

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. letter	Dr Duvall to Dr Varmis re background correspondence (2 pages)	05/01/1995	b(6)
001b. letter	Linda Ruiz to Dr Duvall re response (2 pages)	04/12/1995	b(6)
001c. letter	Dr Duvall to Linda Ruiz re thank you (1 page)	04/17/1995	b(6)
001d. letter	Maryland Medicare Part A to patient re corrected bill (1 page)	04/05/1995	b(6)

COLLECTION:

Clinton Presidential Records
First Lady's Office
Jennifer Klein
OA/Box Number: 13530

FOLDER TITLE:

Mammogram Frequency [1]

2014-0536-S

kc1561

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

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MAY 31 1995

Charles P. Duvall, M.D.
American Society of Internal Medicine
2011 Pennsylvania Avenue, N.W., Suite 800
Washington, DC 20006-1808

Dear Dr. Duvall:

Thank you for your inquiry regarding appropriate breast cancer screening intervals. Dr. Varnus has asked me to respond since the issue of screening effectiveness falls within the purview of this scientific program.

A large volume of scientific information has become available regarding the effectiveness of breast cancer screening by mammography in the past three years. The National Cancer Institute (NCI) reviewed its Working Guidelines on Screening for Breast Cancer in light of this new information. Following extensive discussion, the Division of Cancer Prevention and Control's Board of Scientific Counselors voted to discontinue the NCI guidelines in favor of statements of scientific knowledge issued through the Physician's Data Query (PDQ). The National Cancer Advisory Board subsequently endorsed this decision. Other federal organizations, such as the Agency for Health Care Policy Research, were felt to be better suited by mission and staffing to deal with guidelines development; and the Health Care Financing Agency (HCFA) determines levels of payment for medical procedures funded by the federal government.

New results from eight randomized, controlled screening trials in Sweden, the United Kingdom, and Canada were reported in the scientific literature in 1993. There were reports from individual trials and overview analyses combining the results from all trials. The data and findings from these trials were critically reviewed at the NCI's International Workshop on Screening for Breast Cancer, February 24-25, 1993, and the Workshop Report published in the Journal of the National Cancer Institute (Fletcher, et al., JNCI, Vol. 20, No. 20, October 20, 1993).

Screening intervals from 12 to 33 months were employed in the trials. The benefits of screening, mortality reductions of 30-35 percent were quite consistent across trials for women aged 50 to 69 years irrespective of screening interval. To quote from the Fletcher report, "Because the effectiveness of screening women aged 50 or older varied little across the studies, there is little evidence to show that shorter screening intervals were more effective in reducing breast cancer mortality." This conclusion remains as valid in 1995 as it was in 1993, so far as we can determine from the literature.

Page 2 -- Dr. Duvall

One of the most important screening issues we face today is encouraging women of 50 years and older to undergo regular breast cancer screening. It has been reported in a number of studies that a substantial proportion of women in this age group are not having mammograms even at biennial intervals. Yet the weight of clinical trial results assures us that these are the women who will benefit most from screening at intervals of one to two years.

Thank you again for the opportunity to share with you some of what has been learned regarding the effectiveness of breast cancer screening, due in part to deliberations sponsored by the NCI.

Sincerely yours,



Peter Greenwald, M.D.
Director
Division of Cancer Prevention
and Control

M E M O R A N D U M

To: Jennifer Klein
From: Karen Guss
Date: May 22, 1995
Re: Recommended frequency of mammography screening.

Women under age 40:

There is a nearly universal belief that women in this age group should not receive regular mammography screening. The American Cancer Society used to recommend that women get a "baseline mammogram" at approximately age 35, but they no longer do so. Some advocates in the African-American women's health community believe that African-American women in this age group should be screened because they are at higher risk of developing breast cancer than are younger white women.

Women aged 40-49:

This is a controversial topic, with recent articles having been published on both sides of the issue. The National Cancer Institute (NCI) recommends that women in this age group make individual determinations, in consultation with their physicians, whether to get regular mammograms. The United States Preventive Services Task Force and the American College of Physicians, among other groups, do not recommend screening in younger women; the American Cancer Society and the American College of Radiology are two of the organizations in favor of screening women in this age group.

Women aged 50+:

Here, everyone is in agreement that women should receive regular mammograms once they reach age 50 (although it is less clear when the regular screening should stop (see below)). The controversy is whether women should be screened every year or every other year.

NCI recommends screening "every 1 to 2 years" because clinical trials show essentially the same mortality reduction resulting from bi-annual as from annual screening. The American Cancer Society and several other groups recommend annual screening.

Studies of the efficacy of regular mammography have not been performed on women over the age of 69. However, most experts, including NCI, believe that the results of studies on women aged 50 to 69 do apply to women aged 70 and over who are in reasonably good health and who are expected to live long enough to warrant an effort to detect breast cancer early.

The ASIM letter:

Dr. Duvall states that "he thinks" that NIH and CDC recommend annual screening for women aged 65 and older. However, CDC does not have a position on screening frequency, and, as stated above, NIH (through NCI) has stated that bi-annual screening is appropriate. Accordingly, Medicare coverage of bi-annual screening mammograms (remember that more frequent diagnostic screening is also available under certain conditions) is consistent with the NIH guidelines. In fact, the Health and Human Services Secretary is required to establish Medicare's coverage rules with respect to mammography in consultation with NCI.

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Jennifer Klein
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Improving Compliance With Breast Cancer Screening in Older Women

Results of a Randomized Controlled Trial

Carla J. Herman, MD, MPH; Theodore Speroff, PhD; Randall D. Cebul, MD

Background: To compare three approaches for improving compliance with breast cancer screening in older women.

Methods: Randomized controlled trial using three parallel group practices at a public hospital. Subjects included women aged 65 years and older (n=803) who were seen by residents (n=66) attending the ambulatory clinic from October 1, 1989, through March 31, 1990. All provider groups received intensive education in breast cancer screening. The control group received no further intervention. Staff in the second group offered education to patients at their visit. In addition, flowsheets were used in the "Prevention Team" group and staff had their tasks redefined to facilitate compliance.

