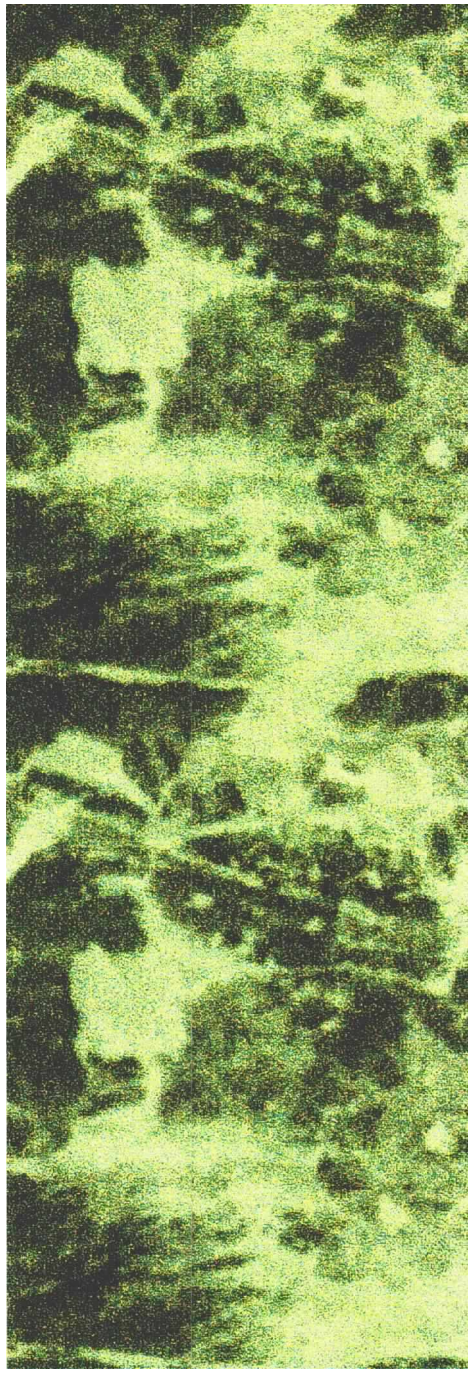
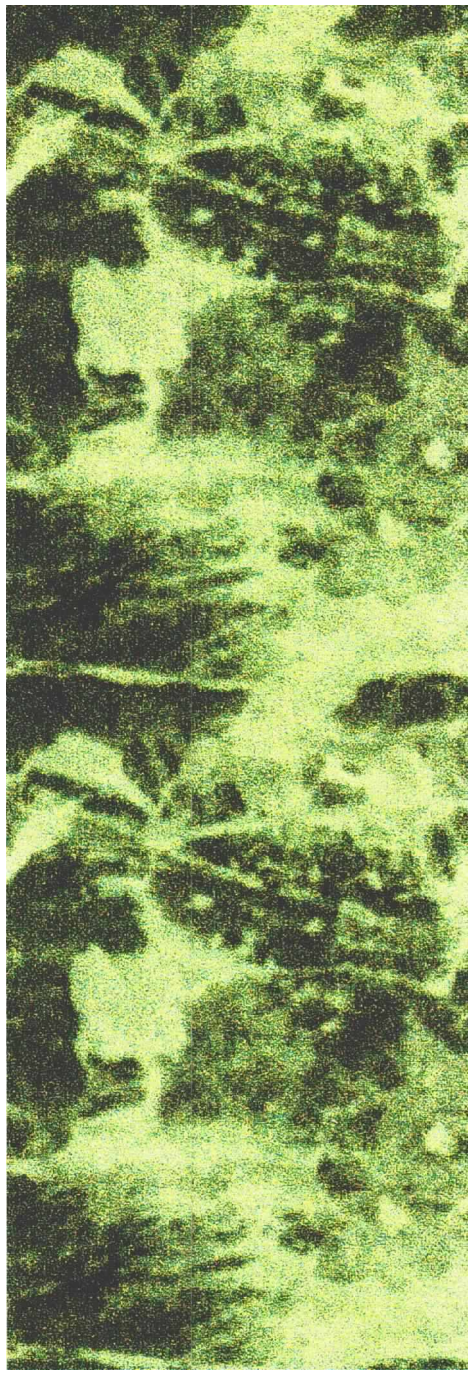


Screening & Diagnosis of Breast Cancer For Primary Care Physicians



Sponsors

Sponsors

The support of the following sponsors has allowed us to present "Screening and Diagnosis of Breast Cancer for Primary Care Physicians" to you. We are indebted to them for their continuing support.

• The National Cancer (NCI) Institute provided the funding to study ways to increase breast cancer screening in women between the ages of 50 to 80 who do not comply with the recommended guidelines. The NCI goal is to significantly decrease breast cancer mortality by the year 2000.

• The NCI grant was awarded to investigators at the University of Massachusetts Medical School who have developed this course to **E**nable **P**hysician to **I**mprove **B**reast **C**ancer **S**creening. **(EPICS)**

• The American Cancer Society (ACS) accredited the course and granted five hours of continuing education credit in Category 1 (Risk Management) of the Physician's Recognition Award of the American Medical Association. Widespread cancer screening and early diagnosis continues to be a major objective of the ACS.

• The Massachusetts Medical Society endorses our efforts to assist physicians in assessing their skills and plans to disseminate this program throughout Massachusetts.

• Pilgrim Health Care and Central Massachusetts Health Care (CHMC) have both stressed the importance of improving preventive services, and have supported our efforts at every turn.

Schedule

Screening and Diagnosis of Breast Cancer for Primary Care Physicians
May 18, 1995

12:30 - 1:00	Buffet Lunch
1:00 - 1:10	Pre-Test
1:10 - 1:40	Mary E. Costanza, M.D. Introduction **UPDATE ON BREAST CANCER AND MAMMOGRAPHY**
1:45 - 2:15	Lynn Clemow, Ph.D. and Mark Quirk, Ed.D. **DIAGNOSING AND TREATING NON-ADHERENCE WITH RECOMMENDATION OF MAMMOGRAPHY**
2:15 - 2:30	Roger Luckmann, M.D. and Acting Patient **DEMONSTRATION OF DOCTOR-PATIENT INTERACTION**
2:35 - 3:50	Practice Groups with Acting Patients Demonstrating: **HOW TO DIAGNOSE AND TREAT NON-COMPLIANT PATIENTS**
3:50 - 4:90	Break
4:00 - 4:15	Mary Costanza, M.D. **MAMMACARE CLINICAL BREAST EXAM**

For the next hour, the physicians will be divided into Groups A and B for workshops.

	Group A	**Group B**
4:15 - 4:45	Practice Groups with Acting Patients **Providing Feedback on:** **THE CLINICAL BREAST EXAM**	Allen Dietrich, M.D. **AN OFFICE SYSTEM TO SUPPORT BREAST CANCER SCREENING**
4:45 - 5:15	Allen Dietrich, MD. **AN OFFICE SYSTEM TO SUPPORT BREAST CANCER SCREENING**	Practice Groups with Acting Patients **Providing Feedback on:** **THE CLINICAL BREAST EXAM**

5:20 - 5:50	Robert Quinlan, M.D. **IDENTIFYING AND DEALING WITH POSITIVE FINDINGS IN THE CLINICAL BREAST EXAM**
5:55 - 6:15	Summary, Questions, Post-Test

Faculty

Mary E. Costanza, M.D.

Mary E. Costanza, M.D., is professor of Medicine at the University of Massachusetts Medical School in Worcester, and president elect of the Massachusetts Chapter of the American Cancer Society. Dr. Costanza earned her medical degree in 1968 from the University of Rochester Medical School in Rochester, NY. Her internship and residency in medicine were served at Tufts - New England Medical Center Hospital, Boston, MA, where she continued on to be a clinical fellow in the department of Medical Oncology. Since 1979, Dr. Costanza has been at the University of Massachusetts Medical Center, and was visiting scientist at the Dana Farber Cancer Institute in 1989 - 1990.

Dr. Costanza has been the recipient of several awards and honors which include the Woodrow Wilson Fellowship at the University of California - Berkeley and Oxford University, Somerville College (1961-63). Dr. Costanza has been a member of various national committees at the National Cancer Institute dealing with breast cancer screening, prevention, and control. She was chair of the National Forum on Breast Cancer Screening in Older Women (1989 - 1991). Dr. Costanza is currently the regional chair of the breast cancer task force of the American Cancer Society Massachusetts Division, and a member of the Massachusetts Department of Public Health: Advisory Committee for Breast Cancer Screening. In addition, she is a member of the editorial boards of several cancer and breast disease journals.

An active medical investigator, Dr. Costanza has authored many scientific papers most of which are about breast cancer screening, diagnosis, or treatment. Dr. Costanza is currently the principle investigator of a five year grant from the National Cancer Institute to study women between the ages of 50 and 80 who do not comply with the recommended guidelines for breast cancer screening.

Lynn P. Clemow, Ph.D.

Lynn P. Clemow, Ph.D. is assistant professor of Medicine, and director of the Behavioral Medicine Clinic at the University of Massachusetts Medical Center in Worcester, MA., and on the faculty at the University of Massachusetts - Amherst, School of Public Health and the University of Massachusetts - Boston, department of Psychology. At the University of Massachusetts Medical Center, Dr. Clemow is the attending psychologist in the Breast Clinic, counseling women who are going through treatment for breast cancer. Dr. Clemow completed her education in clinical psychology/behavioral medicine in 1984 at Louisiana State University, and served a year of internship at Rutgers Medical School in New Brunswick, N.J. Prior to assuming her present position, Dr. Clemow held clinical positions at Rutgers Medical School as director of the Center for Stress Management and Behavioral Medicine in the department of Psychiatry, and as Clinical assistant professor of Psychiatry and Medicine and director of Psychosocial Services in the division of Hematology/Oncology.

Dr. Clemow has been a consultant on a variety of projects which include working with the Centers of Disease Control and the National Hemophilia Foundation. Dr. Clemow has published 18 scientific papers and has presented 13 papers dealing with psychological factors influencing the care and outcome of variety of illnesses.

Mark E. Quirk, Ed.D.

Mark E. Quirk, Ed.D. is professor in the department of Family and Community Medicine, and Assistant Dean for student academic achievement at the University of Massachusetts Medical School. Dr. Quirk received his M.Ed in 1975 at Boston College in Chestnut Hill, MA and was awarded an Ed.D. at Clark University in 1982. Dr. Quirk has extensive consultation experience within other departments at the University of Massachusetts Medical Center and at other institutions throughout the northeast. Dr. Quirk has been instrumental in developing a national physician training program in communication skills. He is an active medical investigator and has published over 25 scientific papers. He has recently published a book entitled How to Learn and Teach in Medical School: A learner-centered Approach *(Charles C. Thomas Publisher).*

Roger Luckmann, M.D., M.P.H.

Roger Luckmann, M.D., M.P.H. is assistant professor in the department of Family and Community Medicine and director of the general preventive medicine residency program at the University of Massachusetts Medical School in Worcester, MA. Dr. Luckmann earned his medical degree in 1976 from Boston University School of Medicine, Boston, MA, and his M.P.H. in 1988 from the University of California, Berkeley, CA. His residency in Internal Medicine was served at Hennepin County Medical Center in Minneapolis, MN. Dr. Luckmann served an additional residency in Preventive Medicine at the California Department of Health Services, Sacramento, CA, and was awarded a fellowship in geriatrics and preventive medicine at the School of Medicine, University of California, Davis, CA.

Prior to coming to the University of Massachusetts Medical School, Dr. Luckmann was a staff physician at St. Paul-Ramsey Medical Center in St. Paul, MN. During that time he was also medical director of the corporate occupational health program at Medtronic, Inc. and medical director of the University Health Care Center both of which are located in Minneapolis, MN. Dr. Luckmann then served as public health medical officer for the chronic disease branch of the California Department of Health Services in Sacramento, CA.

Dr. Luckmann's research interest, include the delivery of clinical preventive services in primary care, the epidemiology of Alzheimer's disease, and appendicitis.

Allen J. Dietrich, M.D.

Allen J. Dietrich, M.D. is professor of Community and Family Medicine and director of Family Medicine Undergraduate Education at Dartmouth Medical School in Hanover, NH. Dr. Dietrich earned his medical degree in 1973 from Case Western Reserve in Cleveland, OH. His internship in medicine was served at Cambridge (MA) Hospital, and his residency in family practice was completed at the University of Rochester in Rochester, NY. Prior to coming to Dartmouth, Dr. Dietrich was the Robert Wood Johnson Clinical Scholar at Stanford University and Palo Alto Veterans Hospital in Palo Alto, CA. He had also held clinical instructor positions at Harvard University, and the University of New Mexico, and was family physician and clinical director of the Zuni Indian Health Service Hospital in Zuni, NM.

Dr. Dietrich has been the recipient of various awards and honors that include distinguished lecturer at the Jonsson Comprehensive Cancer Center, UCLA in 1994 and a participant in the Senior International Fellowship Program at the John E. Fogarty International Center in 1991. Dr. Dietrich has been a member of national and regional committees which include a special study section, National Heart, Lung, and Blood Institute Review Committee and Executive Committee of the New Hampshire Academy of Family Practice. Dr. Dietrich is on the editorial board for the Archives of Family Medicine and a reviewer for several preventive medicine and family practice publications. His interest in changing office routines to enhance preventive care is the subject of many of his publications. He has authored or coauthored over 30 scientific papers, 4 textbook chapters, and has edited 3 books.

Leonard M. Finn, M.D.

Leonard M. Finn, M.D. is a partner in Needham Family Practice in Needham, MA and past president of the Massachusets Academy of Family Physicians (1992-1994). Dr. Finn earned his medical degree in 1974 from the University of Massachusetts Medical School in Worcester, MA. He continued on at the University Of Massachusetts Medical School and completed his residency in Family Practice in 1977. Dr. Finn is an associate faculty member at the University of Massachusetts Medical School in the department of Family and Community Medicine, and clinical instructor of socio-medical sciences and community medicine at Boston University School of Medicine. In both of these institutions, he acts as a preceptor for medical students. Dr. Finn's hospital affiliations include Deaconess-Glover Hospital in Needham, Metrowest Medical Center - Natick Campus, and Newton-Wellesley Hospital in Newton.

In 1981, Dr. Finn was the recipient of the Frederick S. Troy Medal for Outstanding Alumni Achievement in Medicine which is given by the University of Massachusetts President's Advisory council. Dr. Finn's activities with the Massachusetts Academy of Family Physicians have been extensive, he recently joined the AAFP Policies Task Force. he is also an active member of the American Cancer Society, and currently chairs the national Advisory Group on Preventive Health Care Reminder Systems, and is a member of the professional education committee of the Massachusets Chapter.

Dr. Finn's research and professional education interests include smoking cessation programs for medical professionals in office practice, and reminder systems for preventive health services in primary care settings.

Robert M. Quinlan, M.D.

Robert M. Quinlan, M.D. is chief of Surgical Oncology at The Medical Center of Central Massachusets in Worcester, MD, and professor of Surgery at the University of Massachusets Medical School, Worcester, MA. Dr. Quinlan earned his medical degree in 1970 at Cornell University Medical College, New York, NY. His surgical internship and residency were served at Peter Bent Brigham Hospital, and Children's Hospital in Boston, MA. As chief surgical resident at Peter Bent Brigham Hospital, he was named the Arthur Tracy Fellow in Surgery. Prior to coming to The Medical Center of Central Massachusetts Dr. Quinlan was assistant professor of surgery and surgical oncology in the department of Surgery and Oncology at Johns Hopkins University School of Medicine, Baltimore, MD.

Dr. Quinlan has been the recipient of various awards and honors that include the Frederick J. McCready, M.D. Teacher of the Year Award from the University of Massachusetts Coordinated Surgical Residency Program, and the Physician in Chiefs Award at The Medical Center of Central Massachusetts Throughout his career, he has played an active role nationally and regionally on committees for the American College of Surgeons. His clinical interests are in neoplasia of the breast, thyroid, esophagus, stomach, and hepatobiliary systems.

Michael D. Wertheimer, M.D., F.A.C.S.

Michael D. Wertheimer, M.D., F.A.C.S., is professor of Surgery, director of the Breast Center, associate director of the Comprehensive Cancer Center, and physician director of the Ambulatory Services at the University of Massachusetts Medical Center in Worcester. He is also an attending surgeon at the University of Massachusetts Medical Center, St. Vincent Hospital, and the Medical Center of Central Massachusetts in Worcester. Dr. Wertheimer earned his medical degree in 1971 from the University of Pennsylvania School of Medicine in Philadelphia, PA. His internship and residency in surgery were served at Beth Israel Hospital in Boston, MA. He completed his surgical training as chief surgical resident at the University of Massachusetts Medical School in Worcester, MA. In addition to his current appointments, Dr. Wertheimer is a member of the faculty advanced trauma life support, American College of Surgeons and Advanced Cardiac Life Support, American College of Cardiology. Dr. Wertheimer is the co-chair of the quality assurance subcommittee for the breast cancer task force for the Massachusetts chapter of the American Cancer Society.

Dr. Wertheimer is an editorial reviewer for the Archives of Internal Medicine, JAMA, and Preventive Oncology, as well as an active medical investigator who has authored or coauthored 16 scientific papers, 1 textbook, and 9 textbook chapters. He has presented over 80 postgraduate educational presentations, many which have dealt with the diagnosis and treatment of breast cancer.

Maureen Mondor

Maureen Mondor is the director of risk management services at the Massachusetts Medical Professional Insurance Association. She is a member of the Massachusetts Society of Hospital Risk Managers and the American Heart Association. Ms. Mondor has clinical experience at Peter Bent Brigham Hospital as charge nurse in Intensive Care/Recovery Room, and was staff education coordinator at Worcester Hahnemann Hospital before joining the Massachusetts Joint Underwriters Association which has been renamed the Massachusetts Medical Professional Insurance Association.

University of Massachusetts Standardized Patients

The "Standardized Patients" are non-physician instructors trained to simulate patient encounters in a realistic and consistent manner. Our standardized patients are also taught to provide feedback to physicians as to the quality and completeness of their clinical skills. The use of standardized patients at the University of Massachusetts Medical School is now an integral part of the four year medical school curriculum providing the opportunity for the students to practice their clinical skills in an interactive situation.

Outside the University of Massachusetts Medical School the standardized patients are providing education services to several regional New England medical schools and hospitals where they are involved in clinical skills assessment training workshops for students and residents.

The patient instructors involved in our course are:

- Gloria Kennedy
- Laurie LaBrecque
- Ulrike Lies
- Judy MacRae
- Betty Paulsen
- Jodie Poland
- Joanne Wanczyk

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Mammography
1995

Mary E. Costanza, M.D.
Update on Breast Cancer and on Mammography

I. Incidence and Rate

A. Breast cancer incidence
- Doubled since 1940
- Mortality rate unchanged until 1987

II. Breast cancer screening

A. Mammography: 1995 Update
- Accuracy
  - Age dependence
  - Sensitivity
  - Positive Predictive Value
- Evidence that mammography saves lives
- Who should get mammograms?
- At what interval?

III. Who Is At Risk

A. Highest risk
B. Moderate risk
C. Slightly increased risk
D. Questionable risk
E. Is there anyone without risk?

IV. Mammography Utilization

A. Why women don't get screened
- No symptoms
- No perceived need
- No physician recommendation

B. Why doctors don't recommend screening
- Forgot
- No time
- Women are resistant
- Women are too old

V. Practice Decisions Regarding Mammography

A. Your decision
B. National guidelines

Breast Cancer Facts: Age, Incidence, Survival

Age and Breast Cancer Incidence:

- Breast cancer is an older woman's disease
- The incidence rises steeply after the age of 40

Age and Survival:

The death rate from breast cancer is higher in the very young (<30) and the old (>65)

Age and Screening:

Most older women live long enough to profit from mammography screening

- A 65 year old woman in average health will live 18 years more.
- A 75 year old woman in average health will live 12 years more.
- An 85 year old woman in average health will live 7 years more.

Breast Cancer Incidence in the United States:

- The incidence has doubled since 1940 while the mortality rate is unchanged.
- Only the most recent rise in incidence can be attributed to more screening activities.
- The lifetime risk has increased from 1 in 20 to 1 in 8.

References:

Norton, JA, Romans, MC, Cruess, DE Mammography Attitudes and Usage Study, Women's Health Issues 1992;2:180-186.

Boring, EE. Cancer Facts and Figures, American Cancer Society 1993.

