, the Coalition would rather women know the truth about BSE than give them false information or a false sense of security.**²

²National Breast Cancer Coalition Fund, July 2008

Evidence-based Breast Cancer Screening: Supports

- Mammography is routinely recommended by health care providers.
 - For example, mammography is more widely recommended than colorectal cancer screening, which is the second leading cause of cancer death and, to a great extent, preventable.
- Programmatic efforts (for example, BCCCP and Komen Affiliates) help ensure that evidence-based screening guidelines are applied to under- and uninsured women
- An advocacy movement that continues to raise awareness and link women, especially in some hard-to-reach communities, to screening services and care.

Evidence-based Breast Cancer Screening: The Challenges

- Good, but still inadequate screening technology
 - Not only to detect smaller abnormalities in dense tissue
 - Also, to assess how much risk an abnormality poses to a woman's health and the most effective ways to treat or monitor potential problems
- Insufficient knowledge about how to help women and their providers weigh potential benefits and harms of breast cancer screening
- More effective treatment

**“The best is the
enemy of the good”
-Voltaire**

**The problem of randomized trials and
parachutes....**

The effectiveness of parachutes has not been subjected to rigorous evaluation by using randomized controlled trials.... We think that everyone might benefit if the most radical protagonists of evidence based medicine organized and participated in a double blind, randomized, placebo controlled, crossover trial of the parachute.



Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials



www.thecommunityguide.org



www.ahrq.gov/clinic/uspstfix.htm