Results: Medical records were reviewed to determine documented offering/receipt of clinical breast examination and mammography. A subgroup of women without previous clinical breast examination (n=540) and without previous mammography (n=471) were analyzed to determine the effect of the intervention.

During the intervention period, women without a previous clinical breast examination were offered an examination significantly more often in the Prevention Team group than in the control group, adjusting for age, race, and comorbidity and for physicians' gender and training level. The patients in the Prevention Team group were offered clinical breast examination (31.5%) more frequently than those in the patient education or control groups, but this was not significant after adjusting for the above covariates. Likewise, mammography was offered more frequently to patients in the Prevention Team and in the patient education group than to patients in the control group, after adjusting for the factors above using logistic regression.

Conclusions: The results provide support for patient education and organizational changes that involve nonphysician personnel to enhance breast cancer screening among older women, particularly those without previous screening.

(*Arch Intern Med.* 1995;155:717-722)

From the Department of Medicine, Division of Geriatric Medicine, University Hospitals of Cleveland (Dr Herman); Department of Medicine, Division of General Internal Medicine at MetroHealth Medical Center (Drs Speroff and Cebul) and Department of Epidemiology and Biostatistics (Drs Speroff and Cebul), Case Western Reserve University School of Medicine, Cleveland, Ohio. Dr Herman is now with the University of New Mexico, Albuquerque.

FIFTY PERCENT of breast cancers occur in women older than 60 years. The incidence of breast cancer has been increasing during the last 30 years, while the mortality has remained unchanged.¹ A growing body of scientific evidence has shown that breast cancer screening for asymptomatic women aged 50 through 74 years decreases mortality and, using decision analysis, it is estimated that it may remain beneficial for healthy women through their 80s.²⁻⁵ The screening modalities most frequently employed have been mammography and clinical breast examination (CBE).

Compliance with recommended screening is an important issue for older women. Although the percentage of older women undergoing one-time mammography screening has increased to 67% since

1987, the number of women obtaining regular screening remains at 33%.⁶ Many barriers exist that have prevented optimum screening for breast cancer: physician and patient attitudes,⁷⁻¹² accessibility, lack of information, and competing concurrent acute medical conditions.¹³⁻¹⁵ Women with lower income, less education, and minority women have traditionally underused mammography.¹⁶⁻¹⁹

Attempts to increase breast cancer screening have included public education programs, a variety of physician office prompts, and physician education.²⁰⁻³⁴ In general, however, successful

*See Materials and Methods
on next page*

Clinical Strategies for Breast Cancer Screening: Weighing and Using the Evidence

Russell Harris, MD, MPH, and Linda Leininger, MD, MPH

■ When balancing the benefits of screening women for breast cancer against the harms and costs of such screening, one needs to consider the risk for dying of breast cancer, the relative reduction in that risk that will result from screening women in different age groups, and the harms and costs associated with screening. Seven randomized controlled trials provide evidence of the relative risk reduction that results from screening women in different age groups; other studies estimate the harms and costs of screening. These studies indicate that the benefit of screening, expressed as the absolute number of lives extended per 1000 women screened, increases with age and that the harm of screening, expressed as the number of follow-up procedures per cancer detected, decreases with age. Thus, the tradeoff between the benefits and the harms and costs of screening is better for older than for younger women. Because there is no clear cut-point for determining when benefits outweigh harms and costs, it is important to involve women in discussions of breast cancer screening. The women who most need to be involved are those for whom the benefits of screening clearly outweigh the harms and costs and those for whom the benefits and the harms and costs constitute a "close call." For women in both groups, the physician should routinely raise the issue of screening, first eliciting the patient's perceptions and then providing information and discussion about the risk for breast cancer and about the benefits and the harms and costs of screening. Furthermore, the physician should encourage the patient to use her own values to weigh the benefits against the harms and costs, pointing out biases in reasoning and minimizing socioeconomic barriers. Finally, when the benefits obviously outweigh the harms and costs, the physician should make a clear recommendation for screening.

Screening for any disease is a seductive activity. Who could oppose finding disease in an early stage, before symptoms appear? This may be one reason why screening is omnipresent in medical care. It is also one of the reasons why it is so difficult to explain to patients that screening is a "two-edged sword," that it has the potential to injure as well as to help (1). From this perspective, it is particularly relevant to examine the issue of screening for breast cancer in an "In the Balance" article. Only by weighing the benefits against the harms and costs of screening can we, patients and physicians alike, make a rational decision about who should be screened and how often.

The question of who should be screened for breast cancer is not simply an academic debate. The real problem is a practical one: What do we say to the patient we will see this afternoon? How do we explain her risk for breast cancer, the effect that screening will have on that risk, and the harms and costs of screening? How do we help her make an informed decision? We will focus on this issue by reviewing the risk for breast cancer, weighing the evidence of benefits and of the harms and costs of screening, and offering some preliminary ideas about what to say to our patients.

The Risk for Breast Cancer

Age is the most important risk factor for breast cancer. The risk for being diagnosed with invasive breast cancer in the coming year increases with age up to 75 or 80 years of age, increasing more than 15-fold between 30 and 70 years of age (Figure 1) (2). For a woman aged 30 to 34 years, the risk for being diagnosed with breast cancer in the coming year is about 2.7 per 10 000 women; for a woman aged 70 to 74 years, it is about 43.4 per 10 000 women.

Another common way of expressing the risk for being diagnosed with breast cancer is lifetime risk at a given age. As most people know, a white woman's lifetime risk at birth for being diagnosed with invasive breast cancer has increased from 1 in 10 to about 1 in 8 in the past 10 to 20 years (2, 3). The lifetime risk at birth for a black woman is about 1 in 11. The lifetime risk for being diagnosed with breast cancer remains about the same until 40 years of age when, because fewer years of life remain in which a woman can be diagnosed with breast cancer, the lifetime risk actually declines. At 60 years of age, a white woman's risk for being diagnosed with breast cancer during the rest of her life is about 1 in 10, and at 70 years of age, her risk is about 1 in 14. For a black woman at 70 years of age, the lifetime risk is about 1 in 20 (2, 3).