Costanza, ME. Breast Cancer Screening in Older Women, Synopsis of a Forum, Cancer 1992;69:1925-1931

Breast Cancer Prevention

1. Reproductive Factors and Increased Risks

   Early age of menarche: < 12 y.o.
   Late age of menopause: > 55 y.o.
   Late first live birth: > 30 y.o.
   Nulliparity
   Estrogen Replacement Therapy: > 15 yrs on estrogen
   Women with these risks should consider prevention actions

2. What can a women do

   - Plan first pregnancy before the age of 30.
   - Reconsider the reasons for Estrogen Replacement Therapy (ERT)
   - Join the Women's Health Initiative Trial. (WHIT)
   - Join the Tamoxifen Trial
   - Dietary Change
   - Other

3. The WHIT study of women is just now accruing post-menopausal women. Thousands of women will be randomized to ERT ± progestin or no replacement therapy. Endpoints will be the incidence of breast cancer, uterine cancer, heart disease, myocardial infarction, bone fractures, and osteoporosis. A cost-benefit study will evaluate relative merits of replacement therapy. For more information call 508-856-5495.

4. Anti-Estrogen Therapy - Breast Cancer Prevention Trial
   Tamoxifen is an anti-estrogen and has been shown in breast cancer patients to decrease the recurrence of, and death rate from, breast cancer and to decrease the incidence of new breast cancers. The NSABP is enrolling up to 16,000 women at high risk for developing breast cancer. They will be randomized to Tamoxifen or placebo for 5 years. Call 508 856-1809 for more information.

5. Dietary Change

   The evidence that certain dietary patterns increase breast cancer is controversial. While there is clear evidence that a diet high in animal fats increases cardiac disease and colon cancer, there are conflicting reports about its relationship to breast cancer incidence. There is also evidence that alcohol consumption increases the risk.

   The Women's Health Initiative Trial will look at the relationship of diet and certain diseases. Eighty thousand women will be randomized to the ordinary American diet of 38% calories from fat or to a special diet of less than 25% calories from fat. End points will be the comparative incidence of breast cancer, heart disease, colon cancer, and uterine cancer. For more information call 508-856-5495.

6. Other

There is some, but not overwhelming, evidence that exercise may decrease the risk of developing breast cancer. Vitamin and trace element additions to diet are also the subject of a variety of studies.

Mammography: Evidence For Benefit

- There have been eight controlled randomized trials including approximately 490,000 women who received regular mammography ± CBE or who received no mammography. The evidence is overwhelming that women 50 and older will have a 30% reduction in mortality from breast cancer when they get mammograms every one or two years.

- The dose of radiation has been reduced from 2-3 rads (1970's and 1980's) to 0.1 - 0.2 rads per view.

- The image quality of the mammogram has simultaneously improved. Cancers 2-3 mm can be regularly identified.

- The lead time (from positive mammogram to visual clinical detection) may be 4-6 years.

- Even the best quality mammograms read by the best mammographer will miss some easily palpable cancer. This is because the photographic density of the breast and the tumor may be too similar. The false negative mammography rate is about 15%. It is higher in women < 50 (50% in 30 yr olds) but only 5% in women > 70.

Your HMO pays for annual mammograms for women 50 and over. Patients need to get your approval to have them ordered.

Mammography: Utilization.

Use of mammography has increased greatly. In the mid 1980's, the number of women who had ever had a mammogram was about 45%. By 1992, it was 74%!! The number of women who have regular mammograms (every year or every other year) is estimated to be ~ 30% - 60% depending on the age group, locale (city or rural), and socioeconomic status.

Of women 65 years old and older, only 67% have ever had a mammogram. Since half of all breast cancers occur in women 65 years old and older, this low utilization rate is very troublesome.

When women are asked why they didn't get mammograms, the top four reasons are:

• "I have no family history"	49%
• "Mammograms cost too much"	46%
• "My doctor didn't recommend one"	40%
• "I'm not at risk" (e.g. don't need it, have no symptoms)	36%

Mammography Utilization Statistics - 1992
Importance of Sociodemographic Factors

		Ever had a Mammogram
Age*		
	40-40	78%
	50-59	82%
	60-69	67%
	70+	67%
Race*		
	White	76%
	Black	59%
Education**		
	Less than High School	63%
	High School Graduate	74%
	Some College	80%
	College Graduate	87%
Income**		
	Less than $25,000	66%
	$25,000 - 49,000	82%
	$50,000	87%

* From Massachusetts Database
** From U.S. Database

Source: American Cancer Society, 1994

Regular Mammography Utilization: 1994

Receiving mammograms at least every 2 years: 66% women 50-80 years old

From 2 HMO's Database

Mammography: Quality Assurance Issues

During the 1970's and 1980's the emphasis in mammography was on reducing the dose of radiation. Currently, the average mammogram has been reduced from 2-3 rads to 0.1-0.2 rads per view. At the same time the images generated have improved substantially, principally by using dedicated machines with special features. In the late 1980's, review of the quality of films taken in clinical practice revealed that there was wide variation in radiation dose and image quality.

By 1992 in response to pressure from women's groups, the Massachusetts Division of the American Cancer Society, the Massachusetts Medical Society, the Massachusetts College of Radiologists, and others, the legislature enacted a law to mandate a high quality of mammography in Massachusetts effective July, 1993. This program has teeth! The Massachusetts Department of Public Health has now inspected all mammography facilities, and shut down several which have not been able or are not willing to attain the standards required. The regulations specify standards for each facility, including record keeping, patient notification, radiologist training, technician training, physical quality of the image and the permissible radiation dose. As of January 1995, only accredited mammography facilities will be operating in Massachusetts. In 1993, Congress enacted similar legislation binding all states. These national regulations became effective in October 1994, and in Massachusetts they are enforced by the Massachusetts Department of Public Health.

If all women 50 and over were to have screening mammograms every year or two, the mortality rate from breast cancer would decrease by at least 30%.

Remember that even with the highest standards, mammograms are not able to detect all cancers. Some breast cancers are "invisible", but can be felt on clinical exam!

Robert M. Faulk, MD • Edward A. Sickles, MD • Richard A. Sollitto, MD
Steven H. Ominsky, MD • Helen B. Galvin, MD • Steven D. Frankel, MD

Clinical Efficacy of Mammographic Screening in the Elderly[1]

PURPOSE: To compare mammographic screening results for women aged 65 years and older (elderly group) with those for women aged 50-64 years (younger group).

MATERIALS AND METHODS: **Mammography was performed in 32,140 women aged 50 years and older (10,914 elderly, 21,226 younger). Parameters studied included demographic data, screening interpretations, disposition of abnormal interpretations, results of biopsies, and characteristics of breast cancers.**

RESULTS: **The cancer detection rate is substantially higher in elderly women (9.2 per 1,000 women) than in younger women (5.7 per 1,000 women). The median size of cancers in elderly women is 11 mm (vs 12 mm in younger women). Axillary nodal status is 93% node negative in elderly women (vs 88% node negative in younger women). Cancer stage is earlier in elderly women than it is in younger women (84% stage 0 or I vs *75%* stage 0 or I).**

CONCLUSION: **Mammographic screening is at least as effective in detecting cancers for which there is a favorable prognosis in women aged 65 years and older as it is in women aged 50-64 years. Because the efficacy of screening in younger-group women has already been proved, it may be inferred that screening also benefits elderly-group women.**

Index terms: Breast, diseases, 00.31.00.32 • Breast neoplasms, diagnosis, 00.11, 00.31,00.32 • Breast neoplasms, radiography, 00.11,00.31, 00.32 • Breast radiography, utilization, 00.11 • Cancer screening

Radiology 1995; 194:193-197

[1]From the Department of Radiology, University of California School of Medicine, San Francisco. Received May 9, 1994; revision requested June 8; revision received July 25; accepted August 8. **Address reprint requests to** R.M.F., 11424 P St, Omaha, NE 68137.

THERE is general consensus, which is sustained by evidence from eight randomized controlled trials, that mammographic screening reduces mortality of breast cancer in women aged 50-64 years (1). For this reason, there is widespread support for recommending periodic mammographic screening for women in this age range. Despite the fact that breast cancer is characterized by progressive increases in incidence and mortality rate as a function of advancing age (2,3), however, there is a paucity of rigorously controlled clinical data on which to base recommendations for mammographic screening in women aged 65 years and older. Only two of the randomized controlled trials have included women aged 65 years and older, and these trials were not designed to test age-specific mortality reduction (4,5). Increased comorbidity and reduced life expectancy further complicate the decision on whether and when to screen elderly women for breast cancer (6-8).

The need for more information to guide screening recommendations in the elderly is becoming increasingly important. Currently, 43% of all newly diagnosed breast cancers in the United States occur in women aged 65 years and older (9). The elderly population is now 12% of the total population and is growing at a rate 4.5 times higher than that of the remainder of the population (3). By 2030, it is estimated that the elderly will represent 20% of the total population (3). The overall incidence of breast cancer also has been rising steadily in the United States (10,11). On the basis of projected population growth and increasing incidence of disease, it is expected that extant breast cancer cases in the elderly will more than double from 630,000 to 1.4 million by the year 2030 (3). Government and third-party payers are expanding coverage for mammographic screening of elderly women. Clearly, there is a great need to justify these expenditures.

In an attempt to clarify many of the mammographic screening issues in the elderly, we have reviewed age-specific screening results from more than 65,000 examinations in our mobile van mammography program. This experience provides information that can help to determine the role of mammographic screening in elderly women.

MATERIALS AND METHODS

Because mammographic screening is widely accepted for women aged 50-64 years, we compared screening results for women in this age range ('younger' group) with data for women aged 65 years and older ("elderly" group). Presumably, if clinical results for elderly women are similar to or even more favorable than those for younger women, it would provide strong support for screening elderly, as well as younger, women.

Between April 1985 and March 1994, the mobile van mammography program at our institution provided 65,610 screening examinations for 36,822 women. Details of the operation of our practice have been reported previously (12). The mobile van mammography program has been designed to provide high-quality mammographic screening at a low cost.

A computerized data management program was used to collect and store all screening records. This allows for easy retrieval of statistical information about every aspect of our practice. Specific descriptions of the data stored and analyzed have also been reported previously (13).

We determined age-specific screening results by using 5-year age ranges. Except where progressive age-related trends have been noted subsequently, however, there were no meaningful differences in data among the 5-year subgroups of either younger or elderly women. Age-specific screening results for women aged younger than 50 years are beyond the scope of

Abbreviations: DCIS = ductal carcinoma in situ, PPV = positive predictive value.

this article; these results will be reported elsewhere (14).

Although the data presented are self-explanatory, one other feature of our study requires clarification. The majority (60%) of screening examinations were interpreted by one board-certified radiologist who specializes in breast imaging; five other board-certified general radiologists interpreted approximately equal numbers of the remaining cases. We have previously reported screening results that have been broken down according to which radiologist interpreted the examinations (15,16). In this article, the data presented generally involve the interpretations of all six radiologists. Because there were substantial differences among radiologists in classifying breast opacity, however, we present the breast opacity data collected only from interpretations by our principal breast imaging radiologist (E.A.S.). Fatty breasts were defined as those entirely or almost entirely devoid of mammographically visible fibroglandular-density tissue.

Table 1
Breast Cancer Risk Factors among Younger and Elderly Women

Age (y)	Nulliparity	First Birth > 35 y	Menarche <10 y	Menopause > 55 y	Minor Family History*	Strong or Very Strong Family History†
50-64 (n = 21,226)	5,421 (26)	706 (3)	194 (1)	525 (5)‡	2,153 (10)	2,180 (10)
65+ (n = 10,914)	3,331 (30)	557 (5)	48 (<1)	695 (6)	730 (7)	1,379 (13)

Note. – Numbers in parentheses are percentages.
*Only a distant relative or relatives with breast cancer.
† First-degree relative or relatives with breast cancer (premenopausal, postmenopausal, unilateral or bilateral).
‡ Percentage calculation is based on the total number of women older than 55 years of age.

RESULTS

Patient Demographics

We examined 10,914 women aged 65 years and older (17% of our patient population) and 21,226 women aged 50-64 years (32% of our patient population). Six thousand seven hundred one (61%) of the elderly women and 11,815 (56%) of the younger women had undergone at least one previous screening examination in our mobile van mammography program.

Because our screening population is physician referred, it probably does not represent a true cross section of women in our service area. Therefore, we believe it is important to describe the frequency with which known breast cancer risk factors were found in our screenees (Table 1). It also is important to note that we attempted to exclude from our screening population symptomatic women and women with abnormal physical findings.

With regard to the major breast cancer risk factors, 657 (1%) of our screening examinations involved women with a previous diagnosis of breast cancer, and 2,541 (4%) involved women with a very strong family history of breast cancer. The frequency of prior breast cancer increased progressively with advancing age, from 0.1% (33 of 33,470) among women aged younger than 40 years to 1% (212 of 21,226) among women aged 50-64 years to 3% (327 of 10,914) among women aged 65 years and older. This is to be expected, not only because older women have been at risk for breast cancer for more years but also because the age-specific incidence of breast cancer in older women steadily increases. There is, however, virtually no difference between age groups in the prevalence of histories of either premenopausal or bilateral breast cancer in a first-degree relative. Indeed, examinations among elderly and younger women are identical in very-strong-family-history profiles.

Small differences in minor breast cancer risk factors are also seen. Slightly more elderly than younger women had family histories of unilateral, postmenopausal breast cancer in a first-degree relative or relatives (10% vs 7%), whereas slightly more younger than elderly women had family histories of breast cancer in a more distant relative or relatives (10% vs 7%). Women aged 65 years and older and women aged 50-64 years had similar frequencies of menarche before the age of 10 years, the birth of a first child after the age of 35 years, nulliparity, and menopause after the age of 55 years.

Breast opacity data were collected for 36,867 screening examinations with normal results (Table 2). As expected, elderly women were slightly more likely than younger women to have fatty breasts (29% vs 21%). Indeed, the percentage of women with fatty breasts increased slightly but progressively with advancing age, from 5% for women aged younger than 40 years to 31% for women aged 70 years and older.

Table 2
Breast Opacity among Younger and Elderly Women

Age (Y)	Fatty	Focally Opaque and Opaque
50-64 (n = 11,872)	2,521 (21)	9,351 (79)
(n = 6,315)	1,859 (29)	4,456 (71)

Note.-Numbers in parentheses are percentages.

Abnormal Interpretations

The overall rate of abnormal interpretations was virtually identical (5%) for both age subgroups. There was, however, some variation in the degree of abnormality as a function of patient age (Table 3). We routinely categorize abnormal screening interpretations as "further tests needed" (24% were found to be malignant), "suspicious for malignancy" (64% were found to be malignant), "characteristic of malignancy" (96% were found to be malignant). Among elderly women, there was a slight but steady decrease in low-suspicion abnormal interpretations (further tests needed; 93% vs 86%) and, thus, a progressive increase in higher-suspicion abnormal interpretations. Elderly women were twice as likely as younger women to have abnormal screening findings judged to be suspicious for malignancy (10% vs 5%). Elderly women were even more likely to have abnormalities judged to be characteristic of malignancy (4% vs 1%).

Until the end of the study period, there were 3,326 abnormal interpretations. Table 4 catalogs according to age group the management outcomes of the 3,256 cases for which more than 3 months had elapsed since screening, which allowed sufficient time for full work-up. Almost one-fourth of abnormalities detected at screening, such as summation shadows and skin calcifications, were reclassified as normal after full evaluation with problem-solving imaging. Elderly women were nearly as likely to have abnormal screening interpretations reclassified to normal (20%) as were younger women (22%). Furthermore, when screening-detected abnormalities in elderly women were compared with those in younger women, there was only a slight difference in the percentage of women with simple benign cysts (10% vs 7%) and virtually no difference in the frequency with which abnormalities were judged to

Table 3
Abnormal Interpretations Classified According to Degree of Abnormality among Younger and Elderly Women

Age (y)	Further Tests Needed	Suspicious for Malignancy	Characteristic of Malignancy
50-64 (n = 1.035)	967 (93)	54 (5)	14 (l)
65+ (n = 513)	444 (86)	50 (10)	19 (4)

Note. – Numbers in parentheses are percentages.

Table 4
Disposition of Resolved Abnormal Interpretations among Younger and Elderly Women

Age (y)	Normal Findings	cyst	Follow-up Mammography	Biopsy	No Follow-up
50-64 (n = 1,010)	227 (22)	96 (10)	335 (33)	314 (31)	38 (4)
65+ (n = 509)	102 (20)	33 (7)	168 (33)	187 (37)	17 (3)

Note - Numbers in parentheses are percentages

Table 5
PPV, Biopsy Yield, and Cancer Detection Rate among Younger and Elderly Women

Age (Y)	PPV (%)	Biopsy Yield (%)	Cancer Detection Rate*
50-64	12	40	5.7
65+	20	56	9.2

Note - Numbers in parentheses are percentages.
* Number of women with cancer per 1.000 examinations.

be probably benign (which requires periodic mammographic surveillance rather than immediate tissue diagnosis; 33% for both age groups). There was, however, a steady increase with advancing age in how often biopsy was performed: from 24% (411 cases) in women aged younger than 50 years to 31% in women aged 50-64 years to 37% in women aged 65 years and older.

Biopsy Results

In this article, we define positive predictive value (PPV) as the number of breast cancer cases among abnormal screening interpretations, biopsy yield as the number of malignancies among biopsies prompted by screening, and cancer detection rate as the number of women with cancer per 1,000 examinations. All three of these parameters were derived from the 63,329 examinations and 3,256 abnormal interpretations for which at least 3 months had elapsed since screening. Subsequent evaluation led to the diagnosis of 325 breast cancers in 312 women (true-positive cases). Therefore, the remaining 2,944 cases were false-positive. Table 5 lists PPV, biopsy yield, and cancer detection rate according to age group. All three parameters increased progressively and substantially with advancing age. PPV increased from 4%, (22 of 569) in women aged younger than 40 years to 12% (120 of 1,010) in women aged 50-64 years to 20% (100 of 509) in women aged 65 years and older. Likewise, biopsy yield increased from 16% in women aged younger than 40 years, to 40% (126 of 314) in women aged 50-64 years, to 56% (104 of 187) in women aged 65 years and older; cancer detection rate increased from 1.9 in women aged younger than 40 years to 5.7 in women aged 50-64 years to 9.2 in women aged 65 years and older. Elderly women were only 17% of all women screened but accounted for 32% of all cancers found.

Characteristics of Breast Cancers

Of the 325 breast cancers, 234 were invasive carcinoma and the remaining 91 were ductal carcinoma in situ (DCIS). There was only a minor difference between the relative frequency of invasive carcinoma and that of DCIS when cancers found in elderly women were compared with those found in younger women. Elderly women were slightly less likely than younger women to have invasive carcinoma (77% [80 of 104] vs 78% [98 of 126]). Note that we classified cases of lobular carcinoma in situ and atypical hyperplasia as benign lesions rather than as malignancies.

Eighty-eight percent of breast cancers were nonpalpable before mammographic screening in both elderly (111 of 126) and younger (92 of 104) women. Some cancers, however, are palpated only after a mammographic lesion has been reported and its location has been described. In our series, this effect reduced the frequency of the nonpalpable cancer to 78% (81 of 104) in elderly women and 70% (88 of 126) in younger women.

The most reliable prognostic indicators for breast cancer are tumor size, axillary lymph node status, and overall tumor stage. Cancers in our study have been categorized according to size as a function of age in Table 6. The median size for all cancers was 11 mm. Cancers in elderly women were slightly smaller (median; 11 mm) than those in younger women (median, 12 mm). This difference in median size was similar both for cases of invasive carcinoma and for cases of DCIS.

Axillary lymph node sampling or dissection was performed for 274 cancers. In another 35 cases of DCIS, axillary lymph nodes were presumed to be free of metastases (intentionally not sampled) because they were nonpalpable, small, and of noncomedo subtype. Overall, cancers in elderly women have a slightly more favorable nodal status: Elderly women had 92 (93%) node-negative and seven (7%) node-positive tumors, whereas younger women had 106 (88%) node-negative and 15 (12%) node-positive tumors.

All breast cancers were classified according to the TNM staging system of the American Joint Commission on Cancer (17). Table 7 displays cancer staging data as a function of age. There are small differences that suggest a slightly more favorable prognosis in elderly breast cancer patients. For elderly women, 84% of cancers were classified as stage 0 or stage I; for younger women, 75% of cancers were classified as stage 0 or stage I.

DISCUSSION

There is general consensus that mammographic screening is efficacious for women aged 50-64 years because there is consistent evidence of a reduction in the breast cancer mortality rate from the several randomized, controlled trials that have been conducted in the past 30 years

(1). Because these same randomized trials did not include meaningful numbers of women aged 65 years and older, however, the decision of whether to recommend mammographic screening for elderly women must be based on more indirect evidence.