The problem with these expressions of risk is that screening does not reduce the risk for being diagnosed

Ann Intern Med. 1995;122:539-547.

From the Department of Medicine and the UNC-Lineberger Comprehensive Cancer Center, University of North Carolina School of Medicine, Chapel Hill, North Carolina. For current author addresses, see end of text.

SPECIAL ARTICLE

MEDICARE COVERAGE, SUPPLEMENTAL INSURANCE, AND THE USE OF MAMMOGRAPHY BY OLDER WOMEN

JAN BLUSTEIN, M.D., PH.D.

Abstract Background. On January 1, 1991, the Medicare program began offering reimbursement for screening mammography every two years. This study examined the use of mammography in women covered by Medicare during the first two years that the screening benefit was offered.

Methods. Medicare bills for 1991 and 1992 from a nationally representative sample of 4110 women 65 years of age or older were examined to determine the degree of compliance with recognized guidelines for screening mammography and the extent to which the use of mammography was associated with having supplemental insurance, which shields patients from the out-of-pocket costs associated with using Medicare benefits.

Results. A total of 36.9 percent of older U.S. women had mammography during the first two years of the Medicare benefit for screening mammography. Only 14.4 percent of the women lacking supplemental insurance had mammography, as compared with 44.7 percent of those with employer-sponsored supplemental insurance, 40.1

percent of those with self-purchased supplemental insurance, and 23.9 percent of those with Medicaid supplemental insurance. These differences persisted in the stratified and multivariate analyses. As compared with women lacking supplemental insurance, women with employment-based supplemental insurance were more likely to undergo mammography (adjusted odds ratio, 3.03; 95 percent confidence interval, 2.17 to 4.23), as were women with self-purchased supplemental insurance (adjusted odds ratio, 2.97; 95 percent confidence interval, 2.13 to 4.15) and women with Medicaid supplemental insurance (adjusted odds ratio, 1.99; 95 percent confidence interval, 1.30 to 3.07).

Conclusions. The use of mammography was substantially below recommended levels during the first two years of Medicare coverage for screening mammography. Women lacking supplemental health insurance were at particularly high risk of failing to undergo mammography. Requiring copayments for preventive services is an obstacle to the effective mass screening of older women for breast cancer. (N Engl J Med 1995;332:1138-43.)

BREAST cancer is the most common cancer in women, and its incidence increases with age.¹ Since the late 1970s and early 1980s, key organizations — including the National Cancer Institute and the American Cancer Society — have recommended regular screening mammography for women more than 50 years of age.² However, it was not until January 1, 1991, that the Medicare program instituted coverage for biennial screening mammograms.²

Many Medicare beneficiaries have supplemental health insurance — employer-sponsored, individually purchased (so-called Medigap), or Medicaid.³ To varying degrees, these supplemental policies shield patients from the copayments, deductibles, and “balance bills” associated with using Medicare-reimbursed services.³⁻⁶ Out-of-pocket health care costs can be substantial for older people lacking supplemental insurance, many of whom have low incomes, do not qualify for Medicaid insurance, and are unable to purchase private supplemental plans.^{3,6} For these patients, the extra costs associated with the use of Medicare-reimbursed services may keep them from taking advantage of Medicare benefits, particularly for services that are perceived as being discretionary.

This report explores the extent to which supplemental insurance was associated with the use of mammography by older women during the years 1991 and 1992.

on the basis of data from the Medicare Current Beneficiary Survey. The survey provides a detailed picture of the personal, social, and medical circumstances of a large, nationally representative sample of older women.

Several investigators have demonstrated that health insurance is an important determinant of the use of mammography. For example, women with health insurance are more likely to have mammography than are women who are uninsured,⁷ and women enrolled in prepaid health plans are more likely to have mammography than are women receiving their care in the fee-for-service sector.⁸ Preliminary data from the 1992 National Health Interview Survey suggest that supplemental insurance may be an independent predictor of the use of various cancer-screening services by older women.⁹ However, a host of other patient characteristics are associated with the use of mammography, including having a usual source of care, higher income, white race, higher educational attainment, and younger age. Patients’ knowledge and attitudes about preventive care¹⁰⁻¹³ as well as physicians’ behavior^{10,14,15} are also important determinants of whether mammography is used. The analysis reported here incorporates measures reflecting some of these important determinants of mammography use to estimate the effect of supplemental insurance.

METHODS

Study Population

The Medicare Current Beneficiary Survey is a probability survey based on a multistage, stratified cluster sample of Medicare beneficiaries in the 50 states, the District of Columbia, and Puerto Rico.¹⁶ Both community-dwelling people and people living in long-term-

From the Division of General Medicine, College of Physicians and Surgeons, and the Division of Health Policy and Management, School of Public Health, Columbia University, New York. Address reprint requests to Dr. Blustein at the Division of General Medicine, PH9 East, College of Physicians and Surgeons, 630 W. 168th St., New York, NY 10032.

Supported by a grant from the Commonwealth Fund.



HEALTH CARE FINANCING ADMINISTRATION



456-2878

ADDRESSEE: <i>Jennifer Klein</i>		FROM: <i>Ruth King</i> OFFICE OF THE ADMINISTRATOR 200 INDEPENDENCE AVE., S.W. ROOM 314G WASHINGTON, DC 20201 PHONE: 202-690-6726 FAX : 202-690-6262	
PHONE: _____			
TOTAL PAGES: <i>GT2</i>	ADDRESSEE'S FAX MACHINE NUMBER: <i>456-2878</i>	DATE:	
REMARKS:			

MAMMOGRAPHY ESTIMATES

Current policy: Medicare helps pay for screening mammograms once every two years for women age 65 and older. Coverage for beneficiaries under age 65 varies according to the age and risk category of the patient. Mammograms currently are subject to the Part B deductible and coinsurance.

Proposal 1: To eliminate cost-sharing on the screening mammography benefit.

- o Effective 1/1/97.
- o Estimates reflect the deductible and coinsurance for screening mammograms only; however, mammograms used for screening purposes are commonly miscoded as diagnostic mammograms. Eliminating cost-sharing for diagnostic mammograms is shown separately.
- o The screening fee used in the estimates includes the cost of biopsies and other ancillary services resulting from false positives. The costs of eliminating cost-sharing were computed for the mammography screening only.
- o Pay-as-you-go estimates from OACT:

5-year	FY 1997-2001	\$90m
7-year	FY 1997-2003	\$130m
10-year	FY 1997-2006	\$205m

Proposal 2: To cover annual mammography screenings with current deductibles and coinsurance.

- o Effective 1/1/97.
- o Pay-as-you-go estimates from OACT:

5-year	FY 1997-2001	\$245m
7-year	FY 1997-2003	\$370m
10-year	FY 1997-2006	\$580m

Proposal 3:

To cover annual mammography screenings with no cost-sharing.

- o Effective 1/1/97.
- o Pay-as-you-go estimates from OACT:

5-year	FY 1997-2001	\$380m
7-year	FY 1997-2003	\$585m
10-year	FY 1997-2006	\$930m

Addendum:

Additional cost of eliminating cost-sharing for diagnostic mammograms.

- o Effective 1/1/97.
- o Pay-as-you-go estimates from OACT:

5-year	FY 1997-2001	\$175m
7-year	FY 1997-2003	\$265m
10-year	FY 1997-2006	\$420m

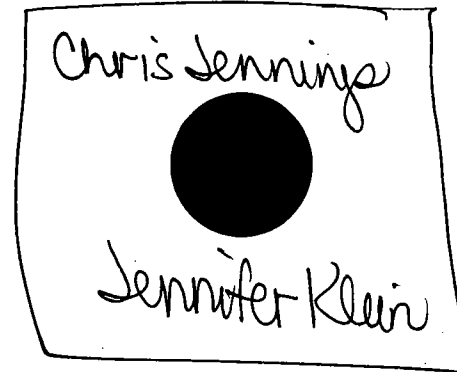
FROM THE OFFICE OF CABINET SECRETARY

202-456-2572

Date: 10/26/94

Response Needed by: N/A

- | | |
|---|---|
| ☐ Joan Baggett | ☐ Mack McLarty |
| ☐ Erskine Bowles | ☐ Abner Mikva |
| ☐ Rahm Emanuel | ☐ Dee Dee Myers |
| ☐ Mark Gearan | ☐ Jack Quinn |
| ☐ Pat Griffen | ☐ Leon Panetta |
| ☐ Marcia Hale | ☐ John Podesta |
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| ☐ N. Hernreich | ☐ Bob Rubin |
| ☐ Harold Ickes | ☐ Alice Rivlin |
| ☐ Anthony Lake | ☐ G. Stephanopoulos |
| ☐ Bruce Lindsey | ☐ Billy Webster |
| ☐ Katie McGinty | ☐ M. Williams |



Remarks:

Urgent: Please see attached wire story regarding NIH study linking (supposedly) abortions + breast cancer

-Jen.

Response:

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

26-Oct-1994 02:26pm

TO: Carol H. Rasco
FROM: Jennifer M. O'Connor
Office of Cabinet Affairs
CC: Jeremy D. Benami
SUBJECT: Abortion story out today

FYI --

HHS just called to tell me there are a few stories in Seattle papers today and 1 wire story today that say that an NIH study shows that young women who have abortions are more likely to get breast cancer. It also supposedly shows that the likelihood of breast cancer doubles when the woman has a second abortion. HHS is talking to NIH to see if there is truth to the report, and they will send the clips/ talking points when they get them. (They don't have the clips yet because they were alerted to the story by Kate Michelman).

v50933exec

r w AP-Abortions-Cancer 10-26 0324

^AP-Abortions-Cancer, 300(

^Study Finds Abortion Increases Risk Of Breast Cancer(

^By PAUL REGER=

^AP Science Writers=

WASHINGTON (AP) - Women aged 45 or younger who have undergone an abortion are 50 percent more likely to develop breast cancer than other women that age, according to a study released today.

The study, by a team at the Fred Hutchinson Cancer Center in Seattle, is based on interviews with 845 breast cancer patients and 961 women of the same age group who were healthy.

Using data from the interviews, researchers compared the reproductive history of the two groups and found that induced abortions appear to increase the risk of breast cancer by about 50 percent.

"This increased risk did not vary by the number of induced abortions or by the history of a completed pregnancy, but it was higher if the abortion was performed ages younger than 18 years," according to a summary of the study by the Journal of the National Cancer Institute, which will publish the research next week.

There was no breast cancer risk found for abortions that occurred spontaneously, the study said.

An editorial in the Journal by Lynn Rosenberg said that the study, led by Janet R. Daling, was carefully designed and conducted, but that additional research is needed before a proven link between abortion and breast cancer can be drawn.

The editorial also noted that some earlier studies have failed to find a link between induced abortions and breast cancer.

Both Rosenberg and Daling pointed out that a 50 percent increase in risk is considered small in epidemiology and that statistical distortions are enhanced in such studies when the detected risk is small.

Daling and her colleagues note that the study limitations include the possibility of reporting inaccuracies, particularly among the health group that was interviewed, and the inability to validate whether abortions were spontaneous or induced.

APWR-10-26-94 1031EDT(

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Room 713E, 200 Independence Avenue, SW

Washington, DC, 20201

tel (202) 401-7736

fax (202) 690-5432

fax t r a n s m i t t a l

to: Jennifer Klein

fax #: 456-2878

from: Lisa Simpson, MB, BCh, MPH

date: 3/8/94

re: ime

pages: , including this cover sheet

NOTES: Here it is - hope it meets your needs. We are all working on the side by side for benefits.
Apparently AGI is releasing the results of a study on the coverage of abortion and other services by plans tomorrow - it is embargoed til 2:00 - I am getting a copy for us (Most plans cover...)