Wilson et al (18) recently addressed this issue for the subset of elderly women aged 75 years and older by comparing several predictors of prognosis of cancers found at screening with those of cancers identified in symptomatic women. They reported that screening-detected cancers were significantly smaller in diameter and earlier in stage than were cancers that manifested as palpable masses.

This study assesses the value of mammographic screening in elderly women by using a different methodology: Available clinical outcome data from the screening of women aged 65 years and older have been compared with parallel data from the screening of women aged 50-64 years, the age range within which screening is already widely accepted. Underlying this approach is the assumption that, if clinical outcomes are similar or more favorable for elderly women than for younger women, this would argue strongly for screening elderly as well as younger women.

At the outset, a basic requirement must be satisfied: Cases of breast cancer should be common in the targeted population. In our series, elderly women were 34% of all women aged 50 years and older but accounted for 45% of all the cancers. Stated in another manner, the breast cancer detection rate in women aged 65 years and older is more than 50% higher than that of women aged 50-64 years. These observations, which are consistent with the known increase in the incidence of breast cancer with advancing age, indicate that if breast cancer is sufficiently common to support the recommendation for screening at the ages of 50-64 years, then the frequency of disease is high enough to justify screening elderly women as well.

Because the prognosis for breast cancer is most dependent on tumor size, axillary lymph node status, and stage of disease at diagnosis (19,20), we have focused our attention on these parameters in comparing the breast cancers detected in the elderly and younger women in our screening population. Although the differences observed in our data are small and do not approach statistical significance, they show a consistent trend. Tumor size is smaller, metastasis to regional lymph nodes occurs less frequently, and stage at diagnosis is lower in women aged 65 years and older than in women aged 50-64 years. These findings suggest that the prognosis of screening-detected cancers is at least as favorable among women aged 65 years and older as it is among women aged 50-64 years, for whom screening already has been shown to be efficacious. This observation is especially important, because recent evidence indicates that survival with localized and regional disease is equal for elderly and younger women (9).

Table 6
Sizes of Breast Cancers among Younger and Elderly Women

Age (y)	1-5 mm	6-10 mm	11-20 mm	>20 mm	Median (mm)
50-64 (n = 126)	13 (10)	46 (36)	46 (36)	21 (17)	12
65+ (n = 104)	16 (15)	36 (35)	38 (36)	14 (13)	11

Note.-Numbers in parentheses are percentages.

Table 7
Stages of Breast Cancers among Younger and Elderly Women

Age (y)	Stage 0	Stage I	Stage II	Stage III	Stage IV
50-64 (n = 126)	28 (22)	66 (52)	29 (23)	2 (2)	1 (1)
65+ (n = 104)	24 (23)	63 (61)	15 (14)	1 (1)	1 (1)

Note - Numbers in parentheses are percentages.

The frequency of detection of more advanced breast cancer can also be informative in predicting mortality from the disease. The Swedish Two-County randomized controlled trial showed a parallel between the cumulative rate of detection of advanced cancer and the breast cancer mortality rate (21). The percentages of cancers diagnosed at stage II and higher in our study (16% in elderly women vs 25% in younger women) indicate that the mortality rate from breast cancer should be no greater in elderly women than it is in younger women.

A complete analysis of the cost-benefit relationship of screening mammography in elderly women is beyond the scope of this study. We can, however, examine some of the factors that affect the costs of screening. Our study shows an identical abnormal interpretation rate (5%) in elderly and younger women. In addition, the availability of prior mammograms for comparison lowers the abnormal interpretation rate equally among all age groups. Therefore, one would not expect greater induced costs from an increased number of abnormal interpretations in the elderly. Furthermore, the higher PPV in elderly women should result in a lower cost per cancer found. Finally, because elderly women are diagnosed with cancers of stages similar to those found in younger women, the cost of treatment also should be comparable.

The decision to screen elderly women is complicated by considerations of increased comorbidity and reduced life expectancy (6-8). General perceptions of life expectancy among elderly women, however, are often misleading. Actually, most elderly women have a life expectancy that exceeds 10 years; indeed, life expectancies for women aged 65 and 75 years are 18 and 12 years, respectively (22). Detection at screening of breast cancers with favorable prognoses in these women, therefore, is likely to provide a substantial benefit. Women aged 85 years, with a life expectancy of only 7 years (22), are less likely to receive as great a benefit from screening. Ultimately, decisions for or against mammographic screening should be based on the importance of life expectancy and comorbidity and must be made on a case by case basis by each woman and her primary care physician.

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Feasibility of Universal Screening Mammography

Lessons From a Community Intervention

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• It is estimated that 44500 American women will die of breast cancer in 1991. The breast cancer screening guidelines of the American Cancer Society and the National Cancer Institute calling for annual mammography for all women older than 50 years have been endorsed by numerous professional groups. Third-party reimbursement for screening mammography is becoming more prevalent, and payment for screening mammography is now a Medicare benefit. Our studies, conducted as part of a National Cancer Institute grant to increase the routine use of screening mammography and clinical breast examination in women 50 to 75 years of age, have uncovered a number of significant barriers to the implementation of screening guidelines among women, primary care physicians, and providers of mammography services. These barriers, as well as methods to assure the quality of mammography, need to be addressed before universal screening is feasible.

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Breast cancer will affect one of every nine American women. In 1991, the mortality rate of this major disease is expected to be 44500, or 30% of the number of newly diagnosed cases.[1] The prevention of breast cancer is not yet possible. Significant decrease in the mortality rates of breast cancer has been possible through the early detection of those tumors that are amenable to screening techniques. Mammography is the best available test to find such small, nonclinically evident, nonmetastatic lesions. Therefore, it is of paramount importance to understand why, universal regular mammography is not yet a reality.

The breast cancer screening guidelines of the National Cancer Institute and the American Cancer Society call for annual screening mammography of all women 50 years and older and are endorsed by many professional societies.[2] More conservative groups, such as the Preventive Health Services Task Force, recommend screening mammography every 1 to 2 years.[3] Whatever interval one chooses, the feasibility of implementing a regular screening program for women in this age group needs to be carefully considered.

In 1987, as part of a funded National Cancer Institute grant, the Breast Cancer Screening Project (BCSP) of the University of Massachusetts, Worcester, undertook surveys and interventions in a northeastern urban community to study and to increase mammography use among women 50 to 75 years of age. This experience, and that of other investigators, has provided practical perspectives on barriers to universal breast cancer screening using mammography. A review of this subject is particularly timely given the recent dramatic increase in mammography utilization and the inclusion of screening mammography as a Medicare benefit.

We will review the major barriers for the three major participants in the mammography process: women, or screenees; the mammography providers; and primary care physicians. The interrelationships of these groups are complex; however, for the sake of simplicity, the groups will be individually addressed as though they were largely independent of one another. We will only touch on the fourth and perhaps most critical component of the equation, ie, the overall cost of such screening initiatives,to the health care system. We shall assume that low-cost mammography (ie, $50 per mammogram) can be achieved. The barriers discussed will include women's knowledge and motivation to seek screening; women's access to screening; the quality of the examinations, including quality control measures for mammography equipment; the skill and availability of the technologists and radiologists who perform the examinations; and the impact of following these guidelines for the primary care physician. We anticipate increasing discord among these three participant groups in the mammography process as the pressure to comply with screening guidelines increases.

BARRIERS FOR WOMEN

There are approximately 28 million women between the ages of 50 and 75 years in the United States. In October

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1987; the BCSP surveyed 885 women aged 50 through 74 years in the northeastern United States. Only 55% of them had ever had a mammogram.[4] In 1989, a second survey of 677 women showed that 75% had had at least one mammogram. However, regularity of screening mammography remains a significant problem, as only 31% of the latter group had undergone mammography within the past year.

Knowledge of Breast Cancer Risk/Importance of Mammography

When asked why they did not get mammograms, women in the BCSP survey said that they were unaware that they needed one or said that their physician did not recommend one. The survey also demonstrated that women who are older than 50 years often lack accurate knowledge about breast cancer risk factors and the benefits of early detection. For example, while the risk of breast cancer increases in women older than 50, the BCSP surveys show that women aged 50 to 75 believe that they are at less risk than younger women.[4] This finding has been confirmed by the National Cancer Institute Breast Cancer Screening Consortium findings.[5]

Access Issues: Cost

Cost is assumed to be a significant barrier to mammography. However, according to 1987 surveys by the National Cancer Institute Breast Cancer Screening Consortium and the BCSP, cost was not an immediate issue for the majority of women themselves.[4,5] In 1990, 40% of respondents in the Mammography Attitudes and Usage Study thought that "mammograms cost too much."[6] This change may be due, in part, to the increased number of women who have had several mammograms and are now recognizing the recurring cost.

Although only 3% of women surveyed by the BCSP were uninsured, insurance coverage for screening mammography is neither universal nor uniform. The provision of insurance benefits has been addressed through legislation at the state and federal levels. By May 1989, 18 states had mandated some form of third-party payment for mammography, most requiring cost-sharing and forms of coverage similar to those provided for other diagnostic tests.' Thus, depending on the individual insurance policy, this could mean that the test is completely covered, is covered after a specific deductible is met, and/or is only partially covered, with the woman required to make a copayment. Many larger employers are self-insured and exempt from state-mandated coverage by federal regulations.[7]

Now that Medicare will provide an annual reimbursement of $55 for screening mammography for women 60 to 64 years of age and biannual reimbursement for women 65 and older, with a limit on the copayment that can be charged, low-cost mammography is essentially mandated for all older women. There will undoubtedly be political pressure for Medicaid to comply as well.

Other Access Issues

In the BCSP experience, scheduling delays for screening mammography in the northeastern United States range from 1 week to 4 months, or longer. As more women are referred for regular mammography, waiting times could extend into years: If only half of the age-eligible women complied with the guidelines, every radiologist in the country would have to read eight mammograms every working day of the year.[8]

In addition to lengthy delays in getting appointments, there are barriers of physical access for older women and for poor women without private means of transportation A significant number of women in their 50s work outside the home or are caring for elderly relatives, which may keep them from undergoing regular mammography unless facilities have extended hours.

Implications

With the barriers to mammography among women themselves, adherence to screening guidelines will likely proceed very slowly, especially among the older women who are at higher risk, have lower incomes, and are more dependent on their health care provider to initiate screening.

As the BCSP survey demonstrated, older women rely heavily on their physicians for guidance, which indicates that a successful program to reach these older women must include their physicians. Improved methods of public education to present correct knowledge concerning breast cancer and breast cancer screening are also needed. Certainly an instrumental role could be played by organizations committed to improving and maintaining health, such as the American Cancer Society or the American Association for Retired Persons.

As more women receive at least partial coverage for mammography through third-party coverage or Medicare, the examination cost must be brought to a reasonable level so that coverage will remain economically feasible and copayments affordable. Programs to develop high-volume, low-cost, quality examinations should be supported, as should extended hours of service so that access is not an issue.

BARRIERS WITH MAMMOGRAPHY PROVIDERS

The provision of mammography services involves several factors: the technical aspects, including volume of examinations and quality control of the equipment, as well as the training, skill, and availability of radiology technologists and of radiologists themselves. These factors are intimately interdependent. Balancing quantity, quality, manpower, and cost is essential.

Volume and Procedure Issues

The goal of screening mammography is to find breast cancer before it presents with any of the standard clinical signs or symptoms whenever this is possible. Mammograms must be of high quality because there are no accurate corroborating tests or physical findings. An inadequate mammogram may not detect a small curable cancer. By the time it is detected on physical examination, the chance of cure is greatly decreased. Overall, biopsies generated by mammography are positive for malignancy about 20% to 30% of the time,' although in some centers, particularly those dedicated to screening mammography, the positive rate may be as high as 50%. In a pure screening population, approximately 2% of the screenees will require biopsy. Since there are approximately 7 million women who should have annual mammograms, 140000 biopsies should be expected and planned for. A potential major, but as yet unquantified, factor is the number of subsequent examinations required at less-than-yearly

intervals. A portion of this volume may be related to der insecurity in interpretation, or to fear of litigious reprisal at missed subtle findings, as well as by a lack of firm guidelines on how to follow up on borderline findings.

Equipment and Quality Control

Meticulous attention must be given to the technical aspects of mammography, including such parameters as the energy of the x-ray beam, radiation dose, focal spot size, radiation output rating, phototimer, and film processor performance. Specific guidelines relating to imaging performance and radiation dose in mammography have been published.[10] Additional recommendations and quality assurance protocols are currently being developed by a Diagnostic Imaging Task Group of the American Association of Physicists in Medicine as well as by the American College of Radiology. A deficiency in any of these parameters can result in suboptimal contrast and resolution, which severely interferes with the ability to detect the extremely subtle clinical signs associated with breast carcinoma. A suboptimal system may result in the administration of unnecessarily high radiation doses to the patients, without any improvement in image quality. A deficiency in any of these performance characteristics is rarely detectable by the mere review of clinical mammograms but requires measurements of the system's performance by a diagnostic radiology physicist.

The selection and proper maintenance of a high-quality film-screen and processing system are also essential to ensure high image quality. It is often assumed that any commercially available system meets established performance guidelines. However, the design and performance specifications can be vastly different in equipment from different manufacturers, and significant differences in performance have even been observed among different machines of the same model and manufacturer.[11]

Many quality-related problems can be prevented if proper procedures are followed in the specification and selection of roentgenographic equipment and if at installation a physicist performs acceptance tests to verify the advertised imaging capabilities of the system. Unfortunately, many systems are not acquired on the basis of predefined specifications, and comprehensive acceptance tests are often not performed.

Even if the equipment meets performance standards when acquired, continued optimal performance is not assured. In 1986, the Massachusetts Department of Public Health (Radiation Control Program) conducted a survey of mammography facilities in the Commonwealth of Massachusetts. Most of the mammography facilities that were performing film mammography were using a very popular, high-quality mammography machine of a type that is considered "standard" by mammographers. A total number of 81 units of this type were tested. Sixty units employed antiscatter grid, which is considered standard practice for improvement in image quality. Twenty one (26%) did not use any grid. The use of a grid increases the radiation dose but is greatly encouraged for its contribution to improved image quality. Of the 21 units not using grids, the mean glandular dose to the breast ranged from 25% to more than 200% above the recommended mean glandular dose (1 mGy).[12] Similar variation in equipment function was reported by Galkin et al[13] in a study of 29 film-screen imaging systems.

Performance of state-of-the-art equipment may be substandard if careful monitoring is not routine practice. The BCSP evaluated five film-based mammography installations. Of the roentgenography units, four performed at a level compatible with accepted standards, with the exception of suboptimal automatic exposure control, a deficiency the users did not seem to recognize. The remaining unit performed below accepted standards for mammography. A recent report issued by the Government Accounting Office confirms a wide variation in image quality in the units that they surveyed.[14]

It is of great concern that, with the exception of hospital-based mammography units, which are required to perform regular quality control testing in order to receive Joint Commission of the Accreditation of Healthcare Organization accreditation, equipment quality control is strictly voluntary in nonhospital settings.

Technologists

Mammography is one of the most technologist-dependent examinations in radiology. Positioning of the breast, achieving adequate compression, and determining the appropriate settings for the machinery are skills that require a great deal of independent judgment and expertise acquired through careful training and practice. Since the findings of an inadequate examination may be interpreted as falsely negative, the need for skilled technologists cannot be overemphasized.

Requirements for technologists' training vary widely from state to state, with no guarantee that a technologist has developed adequate skill in mammography during the training course. Technologists who perform mammography should also have sound interpersonal skills, be comfortable with the intimate nature of the examination, and receive regular feedback from patients so they can make the experience one that women will willingly repeat on an annual basis.

Radiologists

The radiologist must be well versed in the mammographic evidence of minimal breast cancer. Many radiologists practicing today did not receive training in mammography during their residency program. Although, to our knowledge, no data exist on the subject, the amount of effort radiologists have expended to learn mammographic skills probably varies widely.

The BCSP conducted a pilot program on interpretations of mammograms for radiologists in community practice. The participants were all regularly reading mammograms in their practice. Program participants read a standardized series of test mammograms chosen to demonstrate the variety of common diagnostic situations that a radiologist might encounter. In more than 30% of the test films, there was a significant difference between the participants' and the project radiologist's interpretations and recommendations for follow-up.[15] This wide variability in mammographic interpretation between radiologists has also been demonstrated in other studies[16] and is cause for concern.

The mammography report is often the only source of information on which patient recommendations are made. Unfortunately, there is a tendency for the radiologist to render ambiguous reports that give the clinician little guidance.[17] Given the litigious climate today, a radiologist who is not confident or who is practicing defensive

radiology may unfairly shift the responsibility to the primary care physician with statements such as "malignancy cannot be ruled out," or "follow-up or biopsy is recommended depending on clinical findings." Reports such as these serve little purpose except to anger and confuse the primary care physician, who must determine a course of action and deal with a distraught patient.

In the BCSP study, a brief 6-hour course emphasizing the recognition of subtle mammographic findings and issuing clear interpretations and recommendations resulted in a 30% improvement in practicing radiologists' performances[15]

Implications

Anecdotal data confirm that entrepreneurial groups are already operating portable mammography vans and are offering primary care physicians mammography units for their offices under a profit-sharing arrangement. As pressure to control the cost of mammography builds, the proliferation of high-volume, low-overhead mammography sites, possibly with equipment of questionable quality, and radiologists and technologists whose mammography skills are an unknown factor, could occur. At the same tune, competent, responsible radiologists, already burdened by interpreting an increasing number of mammograms, may limit their established, quality-controlled screening services when threatened with lower reimbursement. There is a real risk that the mammography system may become totally volume driven without quality control. In which case, an unacceptably high false-negative rate could make screening mammography a pointless endeavor.

Volume and Cost

Volume, cost, and quality issues must be addressed simultaneously. Increasing volume is the best way to decrease cost; however, these changes must be tied to quality control. If the average cost for a screening mammogram remains $120,[17] insurers will limit reimbursement and the copayment will be prohibitive. A cost analysis done by the Physician Practice Pricing Board has demonstrated that high-quality $50 mammograms are feasible in well-managed, high-volume facilities.[18]

Equipment Quality

Proposed regulations by the Health Care Financing Agency for Medicare reimbursement are comprehensive.[19] Our comments are meant to be complementary to the Health Care Financing Agency's advocacy of quality-control measures. Unless quality is mandated at the same time cost is lowered, poor-quality examinations will tend to defeat the goal of screening. There must be regular testing of all mammography units by a qualified physicist. For example, every unit could be required to participate in the American College of Radiology Certification Program, which requires each facility to provide extensive. information on both the equipment and the level of training of all personnel and complete extensive equipment testing. The certification is valid for 3 years. Or, states could regularly inspect each unit, charging a per-unit fee that would make the program self-supporting. A similar program is used in Minnesota.

Staffing Issues

All technologists performing mammograms should be required to have special certification of skills and to attend periodic refresher courses. Technologists who are willing to take additional training and accept the extra responsibility for performing mammograms. could receive higher pay. This could decrease turnover and act as an incentive to obtain certification.

Much of mammography cost is for the radiologist's time. The cost of screening mammography performed in the absence of physicians, either after hours or in mobile vans, could be reduced. Patients requiring additional views or consultation would be recalled, with the examinations performed and billed separately. Several recent articles[20,21] have supported the viability of low-cost mammography. It is important that strict criteria relating to communication among clinician, radiologist, and patient must be maintained, especially with mobile mammography vans, which may cover vast distances.

In a recent article,[22] technologists were trained to screen mammograms into suspicious and nonsuspicious groups. This is similar to the method utilized by cytotechnologists screening for cervical cancer with the Papanicolaou smear. These technologists performed as well as or better than radiologists, over the short term. Obviously much more work must be done before the potential cost-saving benefits from such a program can be realized by freeing radiologists to focus on suspicious films, thus increasing the volume of patients a facility can handle.

Training in mammography in residency programs is now being given importance similar to other radiologic subspecialties. Mammography is an individual examination given by the American College of Radiology as part of certification in radiology. Based on the BCSP pilot study, we believe that practicing radiologists should be required to take a portion of their continuing medical education courses in mammography programs that focus on the subtle mammographic signs of breast cancer, as well as on the importance of issuing reports that contain clear recommendations for follow-up. These courses could lead to special accreditation on mammography interpretation for radiologists who finished residency programs without specific training in mammography.

PRIMARY CARE BARRIERS

In this era of managed care, primary care physicians are becoming the appointed gatekeepers of health care services. We also know that women who are older than 50 years rely heavily on their doctor's recommendations for screening and that various attempts to remove the primary care physician from the screening process have failed. Many screening facilities now refuse to perform examinations on women who have no primary care provider. They have found that the follow-up, especially if it includes the need for special examinations or scheduling and interpreting biopsies, requires the intervention of a primary care physician. Thus the involvement of primary care physicians in the screening process is mandatory. The presence or lack of commitment of primary care physicians to advocate regular breast cancer screening for their patients could well be the key to universal screening.