As far as mammograms are concerned, other than the data you have...

42 states mandated coverage of mammograms in 1991;

Institute on women's policy research is looking at costs of specific preventive services for women;

KFF is also funding that institute to look at how women get health insurance and the impact of various policies - should be out next month.

Even on the AGI study they only asked about whether they cover mammography - not with how much cost sharing, or how often.

Finally, we (HHS) is currently doing an employer survey on insurance coverage, but again, the level of information on mammography just won't be there.

Manon -

Any ideas on finding out more on this

Early Detection of Breast Cancer and Health Care Reform

The Congressional Women's Caucus is right to call for a comprehensive benefits package spelled out in law, and for preventive care focusing on early detection and treatment of breast cancer.

Women are increasingly at risk for life-threatening illnesses such as breast cancer, ovarian cancer, and heart and lung disease, yet still anchor the bottom of our medical research agenda. Of all the health problems women face, however, breast cancer is one of the deadliest:

- One in nine women in the U.S. will develop breast cancer in her lifetime. (National Breast Cancer Coalition)
- 2.6 million women in the U.S. have breast cancer today, and this year another 182,000 American women will be diagnosed with the disease, approximately one woman every three minutes. (National Breast Cancer Coalition)

The Health Security Act addresses women's health -- and the threat of breast cancer -- aggressively and comprehensively, guaranteeing all women coverage, regardless of whether they are healthy or sick, married or single, working or unemployed, wealthy or low income. **And the President's approach will provide unprecedented coverage of preventive care, including mammography. It will cover a whole schedule of preventive screenings, tests and check-ups at no cost, protection available in only a few of today's insurance policies.**

Coverage of Mammograms and other preventive services under The Health Security Act:

- **Coverage for all women:**
- Women of any age can receive clinical breast exams and mammograms at any time when the patient and doctor feel it is medically necessary or appropriate, and will pay a standard co-pay (for example, ten dollars) set by their plan.
- **Extra coverage for women at risk:**
- Women of any age who are defined to be at risk of breast cancer will receive additional visits, including clinical breast exams and mammograms, *with no cost sharing*.
- **Additional coverage of mammograms:**
- For certain age groups, at certain intervals, mammograms are free of any cost sharing, so there is no charge when a woman goes to the doctor for these services.

- As part of the preventive services package, all women age 50 and older would have routine mammogram screening every other year, free of charge. Again, any woman who needs more frequent mammograms would be covered, and would pay a co-pay.
- **Additional coverage of clinician visits:**
 - Clinician visits, including clinical breast exams, are covered for all women, and additional coverage is available for women in certain age groups. Clinician visits are free once every three years for women age 20-39, and every other year for women from 40-64.
- **New investments in combating breast cancer**
 - This year, the National Institute of Health's breast cancer research budget increased by 44 percent, from \$208 million to almost \$300 million.
 - Under reform, new research initiatives will concentrate on the prevention of illnesses affecting women, including breast cancer, mental health, reproductive health and osteoporosis.
- **Women's groups support the President's plan:**
 - *"The Older Women's League (OWL) endorses President Clinton's health care reform bill"*
- Older Women's League, March 6, 1994
 - *"In reviewing the current health proposals pending in Congress, only two proposals, the Health Security Act, proposed by President Clinton and introduced by Senator Mitchell and Representative Gephardt, and the American Health Security Act, introduced by Senator Wellstone and Representative McDermott, demonstrate a significant commitment to the principles developed by the Campaign for Women's Health. These plans offer unprecedented opportunities to provide coverage of health care services for women far beyond what is currently available."*
- Campaign for Women's Health, March 1994

We believe that the proposed Health Security Act reflects the most recent and valid scientific evidence. It is also based on the recommendations of the U.S. Preventive Services Task Force and the American College of Physicians. While screening mammography for women over 50 has been shown to reduce mortality by 30%, population-based mammography screening for women between 40 and 50 has not been shown to reduce mortality. Mammography for women under 50 may have a false negative rate as high as 40%, leaving significant numbers of women with a false sense of security. In addition, any test or procedure has both emotional and physical risks associated with it.

Under the Health Security Act, women of any age will be covered for clinician visits, which include clinical breast exams, and screening mammograms when these services are appropriate, and will pay a standard copayment. All women over 50 will receive routine mammogram screening every other year at no cost. Clinician visits will be covered without cost sharing every three years for women ages 20 to 39 and every other year for women ages 40 to 64. In addition, women who are defined to be at risk for breast cancer may receive clinician visits and mammograms beyond those included in the periodicity schedule without cost sharing.

Author: Douglas Kamerow at ~ODPHP
Date: 10/03/1994 11:45
Priority: Normal
TO: Lisa Simpson at ~HHH7
Subject: WH Letter

----- Message Contents -----

I got the fax. Comments:

Add American Academy of Family Physicians to the ACP.
This then includes all of the primary care docs (except
ob-gyns).

At end of first paragraph, mention large number of
false-positives as well, adding to costs and worries of
a substantial number of women (you can use the JAMA
article on positive predictive value-1000 women, xx
procedures, etc).

Last paragraph, add "increased" before "risk" in last
sentence.

I'm off to my clinic. The number there is 301 699-7700.
Push 0 and ask for ext 42. fax there is 301 779 9001.

Cheers.

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 3/8/94
RE: Congressional Women's Caucus

Attached please find talking points written by Christine Heenan in response to the position paper released by the Women's Caucus on mammograms. I will turn this into a letter from you to the Women's Caucus tomorrow.