Knowledge, Skill, and Time

Women, particularly those older than 50, lack knowledge of the need for annual examinations, especially in the absence of symptoms.[4] Primary care physicians are most likely the best source of patient education and counseling to ensure regular screening. We need to

acknowledge the central role of the primary care physician in motivating women to follow the recommended guidelines for screening.

Mammography is more than a roentgenogram. It is a complex health "experience" requiring professional guidance to educate, motivate, and prepare the patient for the examination. The clinician must also interact with the testing facility to provide clinical data if needed, to encourage changes in scheduling depending on patient emotional or work factors, to deal with missed appointments and rescheduling, to interpret the radiologist's report, and to set up a recall system for the woman whose examination findings are normal. It may also be necessary to arrange for follow-up examinations, biopsies, or increased frequency of screening, depending on the results; to share uncertainty with the patient and her family; to write excuses for work absenteeism related to testing or follow-up; to deal with the emotional sequelae of bad news; to interpret contradictory current national guidelines for women; to act as an advocate for the patient who needs the examination more often than the guidelines call for or whose health plan did not cover the examination; to answer patient questions when reports are slow to return or do not arrive at all, and so on. None of the foregoing activities is currently reimbursed.

Primary Care-Radiology Partnership

Screening mammography unites the radiologist and the primary care clinician. The radiologist must ensure that an, optimal examination is performed and that clear recommendations are issued and conveyed to the clinician. The clinician must explain the results of mammography to the patient and ensure that proper follow-up is accomplished. This relationship can be antagonistic when the radiology reports are equivocal or leave the clinician without a firm recommendation to guide his or her approach with the patient. In a recent survey of primary care physicians, the BCSP found that physicians who felt that ambiguous reports were a problem reported ordering significantly fewer screening mammograms.[23]

Lack of Incentive

For the primary care physician, fears of malpractice litigation provide a strong, "unpleasant" reinforcement. Failure to diagnose cancer is a common cause for malpractice claims. In our survey, 44% of physicians felt strongly that ordering mammograms protected them legally. Those who reported such a strong belief also reported ordering significantly more mammograms than did physicians who did not share this belief. Currently there is little positive incentive for primary care physicians to promote mammography. The time needed to explain the procedure and to convince the patient to have the test is uncompensated time. The physician cannot bill for the time spent on the phone reassuring and counseling the woman whose examination findings were abnormal or for the time spent trying to convince a busy radiology practice to speed up the results of the patient's second mammogram so they will be there the next day rather than 2 weeks later.

Implications

Without positive incentives (adequate reimbursement for screening and preventive office interventions), primary care physicians will continue to struggle with conflicting pressures generated by patient demands, ambiguous radiology reports, fear of malpractice litigation, inadequate office systems, and varying degrees of knowledge and skill with respect to breast cancer screening. This will most likely lead to the continued underutilization of screening mammography, especially by older women (who are at most risk) who rely on physician recommendation for screening.

The first and most obvious recommendation is to reimburse physicians for the time they spend in breast cancer screening, ie, in performing an adequate clinical breast examination and in counseling women to have annual mammography. Physicians also need programs to improve their skills in performing breast examinations and in counseling; to inform them of the true benefits and limitations of mammography, of national guidelines for breast cancer screening, and of their legal responsibilities for screening women in their practices; and to give them advice on improving their office practice systems so that they can incorporate screening and preventive measures in their practices.

CONCLUSIONS

The critical problems involving each of the three groups will inhibit adoption of regular screening mammography in this country. Women, particularly those older than 50 years, have less knowledge about the importance of screening mammography and require physician counseling and encouragement to follow recommended screening guidelines. Cost may become a major barrier, even with some form of third-party payment of Medicare coverage, because the copayments may be prohibitive. As more women seek mammography, access may be a problem, with lengthy waits to schedule screening appointments, lack of transportation, and lack of operating hours that serve working women.

Changing to high-volume, low-cost mammography has the potential to solve both the access and the cost problems. However, the quality of equipment, as well as of technologist and radiologist skill, is already variable. Such a change must occur with the simultaneous institution of quality control to ensure quality examinations. Finally, the essential role of the primary health care provider in the implementation of mammography guidelines must be recognized and rewarded through reimbursement for breast cancer screening care. Recognizing only one segment of the problem without addressing or redressing issues among the other major participants will result in the failure of any proposed universal screening program. *Carpe diem.*

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The Extent of Breast Cancer Screening in Older Women

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The Extent of Breast Cancer Screening in Older Women

Mary E. Costanza, M.D.

Women 65 and older present a unique challenge to health professionals, particularly with respect to breast cancer screening. These women are at the highest risk for developing breast cancer; they represent 50% of all newly diagnosed breast cancers. This group represents 60% of the breast cancer deaths, however, demonstrating how serious a disease breast cancer is in the 65-and-older age group. Moreover, the 65-and-older population cohort is growing rapidly. By 2010, it is estimated that greater than 15% of the population will be older than 65, and, as is the case now, the majority of this group will be women. Therefore, preventing breast cancer deaths in, older women is a very significant and pressing issue.

Ironically, most studies have reported that screening for breast cancer is less widespread in women older than 65 than in those younger than 65. Regional surveys emphasize a number of barriers, some of which seem to be age-specific—a lower level of knowledge about the usefulness and benefit of mammography, particularly in the absence of symptoms; less of a sense of personal vulnerability; fewer screening recommendations from family, friends, or physicians; and more problems with access (cost, transportation).

To improve breast cancer screening rates in older women, sound health education interventions are needed to improve knowledge of and belief and attitudes regarding mammography. These should be targeted not only to older women, but also to their physicians and/or primary care givers. In addition, specific attention should be given to those barriers that are particularly burdensome for the elderly: cost, transportation problems, and loss of mobility. ***Cancer*** **1994;74:2046-50.**

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Women 65 and older represent a unique challenge to health professionals, particularly with respect to their low level of participation in breast cancer screening. Women 65 and older are at the highest risk for developing breast cancer. Greater than 50% of the 175,000 newly diagnosed cases of breast cancer occur in women 65 and older. The disease is not unaggressive, as some clinicians have thought, because 60% of the annual 50,000 breast cancer deaths occur in women 65 and older.' This vulnerability is compounded by the steady overall increase in breast cancer incidence that has been noted during the last 40-50 years.[2] Where 1 of 20 women developed breast cancer in a lifetime in 1950, in 1994, 1 of 9 will develop breast cancer in her lifetime-a doubling of incidence.[3]

Although some of the later rise in incidence (after 1986) might be attributed to an increase in mammography use, there is still an underlying increase over time.[4] From a public health standpoint, this epidemic of breast cancer, particularly in older women, can only worsen, because the number of people 65 and older is expected to account for 15% of the U.S. census by the year 2010.

Age and Mammography Usage

Multiple reports[5-13] have noted that mammography screening rates are lower in older women than they are in younger women. Although there has been an increase in mammography utilization in older women since 1987, the rates are still lower than those for younger women, who are at lower risk. If one were to match the utilization goal to the amount of cancer-involved risk, then older women's use of mammography is critically and inappropriately low.

The year 1987 was the beginning of national interest in mammography use.[11] At that time, from 19% to 33% of older women aged 65-74 surveyed across the country reported having ever undergone mammogra-

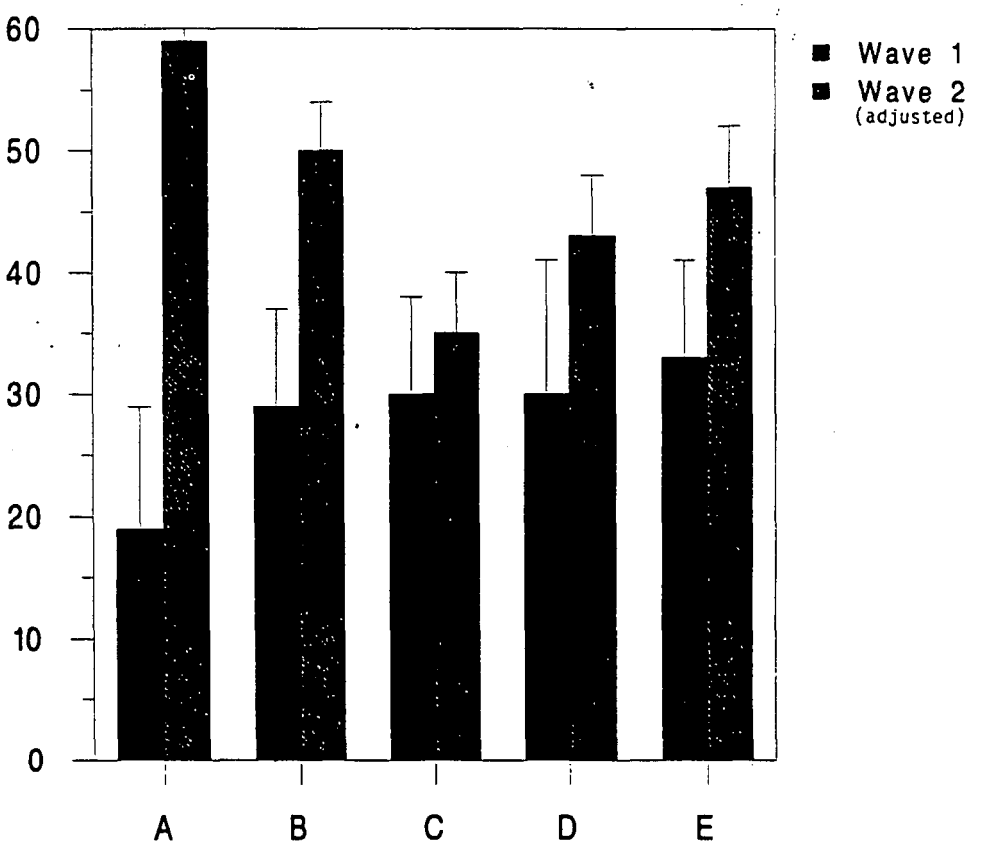

Figure 1. A: Los Angeles; B: Eastern Massachusetts; C: Eastern North Carolina; D: Eastern Long Island; E: Philadelphia. Change in rates of mammography use by women 65-74 years of age in 1987-1988 and 1991. From Coleman EA, Feuer EJ, the NCI Breast Cancer Screening Consortium. Breast cancer screening among women from 65-74 years of age in 1987-88 and 1991. *Ann Intern Med* 1992;117:961-6.

phy. By 1991, a second survey reported that the rate of those who had ever had a mammogram had risen to 35-59%.[12] Figure 1 shows these changes over time in the six geographic sites of the NCI Breast Cancer Screening Consortium. [12] While mammography usage among older women had increased dramatically over a 3-year interval, it was matched by a similar rise in mammography usage in women younger than 65 years in other surveys.[13-15] This means that, given the magnitude of their risk, older women are still far behind in utilization rates. In addition, many investigators now are reporting a leveling-off of mammography usage rates.[16] This suggests that a hard-to-reach older population may have emerged, and special strategies and targeted interventions may be needed to reach these women.

The inverse relationship between age and mammography use holds not only for the younger-than-65 and older-than-65 age groups, but also for subgroups of older women. The San Diego project analyzed the use of mammography, clinical breast examination, and breast self-examination by age.[17] Mammography use was related very significantly and inversely to advancing age (Table 1). Again the very old (80+) have the highest risk of developing breast cancer but the lowest usage of mammography screening. In that study, clinical breast examination and breast self-examination use were not age-dependent. Multivariate analysis continued to show a significant, intense association between age and mammography use even when health status, number of physician visits, income, and education were included.

Barriers to Mammography Use

A number of studies have investigated barriers to mammography utilization. Many of these barriers are not unique to older women, but some are. The most com-

Table 1. Mammography Use and Advancing Age

	Age group (years)			
	65-69	*70-74*	*75-79*	*80+*
Mammogram				
Never had (%)	18	17	30	35
Every few years (%)	40	46	41	39
Every year (%)	43	37	29	26

P = 0.0004.

From Mayer JA. Slymen DJ. Drew JA, Wright BL, Elder JF, Williams SJ. Breast and cervical cancer screening in older women: the San Diego Medicare Preventive Health Project. *Prev Med* 1992; 21:395-404. Reprinted with permission.

monly cited general barriers recently were summarized.[18] They included the following:

- Lack of knowledge that screening mammography is needed, particularly in the absence of symptoms;
- Belief in the benefit of mammography;
- Lack of physician recommendation;
- Cost;
- Access (lack of, transportation or remoteness of mammography facility);
- Lower levels of education;
- Low income; and
- Not having a regular physician.

Several knowledge-related barriers particularly relevant to the older population are a lack of knowledge about age as a risk,[12,14,18] and a lack of knowledge that mammography is necessary in the absence of symptoms.[8,9,12,14,18] A positive support system also is particularly important for older women. The older woman's physician plays a critical role in mammography-seeking behavior. Many studies have shown this relationship for all women, but it is particularly significant for older women.[8,9,12,14,18,19]

Cost or access has been reported variably as a significant barrier for women 65 and Older.[8,9,10,12,14,18] Now that Medicare will pay for mammograms every other year, the actual cost of a mammogram may not be an issue. Hidden costs to be addressed are the cost of getting to the mammography facilities (taxi fare), cost of getting to see the doctor (gatekeeper) to get the necessary forms for health maintenance organization-provided care, and so forth. Repeatedly reported is the fact that women of lower income get fewer mammograms. Financial barriers may be particularly relevant, because the older woman is well represented among widowed, poorly educated, and/or ethnic groups, and therefore is among those of lower income. Other access issues may be more subtle than previously reported, for example, many older women may be reluctant to ask others for help in getting to a mammography facility and access may involve climbing up stairs to the mobile mammography van, which can be difficult for those in this age group.

Health Barriers

Aging often is associated with infirmities of one kind or another. The relationships of health, mobility, and function with mammography use are not, however, what one might expect. A review of mammography utilization and health status found no relationship between these variables.[20] This may be because sicker women see their physicians more often and have a greater chance to get a mammography recommendation than do well women.

Psychologic Barriers

Although many women experience some anxiety about mammography, older women may have unique perceptions that prevent them for participating fully in screening. In one report of older women in focus groups, women said that they were too old and did not care.[21] The perception of being too old is not uncommon. Most women (and their physicians) are not aware of how much life is left to live at 85. (See Table 4 in "Issues in Breast Cancer Screening" elsewhere in this issue for expected years of survival for women of varying ages who have average health.) Clearly, healthier women could expect to live even longer.

Another common psychologic barrier for older persons is that they think they somehow are not worth the effort, perhaps a thought related not only to their perception of being less productive but also to the mistaken view that death is just around the comer. Issues concerning quality rather than the quantity of life also have relevance to older women's enthusiasm for breast cancer screening. Anecdotally, it has been found that the prospect of maintaining one's independence is a more powerful motivation for older women to obtain a screening mammography than is the possibility of living 10 more years.

Physician Barriers

Much has been written about the screening mammography as it relates to physicians' knowledge, attitudes, and behavior. Several recent summaries provide an overview of the many issues facing primary care physicians, radiologists, and other health care provides.[22,23] With respect to older women, physicians have a great opportunity to advocate screening. Because at least 85% of older women visit a physician at least once in a 2-year period, there is ample opportunity to recommend regular mammography[11]; however, physicians apparently purposefully stop recommending mammography for the older population. Of primary care physicians surveyed in Massachusetts, 30% reported not recommending mammography to women who have reached age 75.[24] Because an average woman of 75 years of age will live an average of 12 more years, the lack of a physician recommendation for screening mammograms seems arbitrary and neglectful.

Minority Barriers

Utilization rates for screening mammography among older persons of ethnic minority groups has been de-

Table 2. Race, Age, and Recent Mammography Use

Race/Age	Women who had a mammogram in the last year (%)
Black	
50-64	19
65-74	13
75+	5
Mexican-American	
50-64	20
65-74	0
75+	0
Puerto Rican	
50-64	10
65-74	7
75+	0
Cuban	
50-64	14
65-74	14
75+	0

From Caplin LS, Wells BL, Haynes S. Breast Cancer screening among older racial/ethnic minorities and whites: barriers to early detection. *J Gerontol* 1992; 47(Special Issue):l0l-10. Copyright The Genontological Society of America.

scribed variably.[25-27] A review of stage at diagnosis suggests either that black women have more aggressive disease or that they are not being screened as routinely as white women are. Utilization figures for screening mammography in 1987 by ethnic group are shown in Table 2. The rates are lower than comparable figures for whites (Fig. 1 and Table 1). Note also the decreasing use by age-ethnic groups do poorly, but older ethnic women do worse. Underutilization of mammography by ethnic minorities, however, is not the case in all medical settings. In settings where minority women have access to regular care, such as family health centers, mammography rates may be as high as nonethnic rates. Even in this setting, age is still a powerful barrier. In our experience, older ethnic women were still more unlikely to have had a mammogram than were younger ethnic women (Table 3).[28]

Avenues for Change

There are many opportunities for improving the participation of older women in breast cancer screening and particularly for improving their regular. use of mammography. We already know from published studies that older women will get screening mammographies if their physicians recommend them.[29-32] The role of the physician in advocating for mammography, particularly in influencing the older population, cannot be overstated.[19,33] Clearly then, primary care physicians need to be made aware of the potential benefit and the importance of breast cancer screening in older women and the importance of making a strong, clear recommendation to them.

Table 3. Age and Screening Mammogram Utilization in a Latina Population

	Age (years)	
	55-64	65+
Ever had a mammogram (%)	67	54

From Zapka JC, Stoddard AM, Barth R, Costanza ME, Mas E. Breast cancer screening utilization by Latina community health center clients. *Health Educ Res* 1989; 461-8. By permission of Oxford University Press.

Educational programs for older women should include attention to their special needs.[34,35] Recognizing the frequency of vision, hearing, or memory defects, education for older women should ensure that messages are simple, presented in large print, or given in a loud tone and repeated a number of times. Programs for older women should be targeted carefully to them, as outlined in a brief summary of recent and promising interventions.[18]

In 1994, the American Cancer Society will launch a breast cancer screening campaign focused on older women. The development of this program has had considerable input from behavioral scientists and cancer control researchers and promises to be successful in overcoming so many of the barriers that prevent older women from participating in regular screening.

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Treating Non-Adherence

Diagnosing and Treating Non-Adherence with Recommendation of Mammography

I. Types of Patients Who Don't Comply

A. Patients with lack of knowledge or misinformation
B. Patients who had negative past experiences with mammography
C. Patients dealing with emotional barriers
D. Patients who have logistical issues

II. A Model for Diagnosis and Treatment

A. Steps
   - Identify stage
   - Assess barriers
   - Address barriers
   - Plan and follow-up

B. Skills
   - Questioning
   - Providing information

III. Stages of Readiness and Diagnostic Profiles of Patients

A. Stages of readiness to act; incorporating the understanding of stages into diagnostic and treatment phases
   - Unaware
   - Uninterested
   - Contemplating
   - Acting
   - Maintenance

IV. Videotaped Demonstration

Patients Who Don't Adhere to Regular Mammography Screening

"Getting a mammogram is just looking for trouble."

Patients Who Don't Adhere to Regular Mammography Screening

"I've been busy and haven't gotten around to scheduling one."

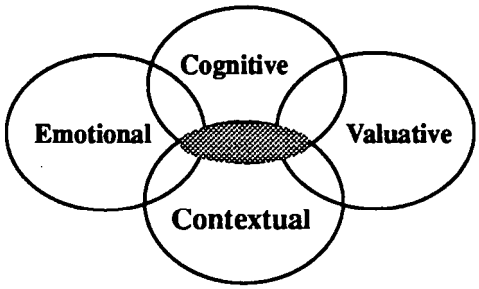
Patients Who Don't Adhere to Regular Mammography Screening

"I've heard they're pretty painful."

Patients Who Don't Adhere to Regular Mammography Screening

"I'm in good health and don't see the need."

Reasons for non-adherence



"People are generally better persuaded by the reasons which they have themselves discovered than by those which have come from others."

Pascal

Diagnosis

Step 1
Identify stage of readiness to act

Step 2
Explore barriers preventing action

Treatment

Step 3
Address barriers & develop a plan

Step 4
Arrange follow-up

Diagnosis

Step 1
Identify stage of readiness to act

- **"Quick Screen"**
  - **Knowledge**
  - **Emotions/attitudes**
  - **Logistics**
- **Staff Support**

Diagnosis

Step 2
Explore barriers preventing action

- **Elicit current knowledge**
- **Assess past experience with mammography**
  - **Communication**
  - **Comfort**
- **Assess emotional response**
  - **Fear of results**
- **Questioning**
  - **Open → Closed**

Treatment

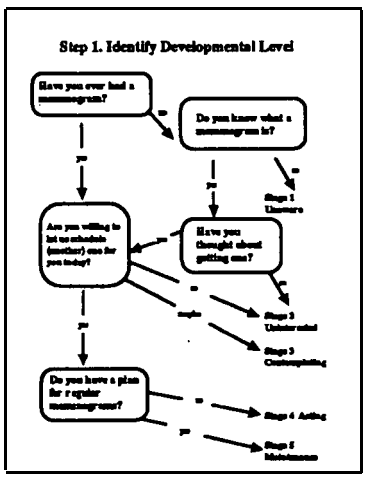
Step 3
Address barriers & develop a plan

- **Provide information**
  - **Relevant to patient's needs**
  - **Limited amount**
  - **In language the patient understands**
- **Provide support and reassurance**
- **Specific timeline**

Treatment

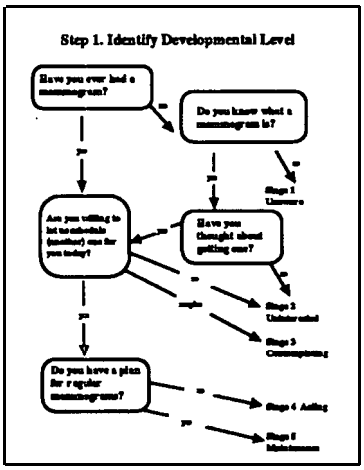
Step 4
Arrange follow-up

- **Discuss further or schedule**
- **Phone call in one week**
- **Offer to meet to discuss results**



Precaution Adoption Process

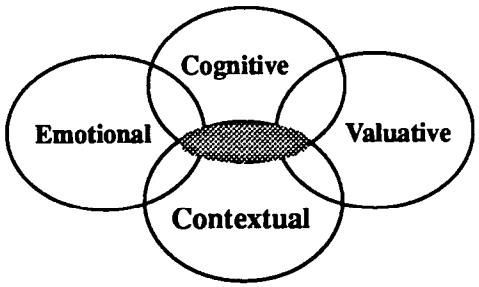
Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Unaware	Uninterested	Contemplating	Acting	Maintaining
Lacks basic information	Minimizes own risk	Accepts own risk	Has decided to or begun to act	



Likely Barriers at Each Stage

Stage 1 Unaware	Stage 2 Uninterested	Stage 3 Contemplating	Stage 4 Acting	Stage 5 Maintaining
Lacks basic information	Has beliefs that minimize own risk for breast cancer	Has fears based on beliefs and/or past experiences	Has scheduling or cost issues; may need plan for sharing results	Needs reminder cues

Reasons for non-adherence



Profile of Patient Stages
Stage 1 - Unaware

Knowledge:	**Lacks basic information (what, why, how)**
Beliefs/ Attitudes:	**May have negative attitude about physicians and preventive medicine**
Emotional Factors:	**Some fears about "looking for trouble"**
Logistics:	**May not see physician except for acute care: seize opportunity**

Profile of Patient Stages
Stage 2 - Uninterested

Knowledge:	**May have specific bits of misinformation (e.g., only needs one, no need if no symptoms)**
Beliefs/ Attitudes:	**Beliefs that minimize own risk for breast cancer ("I'm healthy")**
Emotional Factors:	**Some detachment or distance regarding personal risk**
Logistics:	**May not follow through: follow-up important**

Additional information about discussing breast cancer risks with your patients can be found on the enclosed videotape

Profile of Patient Stages
Stage 3 - Contemplating

Knowledge:	May be uncertain about details
Beliefs/ Attitudes:	May have either and/or past experiences (e.g., pain, anxiety about results)
Emotional Factors:	**Fears based on beliefs and/or past experiences (e.g., pain, anxiety about results)**
Logistics:	May agree but cancel; follow-up important

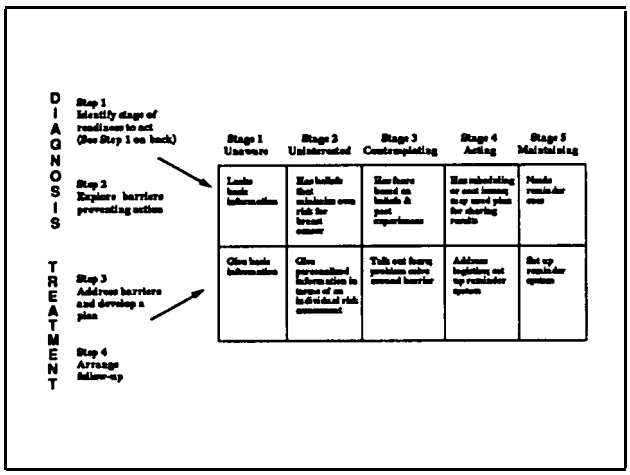
Uncovering barriers that are preventing action are also discussed in "Barrier Specific Telephone Counseling" at the back of the manual under Additional Materials

Profile of Patient Stages
Stage 4 - Acting

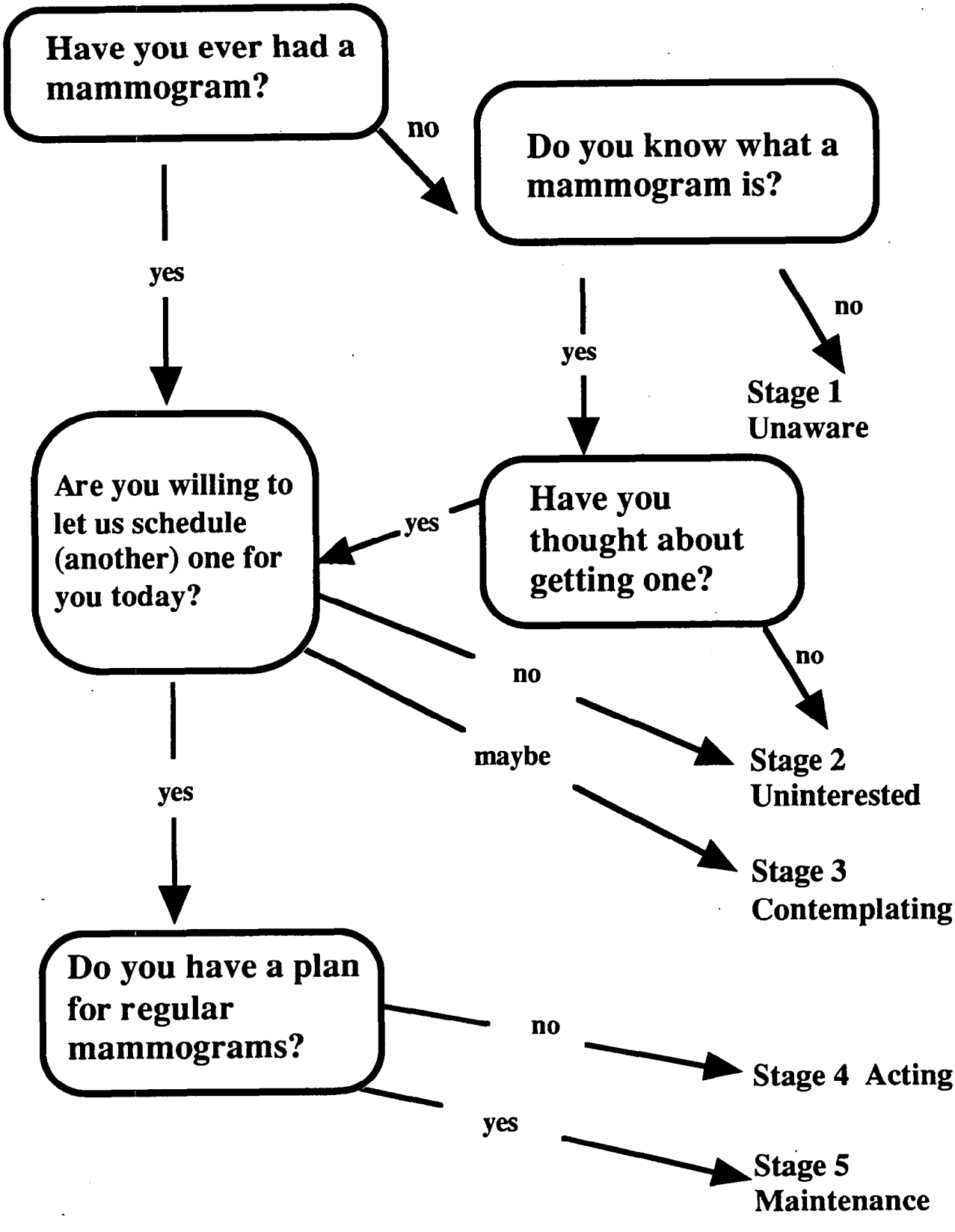
Knowledge:	May lack knowledge of available services/reminders
Beliefs/ Attitudes:	May not set screening as a high priority
Emotional Factors:	May need to improve sense of control or problem solve about past experiences
Logistics:	**Scheduling, cost, may need plan for sharing results**

Profile of Patient Stages
Stage 5 - Maintenance

Knowledge:	May lack information about need for ongoing regular mammograms
Beliefs/ Attitudes:	May not set screening as a high priority
Emotional Factors:	May need to improve sense of control or problem-solve about past experience
Logistics:	**Set up reminder system**


DIAGNOSIS
TREATMENT
Step 1
Identify stage of
readiness to act
(See Step 1 on back)
Step 2
Explore barriers
preventing action
Step 3
Address barriers
and develop a
plan
Step 4
Arrange
follow-up
Stage 1
Unaware
Stage 2
Uninterested
Stage 3
Contemplating
Stage 4
Acting
Stage 5
Maintaining
Looks
basic
information
Has beliefs
that
misbalance own
risk for
breast
cancer
Has fears
based on
beliefs &
past
experiences
Has substituting
or cost issues
may need plan
for sharing
results
Needs
reminder
cues
Gives basic
information
Gives
personalized
information in
terms of an
individual risk
assessment
Talks out fears
problems solve
around barrier
Addresses
logistics, set
up reminder
system
Set up
reminder
system

Step 1. Identify Developmental Level



DIAGNOSIS

Step 1
Identify stage of readiness to act
(See Step 1 on back)

Step 2
Explore barriers preventing action

TREATMENT

Step 3
Address barriers and develop a plan

Step 4
Arrange follow-up

Stage 1 Unaware	Stage 2 Uninterested	Stage 3 Contemplating	Stage 4 Acting	Stage 5 Maintaining
Lacks basic information	Has beliefs that minimize own risk for breast cancer	Has fears based on beliefs & past experiences	Has scheduling or cost issues; may need plan for sharing results	Needs reminder cues
Give basic information	Give personalized information in terms of an individual risk assessment	Talk out fears; problem solve around barrier	Address logistics; set up reminder system	Set up reminder system

Profiles of Patient Stages

	Stage 1 Unaware	Stage 2 Uninterested	Stage 3 Contemplating	Stage 4 Acting	Stage 5 Maintenance
KNOWLEDGE	**Lacks basic information (what, why, how)**	May have specific bits of misinformation (e.g., only needs one; no need if no symptoms	May be uncertain about details	May lack knowledge of available services/ reminders, etc.	May lack information about need for ongoing regular mammograms
BELIEFS/ ATTITUDES	May have negative attitude about physicians and preventive medicine	**Beliefs that minimize own risk for breast cancer: ("I'm healthy")**	May have either minimized or exaggerated risk perception	May not set screening as a high priority	
EMOTIONAL FACTORS	Some fears about "looking for trouble"	Some detachment or distance regarding personal risk	**Fears based on beliefs and past experiences (e.g., pain, anxiety about results)**	May need to improve sense of control or problem solve about past experiences	
LOGISTICS	May not see physician except for acute care; seize opportunity	May not follow through; follow up important	May agree but cancel; follow up important	**Scheduling cost; may need plan for sharing results**	**Set up reminder system**

MammaCare Clinical Breast Exam

Mary E. Costanza, M.D.
The Clinical Breast Exam (CBE) and the MammaCare Method

I. The Value of the CBE

A. Why do it now that we have mammograms?
B. 50% false negative in young females
C. 5 - 10% false negative in very old females

II. Clinical Competence

A. Lack of training
B. Various methods
- ACS
- ACOS
- MammaCare - NCI supported

III. Method

A. Amenities
- Explain procedure
- Make patient comfortable
- Drape appropriately
- Ask if patient has noticed a problem

B. Examination - MammaCare method

1. Sitting position
   - Observe arms at rest and look for symmetry
   - Observe arms raised and look for contour
   - Observe with hands pressed to hips and look for puckering and dimpling
   - Palpate axillary lymph nodes (superior, inferior, anterior, posterior, and central) with patient's arm supported
2. Supine position
   - Patient's arms raised with hands above head
   - Palpate entire breast from axillary line to mid-sternum from infraclavicular area to inframammary fold
   - Finger use - 3 middle finger pads (distal third, not tips) in small dime-sized rotations
   - Pressure at each position: superficial, moderate, and firm
3. Oblique supine position
   - Patient's arms raised with hands on head
   - Palpate Upper Outer Quadrant (well into axillae)
4. Time - take sufficient time

C. Closure

- Review findings and their impact
- Discuss Mammography, Clinical Breast Exam, and Breast Self Exam - three methods of detection, their complementary nature and their recommended screening intervals
- Answer questions

IV. Problems in CBE

A. Defining a discrete nodule
B. Defining a thickening
C. A problem in the patient's mind
D. Return for a follow-up
E. Complementary CBE and nature of mammography

CBE: The Clinical Breast Exam

1. **Is there a preferred method of the clinical breast exam?**

   Yes! While several methods have been promoted (Dr. Byrd of American Cancer Society, the radial method, the wedge method, etc.) recent studies conclude that the MammaCare method of breast exam is the preferred method.

2. **What is different about the MammaCare method?**

   1. Use of a vertical grid method to completely cover the breast.

   2. Use of a small (dime sized) rotation of your examining fingers as you move up and down.

   3. Use of three levels of pressure:
      Superficial
      Moderate
      Deep (firm)

   4. Use of the oblique position to exam the upper outer quadrants.

3. **What is the same?**

   1. Use of three middle fingers.

   2. Use of distal pads (not tips) of fingers.

   3. Observation of breast with maneuvers in sitting position.

   4. Exam of axillary lymph nodes in sitting position.

   5. Exam of breast in supine position.

4. **How long should an adequate exam take?**

   There should be enough time to cover each breast entirely. This may be longer in large breasted women, or in women with “lumpy” breasts. The length of search time should be about 5 minutes! The length of the search time is directly related to the number of lumps which are detectable. Remember a poor or inadequate exam may give false reassurance to the physician and the patient.

5. **What is the evidence that MammaCare really is better?**

The National Cancer Institute has funded several studies.

Fletcher[1]: Randomized trial of 269 physicians

	Number of lumps found
Taught MammaCare method	51%
Taught traditional method	47%
No teaching	45%

$p<.05$

Campbell[2]: Randomized trial of 89 physicians and nurses

	Number of lumps found
Taught MammaCare	63%
Usual CBE training	57%

$p<.05$

References:

1. Fletcher, S, O'Malley M, Bunce, L. Physicians' Abilities to Detect Lumps in Silicone Breast Models. JAMA; 253: 2224-8, 1985.

2. Campbell, HS, Fletcher, SW, Lin, S, Pilgrim, CA, Morgan, TM. Improving Physicians' and Nurses' Clinical Breast Examinations: A Randomized Controlled Trial. Am J Prev Med 1991; 7: 1-8

MammaCare Method of Clinical Breast Examination

• Fingers

Use **middle three** fingers
Use **distal pads** (not tips)

• Pattern

Vertical grid (rather than wedge or circular)
Rotate three fingers in dime-sized circle

• Pressure

Use three levels of pressure:
Superficial, Moderate, Deep

• Positions

Sitting:

- **Observe** for symmetry and dimpling in four positions
  - Hands at side
  - Hands pressed on hips
  - Hands over head
  - Leaning forward
- **Palpate** axillary lymph nodes
  - Patient arm supported

Supine:

- **Palpate** entire breast
  - Patient arm above head

Oblique:

- **Palpate** upper outer quadrant of breast
  - Patient arm across forehead

• Search Time

5 minutes

• Expected Sensitivity: 3 - 5mm mass

• Remember 15% of breast cancers which can be palpated do not show up on mammograms.

Achieving Competence in Clinical Breast Examination

H.S. Pennypacker PhD, and Carol Ann Pilgrim, PhD

Literature documenting the breadth and quality of prevalent clinical breast examination (CBE) practice is briefly reviewed., A more thorough procedure, emphasizing training in tactile discrimination, is described and illustrated.

Manual clinical examination of the breast (CBE) is a complex skill consisting of two components, one sensory and one motor. The sensory component takes advantage of the exquisite sensitivity of the pressure receptors in the fingertips' to local gradients of stimulation (eg, it is this tactile sense that enables blind people to learn to red Braille). With training, the human finger can detect a spherical ball bearing 2.0 mm in diameter through a medium of silicone gel cured to the density of human breast tissue.[2] It can also detect 3.0 mm structures of a density equivalent to most breast tumors that are embedded in the same silicone gel.[3] For this discrimination to occur, it appears to be both necessary and sufficient that the firmness of the embedded structure exceed that of the surrounding medium by a substantial margin.

The motor component of manual breast examination is the technique of search that brings the finger tips into contact with the breast tissue. No matter how well trained and sensitive the fingers, they are of no value unless they are placed in the exact location of the mass to be detected. A refined technique of examination has been developed[4,5] that involves (1) proper palpation, (2) use of discrete pressures, and (3) a search pattern that maximizes coverage of the torso area over the tissue to be examined. An additional component of this search technique involves positioning of the patient so as to minimize the depth of tissue at specific locations. These procedures will be illustrated throughout this report.

Let us first turn our attention to a brief review of the literature documenting the effectiveness of CBE in the early detection of breast cancer. We will then briefly examine some of the early reports of experimental efforts to improve the quality of CBE instruction.

The Value of CBE

The inverse relationship between prognosis and size of a primary breast tumor at the time of detection and treatment[6,7] is by now well accepted. Because breast tumors grow over time, it follows that maximal benefit will result from discovery of the tumor at the earliest possible point in its natural history. Breast cancer screening strategies involving breast self-examination (BSE), CBE, and mammography are predicated on this principle.

Worldwide, CBE is the most generally available method of breast cancer screening because relatively few women are proficient at BSE, and mammography is restricted on both age and economic grounds. Although there have been no prospective studies on the efficacy of CBE alone,[8] the widely cited Health Insurance Plan study[9] documented that CBE in combination with mammography was more effective than mammography alone. Moreover, mammography misses some cancers that can be discovered by CBE,[10] particularly in younger women. Winchester[11] cites a report by Burns[12] in which mammography was negative in 80 of 613 palpable cancers. Biopsy was delayed in 50 of these cases; by the time treatment, was initiated, 21 of these patients were found to have Stage II or later disease. Of the remaining 30 who received timely treatment, only one was at Stage II.

Thus, the contribution of CBE to reducing breast cancer morbidity and mortality is real enough. On the basis of the embryonic scientific analysis of the practice that is now emerging, its ultimate potential contribution is probably far greater than is now apparent. Let us briefly review that work.

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The authors thank Margaret M. Iwata for her production assistance and many helpful suggestions during preparation of this manuscript.

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Experimental Analysis of CBE

The superficial quality of CBE as generally, practiced is reasonably well documented. Retrospective estimates or CBE sensitivity (likelihood of finding a tumor chat exists) have ranged from 24%[13] to 45%[14] More recently, Fletcher et al have used a standardized series of silicone breast models containing simulated fibroadenomatous tissue as well as simulated tumors of varying size, hardness, and depth to estimate the CBE sensitivity of academic physicians (44%), residents (58%), graduate nurses (57%), and community physicians (55%).[15-18]

Fortunately, this measure of CBE proficiency can be improved with training.[16-19] In an early demonstration,[19] lay women nearly doubled their sensitivity (25% co 48%) in detecting benign lesions in volunteers following a brief session with silicone models similar to those used by Fletcher's group. Since then, it has been established[16,17] that sensitivities approaching 70% can be achieved by a comprehensive training program that emphasizes use of such models. Incorporating practice on a live surrogate not only further increases sensitivity, it enhances the confidence of medical students in their CBE skills.[20]

Learning Sensitive CBE

Manual palpation of the breast is done with the pads (not the tips) of the middle three fingers of either hand as shown in Fig 1. The fingers should be held together and slightly bowed to insure that contact is maintained with only the pads. This accomplishes two things: first, it ensures that the most sensitive pressure receptors of the fingers will be in contact with the tissue and, second, it allows the clinician to distribute palpation pressure across the three fingers so that deep tissue can be examined without causing pain to the patient.