Post-It brand

Fax Transmittal Memo 7672

To *Jennife Kline*
Company *White House*

Location

Fax #

Telephone #

Comments



No. of Pages

Today's Date

Time

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Original
Disposition:☐ Destroy☐ Return☐ Call for pickup*225-6740***Executive Committee Officers**Patricia Schroeder, *Co-chair*
Olympia Snowe, *Co-chair*
Cardiss Collins, *Secretary*
Marcy Kaptur, *Treasurer***Congressional Caucus****Women's Issues**Congress of the United States
Washington, D.C. 205152471 Rayburn Building
(202) 225-6740Lesley Primmer
Executive DirectorFor Release
Tuesday, March 8, 1994Contact: Susan Wood
(202) 225-6740Andrea Camp (Schroeder)
(202) 225-4431Nicholas Graham (Snowe)
(202) 225-6306**NEWS RELEASE****CONGRESSWOMEN CALL FOR BROAD COVERAGE
OF SCREENING MAMMOGRAMS IN HEALTH CARE REFORM**

Today, the Congressional Caucus for Women's Issues called for broader coverage of screening mammograms in any health care reform package that comes before the Congress. With a number of committees about to take up various health care reform measures, the Caucus made clear that screening mammograms must be part of any basic benefits package.

"With all the conflicting recommendations that are coming from a number of highly respected sources, women need to know that screening mammograms will be covered," said Caucus Co-Chair Patricia Schroeder (D-Co). "Sending women the message that some mammograms may not be covered sends the message that mammograms are not important -- and that's a dangerous message."

"Women under 50 have been left once again in the now familiar situation that the research is not clear and the experts are still debating," Caucus Co-Chair Rep. Olympia Snowe (R-ME) pointed out. "We unfortunately have only mammograms in our arsenal against breast cancer -- which will strike one out of every eight women over a lifetime -- so until we have something more to offer these women, we can't take this away."

The position established by the Caucus calls for complete coverage (no copayments or

deductibles) of mammograms for women over 50 every one to two years, where screening mammography has been shown to reduce mortality by 30 percent. Coverage should be provided with applicable cost-sharing every two years for women between the ages of 40-49, where mammography has an uncertain impact on mortality but does help in early detection. In addition, an annual clinical breast exam should be covered for all women over forty.

"This just makes explicit what the President and Mrs. Clinton have been saying that they want all along," said Rep. Louise Slaughter (D-NY), Chair of the Caucus Task Force on Women's Health and the Environment, "Women in their forties will be assured of basic coverage of a screening mammogram without having to argue with a health plan or national board that it is medically appropriate."

"The Caucus will be watching and working with the committees of jurisdiction as they take up health care reform," noted Rep. Nita Lowey (D-NY), Chair of the Caucus Task Force on Reproductive Choice. "We're not just watching the Clinton plan; we want to make sure that all health care proposals reach this standard."

The position adopted by the Caucus is similar to one recently proposed in a Sense of Congress Resolution introduced by Rep. Ed Towns (D-NY) and several Congresswomen.

Attached is a summary of the Caucus position.



Congressional Caucus for Women's Issues

EMBARGOED UNTIL 10:00 AM, TUESDAY, MARCH 8

Caucus Position on Coverage of Screening Mammography in any Basic Benefits Package

- For women age 50 or older, where mammography has proven to bring about a 30 percent reduction in mortality:

- * Plans should provide free screening mammograms, every one to two years.

- For women age 40-49, where mammography has a less certain impact in reducing mortality, but does help in earlier detection:

- * Plans should cover screening mammograms every two years, with applicable co-pays and deductibles for those reform plans that include cost-sharing.
- * All cost-sharing should be based on a sliding scale, so that it does not constitute a barrier to low-income women receiving care.

- For women of any age:

- * Plans should provide free screening mammograms for any woman at high risk for breast cancer.
- * Plans should cover annual clinical breast exams for women over 40.

Released March 8, 1994

The Congressional Women's Caucus and Health Care Reform

The Congressional Women's Caucus is right to call for a comprehensive benefits package spelled out in law, and for preventive care focusing on early detection and treatment of breast cancer.

Women are increasingly at risk for life-threatening illnesses such as breast cancer, ovarian cancer, and heart and lung disease, yet still anchor the bottom of our medical research agenda. Of all the health problems women face, however, breast cancer is one of the deadliest:

- One in nine women in the U.S. will develop breast cancer in her lifetime. (National Breast Cancer Coalition)
- 2.6 million women in the U.S. have breast cancer today, and this year another 182,000 American women will be diagnosed with the disease, approximately one woman every three minutes. (National Breast Cancer Coalition)

The Health Security Act addresses women's health -- and the threat of breast cancer -- aggressively and comprehensively, guaranteeing all women coverage, regardless of whether they are healthy or sick, married or single, working or unemployed, wealthy or low income. **And the President's approach will provide unprecedented coverage of preventive care, including mammography. It will cover a whole schedule of preventive screenings, tests and check-ups at no cost, protection available in only a few of today's insurance policies.**

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- Campaign for Women's Health, March 1994

The Journal of the American Medical Association (January 12, 1994) reported that a recent analysis of all relevant studies ever conducted on screening mammography of asymptomatic women confirmed a clear benefit for screening women over 50 years of age every year or two. It found, however, no basis for promoting mammographic screening in women under 50 in the general population.

within the membership of the American Society of Addiction Medicine and the American Academy of Psychiatrists in Alcoholism and the Addictions, and specialized nurses, counselors, and social workers may also have much to teach us. Generalists can spend time with such experts to learn management principles and can then serve as resources within their own facilities. The Oath of Hippocrates states that "into whatever houses I shall enter, I will go into them for the benefit of the sick . . ."³⁰ In the case of IDUs, we rarely enter their "houses"—certainly not the shooting gallery and not even the drug treatment facility—and we do not allow them to easily enter ours. We can learn to treat IDUs in whichever houses they, or we, may enter.

Alan A. Wartenberg, MD

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Mammographic Screening

Since 1987, the United States has stood alone among major developed countries in having encouraged asymptomatic women under 50 years of age to undergo screening mammography, although US mortality rates for women these ages continue to mirror those of other Western countries.¹ Recent reports in *JAMA* and elsewhere compel a reexamination of this policy.

Diagnostic mammographic evaluation is indicated at any age if a woman has a lump or other signs of disease. In contrast to diagnostic assessments, screening mammography is a routine measure seeking to detect latent disease in asymptomatic women, in order to provide treatment, which may increase the likelihood of a cure.²

From the Office of the Assistant Secretary for Health, Department of Health and Human Services, Washington, DC (Dr Davis) and the UCLA Breast Center, Los Angeles, Calif (Dr Love).

Reprint requests to the Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Ave SW, Washington, DC 20201 (Dr Davis).

A recent meta-analysis of all relevant studies ever conducted on screening mammography of asymptomatic women confirmed a clear benefit—a 30% reduction in deaths for women over 50 years of age who were screened every year or two. It found, however, "no basis for the promotion of mammographic screening in women under age 50 in the general population."³ Kerlikowske et al⁴ provide an important new contribution to this subject in a recent issue of *JAMA* with their carefully conducted study of the positive predictive value of screening mammography in 31 814 women referred to the University of California San Francisco Mobile Mammography Screening Program from 1985 to 1992. They found that "women younger than 50 years will have approximately 2.5 times as many biopsies and three times as many diagnostic procedures for every cancer diagnosed compared with women aged 50 years or older," yet fewer than 20% of all cancers occur in the younger age group. An international workshop on this subject in February 1993 indicated that for every 1000 women under 50 years of age screened with mammography in a decade, 700 would require some sort of diagnostic

...sure to detect fewer than 15 tumors, and seven tumors may be missed entirely.⁵

Screening mammography cannot prevent breast cancer, but it can detect some small tumors early when they are more amenable to treatment and cure in women over 50 years of age. Despite the strong evidence that the number of deaths from breast cancer in women over 50 years of age can be reduced by 30% through regular mammography, women in this group have not been receiving the lifesaving test; thus, in 1990, 40% of women over 50 years of age had never had a mammogram.^{6,7} Over the past two decades at Harlem Hospital Center, New York, NY, one study found that half of all breast cancer cases were incurable on admission, and only 5% were in stage I.⁸

An especially disappointing finding of the study by Kerlikowske et al⁹ was the fact that the proportion of women over 50 years of age seeking mammograms fell between 1985 and 1992 from about 47% to 33%, while it rose for those under 50 years from 53% to 67%, and for those under 40 years from 22% to 29%. The Centers for Disease Control and Prevention report similar trends, with older women with lower levels of education having the lowest rate of mammography screening.⁷

The two biggest risk factors for breast cancer remain sex and age, with nearly 85% of cases occurring in women over 50 years of age. Growing concerns about the rising incidence of breast cancer have fueled screening programs worldwide. Mammography is a major enterprise, involving widespread public efforts including posters, brochures, print and television specials, and public service ads in English and Spanish urging every woman to have a mammogram "once a year for the rest of your life." Despite the fact that the United States has had excess capacity since 1990,⁹ firms continue to sell equipment for use in physicians' offices.

As to the current state of mammography, it is important to consider the newness of the venture. The American Board of Radiology included a section on mammography only in the past three examinations. Last year, Congress passed the National Mammography Standards Quality Assurance Act in response to reports that more than half of the current facilities and technologists failed to meet minimal quality assurance standards. In many southern states, fewer than 30% of all radiology centers currently comply with the American College of Radiology guidelines for safety and effectiveness.¹⁰ A reevaluation of first screening films in one urban practice found that "imaginomas" or ghost images accounted for more than half of those recommended for biopsy (oral communication, Gillian Newstead, MD, director of Breast Imaging, New York University Medical Center, August 6, 1993). In addition, mammography in women younger than 50 years is not without risk. This risk includes the economic and social cost of the procedure, the health hazards linked with radiation exposure begun at a younger age (one cancer induced per 25 000 mammograms), and the considerable human and economic toll of unnecessary diagnostic procedures; overall, about one of 10 biopsies recommended on the basis of mammography will be cancerous.¹¹

Despite efforts to improve current imaging technologies, imaging just may not be the best screening approach in young women because of the density of their breast tissue. A non-invasive biochemical test of blood or urine that pinpoints early markers or risk factors for breast cancer might prove to be a better population screening tool for younger women, with imaging technologies used only to locate occult cancers.

The public policy dilemma posed by these findings for women and their health providers in the United States today is profound. Chalmers¹² has reminded us that "if our society had been oriented towards finding out whether new technology is efficacious as soon as possible after its introduction there would not be much left to debate more than 30 years [later] . . ." ¹² But wistful wishing cannot alter the fact that mammographic screening in women under 50 years of age does not reduce deaths, while for those over the age of 50 years it saves lives. The reasons for these results are unknown and need to be resolved through additional clinical studies that assess the importance of menopausal status and other factors, including breast tissue change with age. In the meantime, women must be told the truth, so that they can make informed choices about their health care. And efforts must proceed apace to develop better techniques to detect early breast cancer in asymptomatic younger women, to ensure that all woman over 50 years of age are provided access to the lifesaving benefit of screening mammography, and to identify avoidable causes of this major cancer.¹³

Devra Lee Davis, PhD, MPH
Susan M. Love, MD

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JOHNS HOPKINS
UNIVERSITY

School of Hygiene and Public Health

624 N. Broadway, Room 482
Baltimore MD 21205-1996
(410) 955-3625 / FAX (410) 955-0876

Department of Health Policy and Management

Sam Shapiro, Acting Chair

January 27, 1994

Dr. Edward Sickles
Associate Professor
Department of Radiology
Box 0628
University of California Medical Center
San Francisco, CA 94143

Dear Ed:

I have just run across two news items on the controversy about NCI's conclusions regarding the status of knowledge about the efficacy of routine screening at ages 40-49 in which you are quoted extensively and in ways that I just do not understand.

You mention a 26% reduction in breast cancer mortality at these ages in a Swedish study. I assume you are referring to the two county study and more specifically to the Kopparberg result. But what about the 28% higher relative risk reported for Ostergotland, the other county? Why was this not mentioned?

You are also cited as describing results of an analysis of data on mammographic screening at the University of California and in British Columbia. Quite aside from the problems in interpreting the findings you report, what about the results described in the JAMA article by Kerlikowske ...Sickles ...? I assume that the mobile unit referred to is yours and that you do not have any problems with the quality of mammography performed.