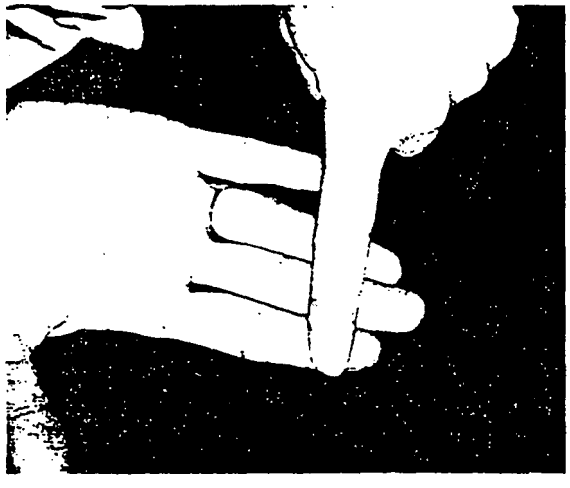

Figure 1. The pads of the last segments of the middle three fingers make up the palpation surface. During palpation, the fingers are held together and bowed back slightly to ensure no involvement of the tips.

Figure 2. Transparent training model in place. This model provides the basic tactile training of the fingers.

A transparent model containing simulated tumors as well as simulated normal nodularity is used to teach the discrimination between these structures and undifferentiated soft breast tissue. Palpating in well controlled, dime-size circles with a complete circle at each of three discrete levels of pressure (light, medium, and deep) results in contact with lumps of different sizes, hardnesses, and depths as well as the simulated nodularity. Fig 2 shows such a model in place on the torso of either a patient or a learning partner. This is preferred to placing the model on a table because it puts the clinician's arm in the actual examination position during training. In addition, the human torso provides the natural background against which breast structures must be discriminated in actual practice. During palpation of the nodularity in the model, the student can compare the model to the texture of normal nodularity in the upper, outer quadrant of the breast of the patient/learning partner (Fig 3).

An opaque model with a square base is used to teach the proper search pattern as well as to refine the palpation skills. This model contains a number of small simulated tumors surrounded by simulated nodularity. Again, as shown in Fig 4, the model is placed on the patient/learning partner's torso during this part of the training. The square base helps develop the vertical strip search technique.[4] It is

Figure 3. Palpation of normal nodularity, usually found in the upper, outer quadrant.

Figure 4. Square-based, opaque training model in place. This model enhances the tactile training while establishing the search pattern.

Figure 5. Visual inspection, first position.

recommended that eight or nine strips, each approximately one finger width wide, be used examine this model. Each strip consists of eight or nine palpations and each palpation is performed with three pressures. Placement of the three fingers at each spot palpated within a strip should slightly overlap the previous spot to ensure that no tissue is left unexamined.

The student should detect all of the simulated tumors in this model and correctly differentiate them from the simulated nodularity (while covering all of the model surface with the correct palpation technique). The student is then ready to transfer this skill to a live patient.

Performing Competent CBE

Even though it is less sensitive than manual palpation, many clinicians like to begin the CBE with the visual inspection component because it is less invasive. It is also an opportunity for the clinician to carry on a conversation that can supply valuable historical information while informing the patient of the features of clinical interest in her breasts. The clinician can also take this opportunity to teach the visual inspection portion of BSE.

The visual inspection should be conducted with the patient in three positions: with her arms relaxed at her sides (Fig 5), with her hands pressed firmly on her hips and her shoulders forward (Fig 6), and leaning forward with her arms over her head (Fig 7). Differences in structural confirmation of either breast as the patient assumes these three positions can alert the clinician to a condition that might not be evident in any single position.

With the patient still in a sitting position, the clinician begins manual examination, first of the

Figure 6. Visual inspection, second position.

Figure 8. Manual examination of the supraclavicular nodes.

supraclavicular nodes (Fig 8), then of the nodes deep in the axilla (Fig 9). The patient should be asked to place her ipsilateral hand on the clinician's shoulder; this not only facilitates access to the axillary pit, it occasions a mutual touching that affirms the partnership between patient and clinician.

The patient then assumes a supine position and the manual examination resumes in the axillary pit (Fig 10). The examination is conducted exactly as it was on the square model, using palpations of three pressures each in vertical strips, with the placement of the three fingers at each palpation spot slightly overlapping the previous palpation spot. The area of each breast to be examined is bounded by the clavicle, a plumb line from the axillary pit to the fifth rib (bra line), the fifth rib, and the midline of the sternum.

We recommend that the manual examination begin in the axilla opposite the clinician and that, for examination of the area from the axillary line to the nipple, the patient assume a variation of the supine position. The patient should lie on her contralateral side with her weight supported by her hip. Her ipsilateral arm should be positioned so that the back of her wrist, rests lightly on the forehead and her shoulder is relaxed. Her torso is then rotated about 45 degrees back toward the supine position. This will cause the deepest lateral breast tissue to be evenly distributed across the chest wall, facilitating deep palpation (Fig 11). In the correct position, the nipple should be "floating" in a plane parallel to the floor (Fig 10).

Particular care should be taken to ensure that the

Figure 7. Visual inspection, third position.

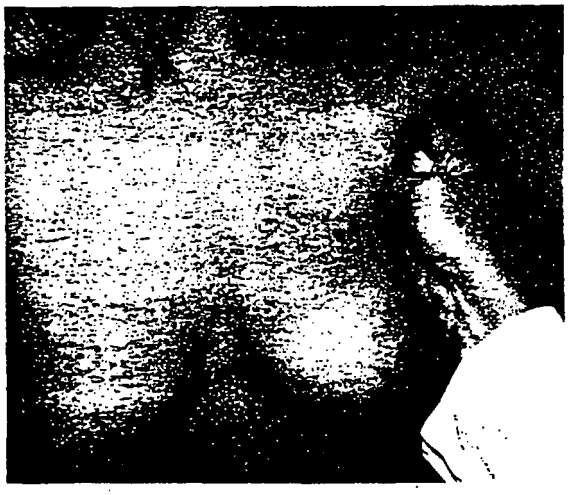

Figure 9. Manual examination of the axillary nodes. Note that Patient's ipsilateral hand is on the examiner's shoulder.

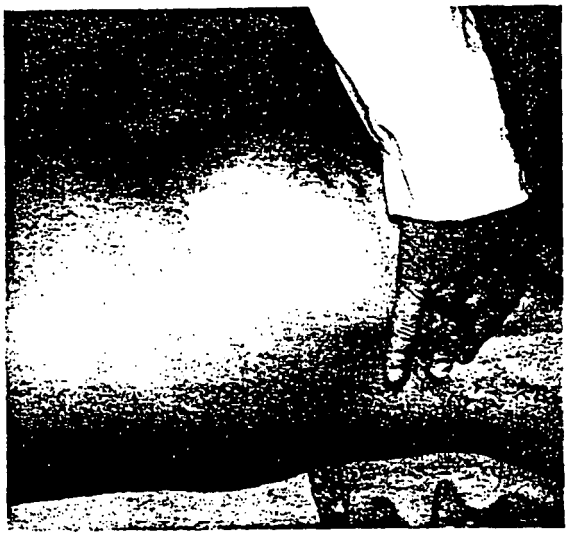

Figure 10. Manual examination of the lateral half of the patient's left breast. See test for details of patient positioning.

nipple and surrounding structures are thoroughly examined (Fig 12). When the nipple has been examined, the patient assumes a full supine position and the remainder of the nipple strip, together with the area to the sternal midline, is then examined (Fig 13).

If, during the course of the examination, the clinician detects something unusual, its location should be noted. During the examination of the contralateral breast, the corresponding area should be searched diligently for a similar structure. Assuming the finding is not bilateral, further study is probably warranted.

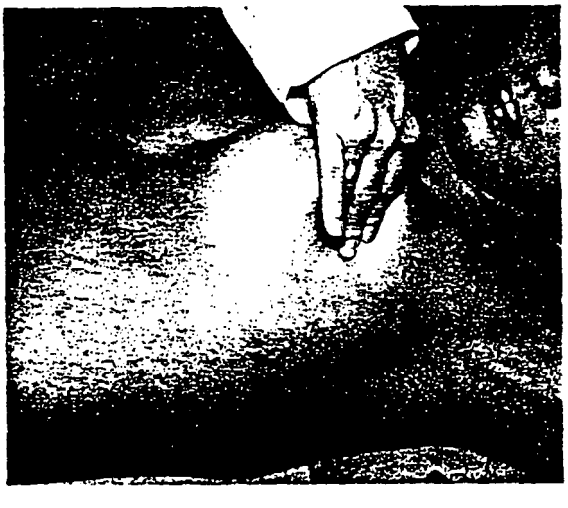

Figure 11. Deep palpation of lateral aspect of left breast. Note the bow in the examiner's fingers, ensuring examination only with the pads.

Figure 12. Manual examination of the nipple area.

Depending on the amount of breast tissue involved and the skill and experience of the clinician, this thorough an examination may require as much as 10 minutes or more per breast. Some patients may find this in such marked contrast to their previous clinical experience that they become uneasy or suspicious. An explanation of the technique and acknowledgement of the volume (area by depth) of tissue involved has important educational benefits and is usually sufficient to allay any concerns.

Figure 13. Manual examination of the medial portion of the left breast. Note patient is now in full supine position.

Conclusion

Research[15,17] has consistently shown a positive correlation between examination duration and CBE sensitivity. Using the time to perform the techniques described here enables the clinician to perform a skill that approaches the upper limits of sensitivity of the human tactile sensory system. The potential benefit in terms of reduced morbidity and mortality that can result from CBE of this quality seems well worth both the time to perform it and the effort required to achieve competence.

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An Office System to Support Breast Cancer Screening

I. Definition of Office Systems

A. Series of routine steps performed consistently for a specific purpose
B. Functional Components:
- Identify patients in need of services
- Monitor receipt of service over time
- Reinforce positive patient behavior
- Feedback of effect of system on rate of delivery of service

II. Review of Evidence From a Community Study That Office Systems Can Improve the Rate of Delivery of Cancer Screening Services

III. Review of the Preventive GAPS Approach to Improving Office Systems

A. Goal Setting
B. Assessment of Current Practice
C. Planning
D. Start-up

IV. Goal Setting: Deciding on guidelines for mammography and clinical breast exam for your practice

A. Who should receive screening mammography and breast exam? (Deciding on ages for starting and stopping screening)
B. How often should services be delivered? (Deciding on frequency of screening)

V. Assessment of Current Practice

A. Performing a mini-audit of records to determine current rate of delivery of mammography and clinical breast exam to patients
B. Review current office system tools available and in use (e.g. flow sheets, reminder systems)
C. Review of current office staff responsibilities for system components (e.g. role of clerical or nursing staff in updating flow sheets)

VI. Planning

A. Use of the Patient Path Worksheet to summarize key systems
B. Modify existing routines to improve effectiveness
C. Introduce new tools (e.g. flow sheets, chart flags, reminder systems)
D. Identify new roles for office staff

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PREVENTION AND HEALTH PROMOTION

Changing Office Routines to Enhance Preventive Care

The Preventive GAPS Approach

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While family physicians aspire to provide their patients with the best possible preventive care, the services actually provided sometimes fall short of this ideal. Enhancing the provision of preventive care may require changes in office operations. Through working with more than 200 community practices in the Cancer Prevention in Community Practice Project, we have developed the Preventive GAPS Approach, which can help physicians and their practice staff to enhance their preventive care. The approach is based on teamwork among clinicians, staff, and patients; routines that encourage opportunistic provision of indicated preventive care; and flexibility, which allows physicians and their staffs to tailor their improvement strategy and the pace of change to their own unique situation. The approach includes the following four-step method (or GAPS): goal setting regarding preventive care; assessment of existing routines that support preventive care and of the current level of attainment of preventive goals; planning to modify existing routines that support preventive care; and starting and maintaining the improved preventive care office system. *(Arch Fam Med. 1994;3:176-183)*

Providing patients with comprehensive preventive care takes precedence in family practice. Yet, responses on the National Health Interview Survey' and other sources[2,3] reveal that ambitious preventive aspirations are hard to meet. Mammography for early detection of cancer is a pertinent case. Most experts agree that periodic mammography screening is appropriate for women aged 50 years or older. However, the National Cancer Institute Breast Cancer Screening Consortium' found that across seven US geographical regions, only 25% to 41% of these women who had seen a physician in the past year had obtained a mammogram.

The barriers to providing optimal preventive care include patient factors such as embarrassment or fear of discomfort, physician factors such as lack of time or uncertainty about which expert recommendations to follow, and health care system factors such as inadequate reimbursement.[4] Manual and computerized physician reminder systems, patient-held diaries, physician continuing medical education, and public education campaigns provide methods to overcome these barriers.[5] In many of the settings where these approaches have been tested rigorously, preventive care has improved. However, much of this research has been conducted in residency and faculty practices and its applicability to community practice is not known.

Through the Cancer Prevention in Community Practice (CPCP) Project, we have assisted more than 200 community primary care practices to enhance the preventive care they provide by involving staff and modifying office operations. Based on this experience, we have developed a four-step method called the Preventive GAPS (goal setting, assessment, planning, and starting) Approach that practices can use themselves to initiate improvements in the preventive care they provide.

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The Preventive GAPS Approach is designed to allow practices maximum flexibility in their choice of strategies and pace for introducing change. It follows no strict dogma, but rather our practical observations based on working with practices. However, similarities to problem-oriented practice,[6] systems thinking,[7] and total quality management[8] will be apparent. The purpose of this report is to provide a guide for practices that wish to enhance their preventive care.

THE CANCER PREVENTION IN COMMUNITY PRACTICE PROJECT

In 1987, we launched a randomized controlled trial testing two interventions directed at enhancing cancer prevention and early detection in office practice. The CPCP Project was sponsored by the National Cancer Institute, Bethesda, Md. About 100 family physician and internist practices in New Hampshire and Vermont volunteered to participate, many of which were members of the Dartmouth Cooperative Information Project (COOP).[9]

Assisting practices to establish a preventive care office system proved to be a more successful intervention than physician continuing medical education. Six of 10 target services improved significantly with the office system intervention, including mammography recommendations, clinical breast examinations, advice on breast self-examination, fecal occult blood testing, smoking cessation advice, and advice to decrease dietary fat. The remaining four target services (Papanicolaou tests, digital rectal examinations, advice to increase or decrease dietary fiber, and sigmoidoscopy recommendations) showed improvements that did not reach statistical significance.[10] The physician continuing medical education intervention is described in detail elsewhere.[11]

The office system assisted practices to share responsibility for providing indicated preventive services and to use tools such as preventive flow sheets, patient intake questionnaires, and patient education materials to address the following four functions[12]: identifying each patient's current needs regarding preventive services; monitoring and meeting each patient's needs over time; reinforcing positive patient behavior; and providing feedback on practice performance.

The CPCP Project entered a new phase in 1990 with the launching of two second-generation projects. The second phase of the CPCP Project is testing strategies to make available the office systems intervention to all practices in New Hampshire and Vermont, not just a subset of physicians who volunteer to participate in research. The Community Health Center Cancer Control Project is testing the office systems intervention through an intermediary organization to federally sponsored community health centers for the underserved in New York and New Jersey. (The intermediary is Clinical Directors' Network of Region II, a professional support organization for the clinical leadership of these health centers.) These projects have allowed us to work with practices in rural, suburban and urban areas that range in size from from solo practices with one part-time staff member to large groups involving scores of clinicians and hundreds of staff.

Acceptability of the office system intervention has been high. The first 50 practices randomly assigned to receive it have been studied in detail.[12] Before the intervention, physicians from these practices indicated that they bore sole responsibility for identifying patient preventive care needs, monitoring those needs over time, and reinforcing positive patient behavior. Attention to feedback or audit of performance was rare. All assigned practices then cooperated with the intervention. After 2 months, clinical or administrative staff in all assigned practices had completedan audit of the preventive care provided and had accepted some responsibility for the other three office system functions.[12] Office staff had responsibility for identifying new patients in need of preventive services in 70% of practices, assisting in monitoring those needs over time in 37%, and reinforcing positive patient behavior in 54%.

OBSERVATIONS ABOUT PREVENTION IN COMMUNITY PRACTICE

Three observations serve as the foundation for the Preventive GAPS Approach to enhance preventive care in community practice. The first is that primary care practices consist of teams of people working toward common ends, but teamwork in prevention care is usually poorly developed. Examples of teamwork abound in most offices. The receptionist checks in a patient for an appointment, then the nurse or medical assistant obtains a brief health history and reason for visit and prepares the patient to be examined by the clinician. Thereafter, the receptionist checks out the patient, arranges billing, andschedules future appointments. Within this basic teamwork structure, subsets of personnel cooperate on specific tasks. For example, the clinician may ask the nurse to review the patient's breast self-examination technique. The receptionist may ask patients aged 65 years and older seen during the autumn months if they would like an influenza immunization, However, these examples of preventive care teamwork are exceptions rather than the rule.

The second observation is that office teams depend on routines to guide much of their work, but these routines are often fragmented rather than integrated into a shared mission and miss many opportunities to enhance indicated preventive care. The nurse or medical assistant knows what instruments and type of suture the physician is likely to use in a laceration repair and may inquire about and document the patient's tetanus immunization status. However, office staff seldom have the opportunity presented by checking patients in for routine visits for acute or chronic disease care to identify when the patient last had a Papanicolaou test or mammogra-

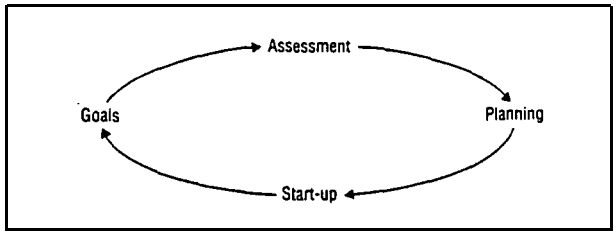


Figure 1. *The Preventive GAPS Approach.*

phy. If asked about this, staff reply that these are the physician's duties or that this is done during the periodic health examination.

Routines may be explicitly established. For example, "all patients who present with a laceration will have their immunization status checked and documented by the person taking vital signs" may be written in a policy manual. Routines that are implicit, evolved through past experience and without formal documentation in a policy manual, may be just as powerful. However, these routines, whether implicit or explicit, usually evolve to meet specific, repetitive needs without attention to the big picture, such as ensuring that all patients get certain age- and gender-appropriate preventive services.

Our third observation is that no two practices are alike in their needs, strengths, and limitations with regard to preventive care, so that appropriate strategies to enhance the quality of preventive care will be different for different practices. Even the same practice may have vastly different profiles of needs, strengths, and limitations at two different time points. Physicians and office staff are usually the best judges of what approach will work for enhancing preventive care or can choose the most promising from among various change strategies.

THE PREVENTIVE GAPS APPROACH

The Preventive GAPS Approach is derived from these observations as well as the CPCP Project intervention and provides a flexible strategy to develop teamwork and routines that enhance preventive care. Unlike the CPCP Project intervention, the GAPS Approach does not require the assistance of a research assistant. The GAPS Approach establishes a cyclical pattern of cooperation, self-assessment, and modification of office activities over time. Steps in the GAPS Approach include the following: goal setting regarding preventive services; assessment of the current process of providing preventive care and the current level of attainment of preventive goals; planning to implement improved office routines that support preventive care; and starting and maintaining the improved preventive care office system.

These steps are represented in Figure 1. Each step does not necessarily need to be repeated during each cycle. For example, practices may wish to audit a series of charts to check the percentage of patients who were provided various indicated preventive services quarterly but who may only review in detail their preventive care goals when revisions in the recommendation of the American Cancer Society[13]) or US Preventive Services Task Force[14] are published.

We are confident that the GAPS Approach is useful because many of the practices that we have worked with could have implemented an office system themselves following the GAPS Approach with no additional outside help. However, some caveats are in order. In the CPCP Project, the research assistant provided an external motivation to practices much as a piano teacher does to a student. Often the best progress toward developing the system happened a few days before an anticipated research assistant contact. Without such external motivation, practices must internally maintain the discipline needed to follow a multistage process of quality improvement. Also required is a period of relative practice stability. More urgent practice priorities, such as changes in practice personnel and/or billing systems or caring for patients during a heavy period of acute illness, can destroy the momentum needed to apply the GAPS Approach.