The conclusion in the abstract, supported by the analysis in the body of the paper, is that "Efforts to promote screening mammography should focus on women in these groups (women aged 50 and over and women 40 and older with a family history of breast cancer), in whom the majority of breast cancers occur and for whom mammography has the highest PPVs." I was at the meeting where Dr. Kerlikowske presented the data and the clear conclusion was that they did not support routine screening for women at ages 40-49, except for those at elevated risk.

So, what's going on? I do not know whether there's an overlap between the 63,000 mammograms noted in the news items and the cases in Kerlikowske et al's paper, but your name appears on the latter paper.

SEE 0 4 000

Dr. Sickles
January 27, 1994
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I know that arguments can be made that evidence is not available regarding the efficacy of routine screening at ages 40-49. That would mean we do not have the data to advocate mass screening at these ages and from a public health standpoint the NCI position remains correct until new evidence becomes available.

I would appreciate hearing from you on the above.

Best regards.

Sincerely,


Sam Shapiro
Acting Chair and
Professor Emeritus

CC: Dr. Suzanne Fletcher
Dr. Ed Sondik
Dr. Barry Kramer



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

JAN 24 1994

TO: Pam Barnett
Office of the First Lady
The White House

FROM: Ray Martinez *RM*
White House Liaison
Health and Human Services

SUBJECT: Breast Cancer Study

Attached please find a copy of the October 20, 1993, Volume 85, Number 20 of the Journal of the National Cancer Institute which contains the study on Breast Cancer that you requested. I apologize for the delay in getting this to you.

Please feel free to call me on 690-6625, for any further information or assistance that you might need. I have also enclosed the business card of Jana S. Johnston, Public Affairs Specialist, NCI, in case you would like to contact them directly for additional copies or other information.

Attachment

301-496-9569

Ed Sunde K.

Sam B. Sunde

NATIONAL
CANCER
INSTITUTE

International Cancer
Information Center

Building 82, Room 123
Bethesda, Maryland 20892
(301) 496-4907

Jana S. Johnston
Public Affairs Specialist
Marketing Office

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OF THE NATIONAL CANCER INSTITUTE

CONTENTS

In This Issue		1617
EDITORIALS	Early Cancer Clinical Trials: Safety, Numbers, and Consent, <i>M. J. Hawkins</i>	1618
	Screening for Breast Cancer: What Should National Health Policy Be? <i>T. C. Chalmers</i>	1619
	Deficiencies in the Analysis of Breast Cancer Screening Data, <i>E. A. Sickles, D. B. Kopans</i>	1621
NEWS	NCI Proposes New Breast Cancer Screening Guidelines, <i>K. Smigel</i>	1626
	NCI's Proposed Breast Cancer Screening Guidelines, <i>K. Smigel</i>	1627
	Stat Bite: Cancer Information Service: Telephone Inquiries	1628
	Angiogenesis Research Yields New Approaches to Cancer Treatment and Prognosis, <i>N. S. Larsen</i>	1629
	Cancer Program Praised and Criticized As Plans Are Forged for the 21st Century, <i>S. Jenks</i>	1631
	Peer Review Put to the Test: Credibility at Stake, <i>C. Vanchieri</i>	1632
	Prostate Cancer Prevention Trial Launched, <i>T. Reynolds</i>	1633
	Awards, Appointments, Announcements	1635
	NIH Appropriations Due, <i>D. A. Tisevich</i>	1636
COMMENTARY	Statistical and Ethical Issues in the Design and Conduct of Phase I and II Clinical Trials of New Anticancer Agents, <i>M. J. Ratain, R. Mick, R. L. Schilsky, M. Siegler</i>	1637
SPECIAL ARTICLE	Report of the International Workshop on Screening for Breast Cancer, <i>S. W. Fletcher, W. Black, R. Harris, B. K. Rimer, S. Shapiro</i>	1644
ARTICLES	p53 Protein Accumulation and Gene Mutation in the Progression of Human Prostate Carcinoma, <i>N. M. Navone, P. Troncoso, L. L. Pisters, T. L. Goodrow, J. L. Palmer, W. W. Nichols, A. C. von Eschenbach, C. J. Conti</i>	1657
	Cancer Mortality Among New Mexico's Hispanics, American Indians, and Non-Hispanic Whites, 1958-1987, <i>C. L. Wiggins, T. M. Becker, C. R. Key, J. M. Samet</i>	1670
REPORTS	Radiation-Induced Breast Cancer: Long-Term Follow-up of Radiation Therapy for Benign Breast Disease, <i>A. Mattsson, B.-I. Rudén, P. Hall, N. Wilking, L. E. Rutqvist</i>	1679
	Measurement of Cremophor EL Following Taxol: Plasma Levels Sufficient to Reverse Drug Exclusion Mediated by the Multidrug-Resistant Phenotype, <i>L. Webster, M. Linsenmeyer, M. Millward, C. Morton, J. Bishop, D. Woodcock</i>	1685
BOOK REVIEWS	Gastrointestinal Cancer, <i>L. M. Weiner • L. Leichman</i>	1691
	Books Received	1692
CORRESPONDENCE	Are Esterases Involved in Multidrug Resistance? <i>O. Markovic, N. Markovic</i>	1693
	Re: Relationship Between Environmental Tobacco Smoke Exposure and Carcinogen-Hemoglobin Adduct Levels in Nonsmokers, <i>M. J. Reasor • Response, S. K. Hammond, J. Coghlin, P. H. Gann, P. L. Skipper, S. R. Tannenbaum</i>	1693
	Re: Blood Levels of Organochlorine Residues and Risk of Breast Cancer, <i>M. P. Longnecker, S. J. London • Response, N. Dubin, P. G. Toniolo, et al.</i>	1696
	Re: Lung Cancer Incidence Among Patients With Beryllium Disease, <i>M. Eisenbud • Response, K. Steenland, E. Ward</i>	1697