Consider a fictitious practice. The clinicians of the Rocky Stream Family Practice Center would like to enhance the preventive care they provide. Rocky Stream personnel include two family physicians, a nurse practitioner, two licensed practical nurses, and a receptionist. They serve a suburban working-class population. About 40% of their patients comply with the practice recommendation that men starting at age 50 years and all women attend for an annual check-up. Rocky Stream personnel believe that the most important barrier to greater compliance with this periodic health examination is the cost to the patient. The clinicians believe that a new preventive flow sheet will help them provide indicated preventive care opportunistically to patients who do not comply with periodic health examinations.

Step 1: Goal Setting for Preventive Care

Practices benefit from explicit preventive care goals, ie, those age- and gender-specific preventive and early detection services that they aim to provide routinely to patients. Clinicians can develop their own goals or modify and adopt recommendations published by experts.[13-19] Either way, explicit goals encourage clinicians to decide on what services to provide. Goals should be an aid and not a burden. New studies and recommendations on preventive care appear weekly in journals and the popular media. Physicians may choose to update their goals at intervals, rather than incorporating new information immediately.

Communicating these goals to office staff promotes teamwork and commitment toward a common mission. Office staff can then identify opportunities in which they can help ensure that indicated preventive care is provided. Patients can participate in their preventive care as

Table 1. The Rocky Stream Practice's Preventive Goals for Well Adults (No Special Risk Factors)

Service	Target Group	Interval
Blood pressure, height, and weight measurement	All	Each visit
Mammogram	Women, age ≥ 50 y	Annual
Breast examination	Women	Annual
Papanicolaou/pelvic tests	Women	2 y
Influenza immunization	Age ≥ 65 y	Annual
Pneumococcal immunization	Age ≥ 65 y	Once
Digital rectal examination	Age ≥ 65 y	Annual
Fecal occult blood test	Age ≥ 65 y	Annual
Sigmoidoscopy	Age ≥ 50 y	10 y
Offer of smoking cessation help	All smokers	Each visit

well. Patients can be given the practice preventive care goals through posters, letters, or bulletin boards and can be encouraged to ask for these services even if they cannot comply with a periodic health examination.

Step 1 at Rocky Stream. The practice's preventive goals are listed in **Table 1.** These are the services on which the three Rocky Stream clinicians could agree. There was disagreement among the clinicians about inclusion of prostate-specific antigen and cholesterol screening, so these were omitted as formal goals addressed by the practice's preventive care office system. For these, clinicians counsel their own patients according to their own analysis of the facts, but to avoid confusion, office staff do not play an active role in their promotion.

Similarly, all Rocky Stream clinicians share a commitment to lifestyle counseling about substance abuse, sexual practices, and diet but have differences about the best counseling approach with patients. The clinicians agreed to pursue counseling without assistance from office staff or practice routines, limiting the practice's preventive care office system goals to the 10 listed in Table 1. They planned to readdress lifestyle counseling during their next review of preventive goals, which they plan in 1994, when the new edition of the US Preventive Services Task Force guide" is due.

Step 2: Assessing the Current Process of Care and Attainment of Goals

How is preventive care routinely provided to patients! How many patients receive indicated services? With respect to preventive goals, if you do not know where you are going, any road will take you. With respect to assessing and improving current preventive performance, if you do not know where you started, you will not know how far you have gone. With a small commitment of time, both these questions can be assessed.

By identifying the current process of providing patients with needed preventive care, the existing preventive care office system is made explicit, allowing scrutiny, inviting innovation, and promoting teamwork among clinicians and all office staff. In our experience, the process of how preventive care is currently provided can be identified in a single practice meeting addressing the functions of a preventive care office system previously described[12]: identifying patient current preventive status; monitoring and addressing that status over time; reinforcing positive patient behavior; and providing feedback to the team.

Table 2. The Rocky Stream Practice's Assessment of Current Office System Functions

Function	Activity/Tools	When Performed	By Whom
Identify preventive status	Ask new patients	First visit to the practice	Nurse
Monitor status over time	Flip through the chart	With patient during periodic health examination	Clinician
Reinforce positive patient behavior	Discussion with patient	Periodic health examination	Clinician
Feedback on practice performance	Not done		

Current performance can be ascertained in various ways. Record review can be directed at one or two services that generate specific reports, such as Papani laou tests and mammography, or more broadly to preclude other services addressed by the physical examination or counseling. A consecutive series of patients recently seen or a series of charts that are systematically selected from all active charts can provide the sample.

Parts of the physical examination lend themselves to record review because many physicians record them consistently in a manner that is well known to their staff. Counseling procedures may be less accessible because of limitations in recording. In some practices, they may be better addressed by a brief patient survey, conducted by the nurse or medical assistant. A systematic series of patients (perhaps every third) checking in for routine visits could be asked when the physician last discussed breast self-examination, exercise, diet, or whichever services the practice chooses to focus on first.

Step 2 at Rocky Stream. All staff and clinicians of the Rocky Stream Family Practice Center met to address the assessment step. **Table 2** summarizes their analysis of how the practice currently meets the four office system functions. They agreed that patients seen for periodic health examinations are provided indicated services unless there is an oversight by the physician or a refusal of a service by a patient. Patients who do not schedule periodic health examinations are provided those served when they specifically request them ("Doctor, I know I'm here for my blood pressure, but I would like a breast

Table 3. The Rock Stream Practice's Planned Revision of Office System Functions for Early Detection of Breast Cancer

Function	Activity/Tools	When Performed	By Whom
Identify preventive status	Hand out health questionnaire to all patients	At least annually	Receptionist
	Review breast cancer screening status with patient and indicate needs on self-stick note	While preparing patient to see clinician	Nurse
Monitor status over time	Initiate/update flow sheet information related to breast (other targets, if time)	Before seeing clinician	Nurse
Reinforce positive patient behavior	Hand out pamphlets about early detection of breast cancer	When patient checks out	Nurse
Feedback on practice performance	Complete mammogram tally sheet	Ask 30 patients	Receptionist

examination"). The clinicians also provide preventive care opportunistically as best they can. For example, while seeing a 65-year-old man who rarely comes in, the clinician flips through the chart, notes that the patient has not had a digital rectal examination in 3 years, and offers to provide one that day. In addition, influenza immunizations are offered by the nurse to patients aged 65 years and older who visit during October and November.

Reliance on periodic health examinations and an informal program of opportunistic preventive care is the current system that exists in the Rocky Stream Practice. How well does it work? The Rocky Stream Practice decided that they had little staff time to devote to an audit and were skeptical of its value. Because of a personal interest in early detection of breast cancer, the receptionist volunteered to ask a consecutive series of 30 women who were at least aged 50 years the date of their most recent mammography at the time they checked in for appointments. The receptionist designed a tally sheet that allowed recording the patient's name, age, and whether a report collaborating what the patient said was in the chart.

The tally sheet showed that 40% of the women aged 50 to 64 years and 32% of those aged 65 years or older stated that they had a mammography during the past year. Several patients admitted that their clinician had recently recommended mammography but they had not followed through yet.

Step 3: Planning to Implement a Preventive Office System

With steps 1 and 2 accomplished, needs and strategies to enhance an office's preventive care activities are often readily apparent. Various tools can be useful. For example, the office system function of identifying the preventive needs of a patient can be aided by a brief health questionnaire administered by the medical assistant or receptionist. The function of monitoring patient preventive needs over time can be aided by a computerized or manual health maintenance flow sheet that the nurse or medical assistant reviews, indicating needed services to the clinician through a preprinted self-stick (Post-it) note **(Figure 2).** The office system function of reinforcing positive patient behavior may be aided by carefully selected patient education materials or posters placed in strategic locations in the office where they are readily available to staff and patients. The Patient Path Model" may be useful in planning how to enhance the practice's preventive care office system. In this model, the patient's path through the practice is traced with an eye toward identifying opportunities to provide preventive care.

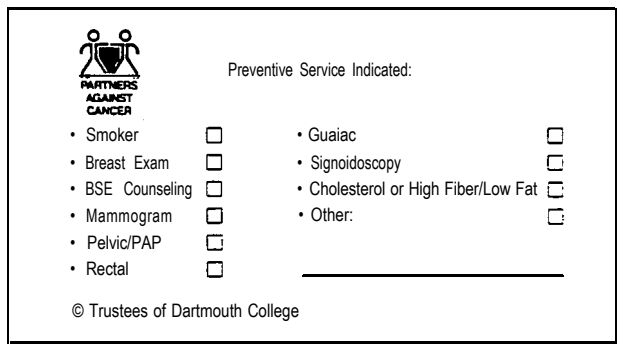
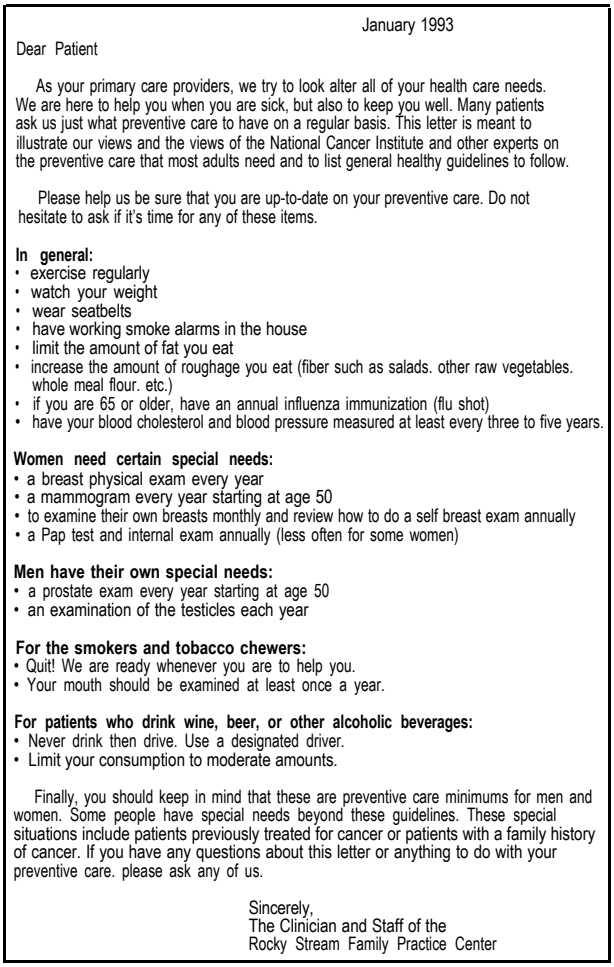


Figure 2. *Preprinted self-stick note used for intraoffice communication about needed preventive care. BSE indicates breast. self-examination; PAP, Papanicolaou test.*

Step 3 at Rocky Stream. A follow-up practice meeting was called to discuss the mammography tally sheet and to plan improvements in the practice's provision of preventive care. **Table 3** shows the results of Rocky Stream's planning. Clinicians and staff concluded that patient compliance with periodic health examinations was unlikely to increase, so they decided to emphasize services offered opportunistically through use of a preventive flow sheet and a brief questionnaire asking about recent preventive care to be administered annually, even if the patient did not attend for a periodic health examination.

The clinicians agreed to review the various preventive flow sheets that they had gathered from their residencies and other sources and to modify the one that best fits their goals and their practice. While the flow sheet and questionnaire would include the 10 services of the practice's goals and some other items, the practice decided to focus on early detection of breast cancer first with their office system rather than diffuse their limited ad-



January 1993

Dear Patient

As your primary care providers, we try to look alter all of your health care needs. We are here to help you when you are sick, but also to keep you well. Many patients ask us just what preventive care to have on a regular basis. This letter is meant to illustrate our views and the views of the National Cancer Institute and other experts on the preventive care that most adults need and to list general healthy guidelines to follow.

Please help us be sure that you are up-to-date on your preventive care. Do not hesitate to ask if it's time for any of these items.

In general:
- exercise regularly
- watch your weight
- wear seatbelts
- have working smoke alarms in the house
- limit the amount of fat you eat
- increase the amount of roughage you eat (fiber such as salads. other raw vegetables. whole meal flour. etc.)
- if you are 65 or older, have an annual influenza immunization (flu shot)
- have your blood cholesterol and blood pressure measured at least every three to five years.

Women need certain special needs:
- a breast physical exam every year
- a mammogram every year starting at age 50
- to examine their own breasts monthly and review how to do a self breast exam annually
- a Pap test and internal exam annually (less often for some women)

Men have their own special needs:
- a prostate exam every year starting at age 50
- an examination of the testicles each year

For the smokers and tobacco chewers:
- Quit! We are ready whenever you are to help you.
- Your mouth should be examined at least once a year.

For patients who drink wine, beer, or other alcoholic beverages:
- Never drink then drive. Use a designated driver.
- Limit your consumption to moderate amounts.

Finally, you should keep in mind that these are preventive care minimums for men and women. Some people have special needs beyond these guidelines. These special situations include patients previously treated for cancer or patients with a family history of cancer. If you have any questions about this letter or anything to do with your preventive care. please ask any of us.

Sincerely,
The Clinician and Staff of the
Rocky Stream Family Practice Center

Figure 3. *Letter to all patients of the Rocky Stream Family Practice Center about preventive care.*

ditional energy across ail 10 services. After this initial trial, the practice will move to the other preventive care goals listed in Table 1 if the effort seemed worthwhile. A unique tool that the Rocky Stream clinicians chose to develop is an annual letter addressed to all patients that provides the practice's goals on indicated preventive care as well as general preventive advice **(Figure 3).**

Step 4: Starting and Maintaining an Enhanced Preventive Office System

Steps 2 and 3 describe the preparation necessary to carefully identify the specific needs of a practice and to design a preventive care office system taking into consideration the routines that are currently in place. Next comes implementation through teamwork and applying the improved office routines. Involving the entire staff in the preceding three steps as well as step 4. the actual implementation of the preventive care office system is crucial. This sharing increases the commitment by everyone to change and improve. Some practices find this notion of teamwork to be truly eye opening for they had seldom. if ever, sat down together to discuss the operation of their practice and everyone's unique role within it. While implementing a preventive care office system, duplicated efforts and wasted time in other routines are sometime identified. Furthermore, this implementation process affords the opportunity to discuss how best to improve the operation of the practice in areas as well as prevention.

At the same time that teamwork is imperative, a designated leader among the office staff ensures that efforts are sustained. The leader can be designated "prevention coordinator" for this initiative. This person could be a nurse, medical assistant, receptionist, office manager, or a combination of several people who form a task force. This person or group would lead the practice through the implementation process, be responsible for communicating with all staff about practice changes, and would lead pertinent meetings. In addition to office staff leadership, attention must be paid to developing and adhering to a time line for implementation. Choosing a specific start date is strongly recommended.

In our experience, the most common barrier to the implementation of an office system using the GAPS Approach that office staff identify is lack of time. This is a valid concern and should not be ignored. However. practices that addressed this concern and persevered discovered that what was initially seen as time-consuming became time-saving. By consolidating responsibilities and using systems already in place, staff were able to see beneficial results quickly. In some cases, the addition of responsibilities was seen as a welcomed opportunity for professional growth.

Step 4 at Rocky Stream. The practice chose to implement their preventive care office system 1 week after the printer promised to deliver the new prevention flow sheets and self-stick notes. The receptionist volunteered to be the prevention coordinator and had frequent informal discussions with others in the practice about their ideas and concerns about enhancing preventive care. As planned, flow sheets were inserted into each patient chart at the same time a billing sheet was prepared for an upcoming visit. In response to concerns voiced by office staff and to limit the number of changes made at one time, the coordinator decided to delay implementation of the patient prevention letter until use of the flow sheets was secure.

When checking the blood pressure, the nurses asked women about their most recent breast clinical examination, mammography, and their breast self-examination practices, recording the patient's status on the flow sheet. Sometimes this prompted a discussion about the merits and barriers to early detection of breast cancer. Overdue early detection of breast cancer services were noted on the self-stick notes, as well as any helpful comments for, the clinicians' benefit (eg, "afraid mammogram hurts": The practice also planned to celebrate Breast Cancer Awareness Month, which was fast approaching. The nurses

Table 4. The Rocky Stream Practice's Time Frame for Starting and Maintaining Their Prevention Office System

Time Frame	Activity/Tool
Start date	Hand out modified health questionnaire Initiate use of flow sheet
4 wk after start date	Complete record review on flow sheet use Preventive coordinator meets informally with staff
6 wk after start date and every 12 wk thereafter	Meeting to assess practice effort, staff support, and status of office system Make any needed refinements to office system
8 wk after start date	Hand out patient prevention letter Introduce prevention bulletin board
12 wk after start date and biannually thereafter	Conduct record review on mammography Consider addressing additional goals
Annually	Review practice goals and revise if indicated Update patient education materials

designed a theme bulletin board that featured patient educational materials and guidelines promoting the early detection of breast cancer. A chart review was planned after the flow sheets were in use for 1 month. If breast cancer screening status was recorded for at least 75% of women who were seen, the clinicians offered to provide a free lunch for the practice. The Rocky Stream practice's time line and strategy for implementing the preventive care office system is summarized in **Table 4.**

THE PREVENTIVE GAPS APPROACH AND THE REAL WORLD

The first 50 practices that we worked with were well known to us, had agreed to participate in a study that included intrusive data collection, and were enthusiatic about ways to improve their preventive care. All of these practices followed the four steps of the GAPS Approach. Full adoption of the CPCP Project office system was achieved by 74% (n=37) within 2 months, as identified by the presence and use of a preventive flow sheet in at least 75% of charts and shared responsibility for the four preventive office system functions among physicians and office staff.[12] After 7 months, 81% (n=41) of assigned practices had achieved full adoption of the system and 19% (n=9) had achieved at least partial adoption defined as use of flow sheets in 50% to 74% of charts and some evidence of shared responsibility.

In the current phase of the CPCP Project, we are working with practices that are less well known to us. We are observing more variation in the response to the GAPS Approach. About one third of these practices have preferred to skip steps 1 and 2 and have moved directly to steps 3 and 4. A few practices have not changed their previously established preventive care routines because of competing priorities or because they concluded that no improvements were needed. This came as no surprise to us as we moved to these more representative settings.

Is the GAPS Approach for every practice? Certainly not. In our experience, many family physicians already provide first-class preventive care. These practices have little need to enhance the informal preventive care office systems already in place. Other practices may be less successful in providing preventive care, but may be unable to change using the GAPS Approach or any other method. Major transitions in personnel, in practice business arrangements, and in other factors that contribute to a practice's "chaos quotient" often indicate that enhancing preventive care should be addressed another time.

Practices in which few patients receive periodic health examinations are likely to benefit from applying the GAPS Approach. In these practices, clinicians may lack the time or inclination to perform periodic health examinations, or patients may lack the money or willingness to comply. Providing preventive care opportunistically may be the only choice. The GAPS Approach can allow these practices to capitalize on directing available resources to preventive care over a realistic time course.

Why not just implement the flow sheet or computer reminder system and forgo the four steps of the GAPS Approach? This will work in some practices and has already worked in practices that have these items up and running. However, about one quarter of the practices we have worked with have flow sheets in patient records that are sporadically used or not used at all. By involving office staff and using a formal planning and feedback approach, the chances of successfully implementing and maintaining a flow sheet and other aspects of a preventive care office system increase.

How much time is required to apply the GAPS Approach? Significant progress can be made in 1 or 2 hours of clinician time and a few hours of office staff time spread over several weeks or months. The goal-setting step can require as little time as it takes for a clinician to obtain and review one set of expert recommendations[13-19] and describe them to colleagues and office staff. Other practices may choose to devote hours to goal setting in a series of meetings during which clinicians review the literature, debate its implications, reach conclusions, then provide in-service education to office staff. The assessment step can require a single brief practice meeting and a tally of responses to a single question as in the Rocky Stream practice, or can involve days reviewing records. The planning step can be narrowly focused or comprehensive. One practice may choose first to focus on mammography screening and plan just one change to improve patient compliance. In one-half hour, personnel could develop a brief letter to accompany an American

Cancer Society pamphlet to be mailed to patients with their bills. Another may target a full range of services supported by flow sheets, patient education materials, and other tools that require weeks of development. The starting step can be similarly ambitious or modest. The Rocky Stream practice implemented their office system slowly and incrementally. Others may choose to start several mutually reinforcing office system components at once.

COMMENT

Certain limitations of the GAPS Approach should be recognized. Patients who seldom visit may be difficult to engage, even with opportunistic preventive care. Certain expenses may be unavoidable, such as the cost of flow sheets. Services provided may be inadequately reimbursed, if at all. Some practices may not be able to apply the GAPS Approach on their own but will require external support, since adding one more initiative to a busy agenda may require more energy than a practice's personnel can muster on their own.

The New Hampshire Division of the American Cancer Society is engaged in a pilot test using trained volunteers to provide this external support. Volunteers visit practices, help them through the GAPS Approach, and assist by providing their time and energy. Similar external support may be available through state chapters of the American Academy of Family Physicians, regional cancer centers, academic departments of family practice, or state health departments.

The GAPS Approach provides a way to implement change through an office system that supports provision of desired preventive services. We strongly believe that teamwork, appropriate routines, and flexibility are fundamental elements of the GAPS Approach. These parallel the concepts central to continuous quality improvement of planning, joint problem solving, participative management, and empowerment of the workforce.[21] Although some critics view continuous quality improvement as a fad, studies that have tested the implementation of continuous quality improvement components have found enhanced performance[22] and cost savings.[23] Most studies of continuous quality improvement have occurred in larger organizations such as hospitals. Less is known about implementing these techniques in smaller organizations such as community practices. The GAPS Approach has demonstrated improved preventive care performance in community practice.[10] Other approaches may work as well or better, but few have received similarly rigorous testing. Family physicians seeking ways to improve the preventive care they provide can apply the GAPS Approach with confidence of its efficacy in practices similar to their own and its basis in established techniques of quality improvement.

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Clinical Diagnostic Pitfalls

Robert M. Quinlan, M.D.
Michael D. Wertheimer, M.D.
Identifying and Dealing with Positive Findings in the Clinical Breast Exam

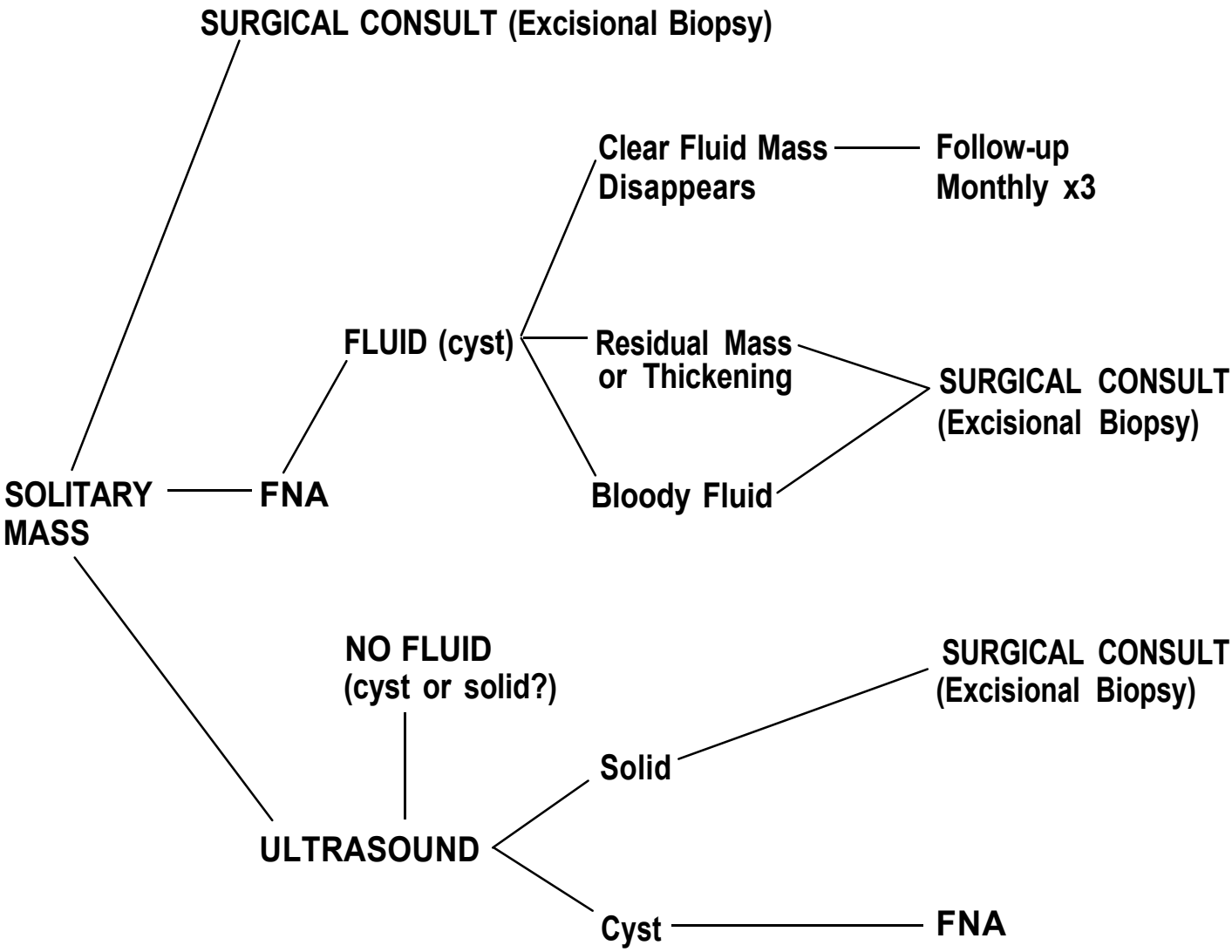
I. Solitary Mass Algorithm

II. For Primary Care Physicians the Major Pitfalls in Diagnosing Breast Cancer

A. Missed clinical findings
B. Positive physical exam: negative mammogram
C. Negative physical exam: positive mammogram
D. Positive mammogram: no physical exam
E. Positive physical exam: positive mammogram
F. Failure to follow accepted screening

III. Importance of Documentation

How to Manage Breast Lumps



Comprehensive Breast Care Progress Note
American Cancer Society
Massachusetts Division

Date:

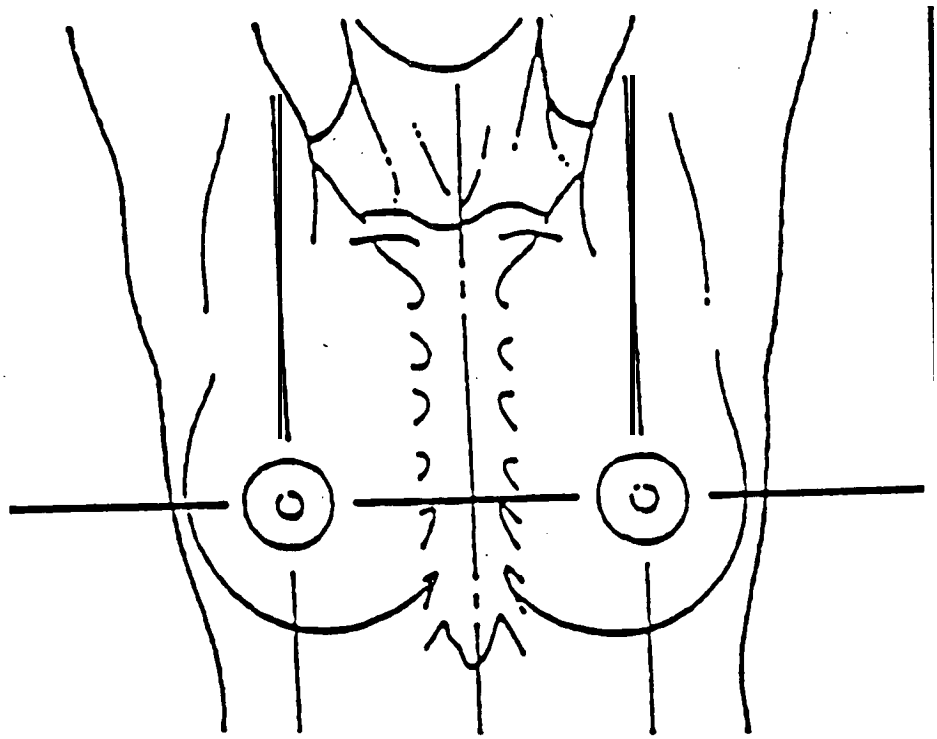
I. HISTORY

1. Age ____ 2. Menstrual History: LMP _____
   Gravida _____ Para _____ Ab _____ Misc _____
   Age 1st Pregnancy _____ Age Last Pregnancy _____
   Menarche _____ Menopause _____
3. Family History: _____
4. Past Medical History: _____ Previous Biopsy: _____
5. Hormone Therapy: Birth Control Pills _____
   Postmenopausal Hormone Replacement _____ Duration _____
6. Breast Symptoms: None: _____
   Pain ___ Lump ___ Nipple Discharge ___ Skin Changes ___

Imprint with Patient I.D. or Print Information

II. PHYSICAL EXAM:

DOCUMENT ALL FINDINGS



III. FOLLOW-UP/QUALITY ASSURANCE

1. Date of Physical Exam: _____
2. Mammogram Ordered: _____ DATE: _____
3. Mammogram Films Reviewed: _____ DATE: _____
4. Mammogram Report Reviewed: _____ DATE: _____
5. Mammogram results communicated to patient: _____ yes
   DATE: _____
   Method: Phone: _____ Letter: _____
6. Follow-up Plan: _____
7. Next Appointment: _____

Signature

print name *pager number*

Wertheimer, UMMC

American Cancer Society Recommendations for The Early Detection of Breast Cancer in Asymptomatic Women

---

BREAST SELF-EXAM
(Age 20 and over)

Once a month:

- Check each breast all over
- Use your finger pads
- Go up and down
- Check under your armpit, too
- Feel for lumps, thickness, other changes

CLINICAL EXAM

- See a doctor or nurse for a physical breast exam
- Age 20-40, every 3 years
- Over 40, every year

MAMMOGRAPHY

- Have your first mammogram by age 40
- Age 40-49, have a mammogram every 1 to 2 years
- Age 50 and over, have a mammogram every year

AMERICAN CANCER SOCIETY®

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William H. Hindle, M.D.
Appleton and Lange,
New York, 1990

14

Diagnosis of Malignant Breast Disease

Michael D. Wertheimer, MD

INTRODUCTION

Cancer Control Objectives

The National Cancer Institute (NCI) has embarked on an ambitious program to significantly reduce the cancer death rate in the United States. The Division of Cancer Prevention and Control of the NCI has established a set of specific objectives in order to try to reduce the national death rate from cancer by 50% of current levels by the year 2000.[1] This goal is considered possible by the widespread application of existing knowledge of cancer prevention, screening and detection technology, and application of state-of-the-art treatment methods. The underlying premise of the "year 2000 target" is that the necessary knowledge and methods are already available but have never been consistently applied across the country.

Some brief observations about the demographics of cancer in the United States will graphically illustrate the point. In 1986, there were approximately one million new cancer cases in the United States and over one-half million deaths due to the disease.[2] Over 130,000 deaths (30%) were smoking related (lung and head and neck). In women, lung cancer accounted for 20% of cancer deaths, breast cancer 18%, colon and rectal cancer 14%, and uterus and ovarian cancer approximately 10%. In terms of incidence, however, breast cancer accounts for 27% of all cancers in women and is therefore the most common malignancy in women. In 1988, approximately 135,000 new cases of breast cancer in females were reported and over 42,000 female deaths occurred.[3] Current incidence data suggests that nearly 10% of American women will develop breast cancer.

There is growing consensus worldwide based on long-term controlled clinical trials that breast cancer screening by physical examination and mammography is effective and can reduce the mortality of the disease by 30% to 50%. In spite of this, breast cancer screening is still not practiced widely. In 1985, a survey performed by the American Cancer Society demonstrated that only 15% of American women over age 50 had been screened by any method and only 11% of doctors across the country did comprehensive breast cancer screening as part of their normal clinical practice.[4]

Screening for cancer of the uterine cervix has long been known to be effective and has been shown repeatedly to reduce the risk of mortality from invasive cervical cancer by as much as 75%. Recent surveys indicate, in the 40 to 70 year age group (for whom the risk of cervical cancer is now greatest), only 57% of these women are regularly screened with Pap smears.[5] More widespread application of these and other screening and early detection methods is expected to have a dramatic impact on early case discovery and is expected to yield improved survival statistics on a potentially large scale. This enhanced interest in prevention, screening, and early detection in diseases such as breast cancer is now public policy and a major new agenda of the National Cancer Institute and the American Cancer Society. The enhanced interest in primary and secondary prevention (screening and early detection) represents a golden opportunity for gynecologists who are the major providers of primary health care for women in many communities. The opportunity thus exists for all clinicians who care for female patients to have a major impact on the survivability of their patients from the breast cancer epidemic in our country and to help turn the tide on a large scale so that the year 2000 target of a 50% reduction in mortality may be a reachable goal. It is the purpose of this chapter to review the pathophysiology of malignant breast disease and to provide the practicing gynecologist with a practical, accurate, and consistent diagnostic ap-

proach for the symptomatic patient in the context of our redefined cancer control objectives.

SCREENING/ EARLY DETECTION

Survival from breast cancer is directly related to the stage at which it is diagnosed even though some of the biological uncertainties about this heterogeneous disease are still unanswered. Stage at diagnosis and its relationship to survival can be related as independent variables to tumor size, nodal involvement, and secondary variables such as estrogen receptor activity, degree of differentiation of the tumor, tumor type, lymphatic and vascular invasion, and other histopathologic criteria. Great strides have been made in the past several decades in earlier stage discovery and improved survival. This has been due largely to the results of screening efforts and the detection of smaller and more treatable tumors that tend to have more favorable prognoses and less chance of nodal metastasis at the time of discovery. The patients who are discovered to have small, relatively early tumors also have the very great benefit of having the option of more conservative breast preservation procedures and thus the treatment is less onerous than in the past.

The factors that are expected to be most responsible for improving the long-term survival of early breast cancer patients are increased public and provider awareness, wide dissemination of appropriate screening and early detection techniques, and the uniform application of state-of-the-art treatment methods. Socioeconomic imbalances influencing access to care further complicate optimum treatment results and need to be overcome by government action.

Symptomatic Versus Asymptomatic Women

It is important to conceptually divide all female patients into two categories with respect to breast disease. Those women without symptoms when first evaluated follow asymptomatic screening guidelines. Those with symptoms of ongoing breast disease undergo diagnostic evaluation. Even though there are risk factors (such as close family history of premenopausal breast cancer) that predispose to increased risk, the vast majority of patients (over 80%) with breast cancer have no risk factors. Since the incidence of breast cancer is 10% in our society, the problem is now so prevalent that the only safe course of action that can lead to more widespread early detection is to consider all women in our society at risk for the disease.

Asymptomatic Women. These women should follow the American Cancer Society guidelines with regard to breast self-examination, clinical breast physical examination, and periodic mammography beginning at age 35. Controversy still exists about the frequency of mammography in asymptomatic women under age 50. No controversy exists any longer about the ability of mammography to discover occult breast cancer in women over the age of 50. American Cancer Society guidelines, described previously, are now accepted as standards of care in most American communities.

Symptomatic Women. Those women harboring symptoms of breast disease who seek medical attention must be evaluated carefully and completely to a clear-cut end point with a diagnosis made. As will be described in the next section, the vast majority of patients with symptoms of breast disease have benign disease or physiologic abnormalities that require no specific treatment. A logical and consistent approach for evaluating the woman with symptoms is essential in order to avoid the pitfalls in diagnosis that lead to unnecessary delays in diagnosis and treatment and an unfavorable outcome in patients with breast cancer.

TYPE OF PATIENT	TYPE OF INTERVENTION
Asymptomatic	Screening Evaluation
Symptomatic	Diagnostic Evaluation

PHYSICAL EXAMINATION OF THE SYMPTOMATIC WOMAN

Symptoms of breast disease are exceedingly common and may occur at some time during the life of most adult women. Symptoms of breast disease in order of frequency are pain, lump, nipple discharge, and to a much lesser extent, skin changes and retraction phenomena. A thorough history and careful physical examination are fundamental in the diagnosis of patients with breast symptoms. Although sophisticated modern mammography may be helpful in a given patient, it is still the clinical assessment-physical examination and simple office diagnostic procedures-that are central to the correct and timely diagnosis of the symptomatic patient. There are several caveats that must be understood and accepted before consistently reliable physical diagnoses of the breast can take place.

As pointed out previously, the lobular anatomy

of the breast is such that, given the expected normal hormonally related proliferation, edema, and cyclical regression of normal breast structures in women in the reproductive years, tremendous anatomic variation occurs. Not only is there great anatomic variation from woman to woman, there may even be marked variability in the breast of a given woman over time, and even in different quadrants of the same or opposite breast. The fact that the normal breast is an endocrine target organ that is subject to somewhat variable hormonal stimulation and the fact that this is superimposed on a very variable underlying anatomy means that the physical examination of the breast under optimum circumstances is problematic (Fig. 14-1). Since the rate of cyclical proliferation and regression that occurs is so variable within a given breast, changing and evolving irregularities and areas of background nodularity are common. The unique individual anatomy of each woman's breast may be as unique in some cases as her fingerprint. This creates tremendous problems in teaching the physical examination of the normal breast to medical students and residents and poses serious pitfalls in the office diagnosis of the symptomatic woman. The same uniqueness exists in mammographic patterns of many women's breasts and poses similar problems in the interpretation of breast images. This again creates grave pitfalls in the accurate diagnosis of the normal radiographic pattern from which abnormalities may be distinguished.

The problem of the unique and evolving physical examination is compounded by the fact that breast symptoms are exceedingly common. As mentioned, **most** women will have one or more of the three most common symptoms of breast disease-pain, lump, or nipple discharge-during their lifetimes and most of these symptoms will be caused by normal physiologic events, physiologic aberrations, or benign pathologic processes. On the other hand, breast cancer is also so common in our society even in women without unusual risk factors that clinicians caring for women face the sometimes difficult task of identifying the small percentage of women harboring serious pathology from among the larger number of women having symptoms of no great pathologic significance. This requires a high index of suspicion and a reliable decision tree for differential diagnosis. The situation is further compounded in the woman with the problematic physical examination and by the mounting pressure on clinicians to discover subtle, occult, preclinical, and potentially curable breast cancer. For all of these reasons, a thorough understanding of the anatomy, physiology, and pathology of the breast is essential for the practicing gynecologist.

The first principle in approaching patients with breast symptoms is that, given the high prevalence of breast cancer, all patients with symptoms must be appropriately evaluated to some logical conclusion. This involves a thorough history, careful physical examination, mammography, and sometimes office diagnostic procedures such as fine needle aspiration cytology.

SYMPTOMS OF BREAST DISEASE

Table 14-l is taken from the large clinical experience of Dr. Christian Haagensen and categorizes the differential diagnoses of a thousand adult women presenting with breast complaints and the final diagnoses made.[6] Fully half (500) of these women had no symp-

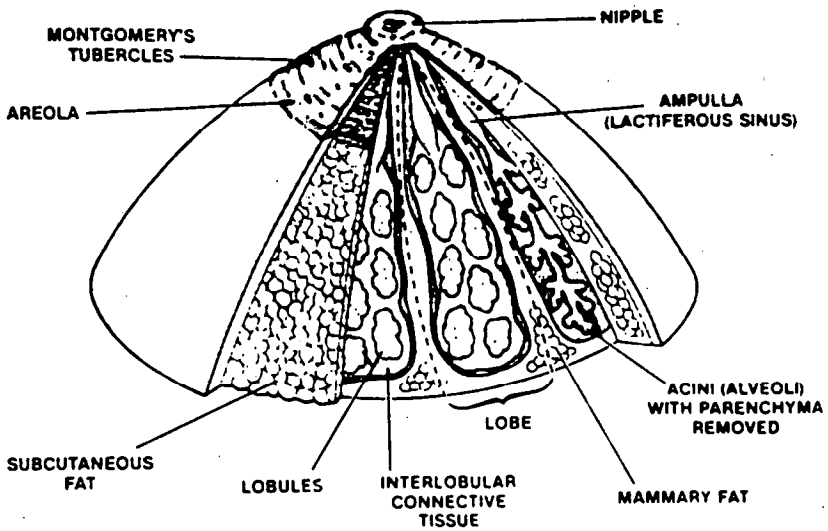

Figure 14-1. Anatomy of the breast.

TABLE 14-1. THE FINAL DIAGNOSIS IN A SERIES OF 1000 PATIENTS WHO RECENTLY CONSULTED ME FOR PRESUMED BREAST DISEASE

Abnormal Physiology/ No Disease	50 %
Infections	0.5 %
Gross Cystic Disease	18 %
Fibrous Disease	2 %
Duct Ectasia	1 %
Adenosis Tumor	0.4 %
Cystosarcoma	0.3 %
Lipoma	0.5 %
Fat Necrosis	0.3 %
Adenofibroma	6 %
Intraductal Papilloma (Solitary or Multiple)	2 %
Lobular Neoplasia	1 %
Carcinoma	18 %

Haagensan, CD: *Disease of the Breast.* W. B. Saunders. 1988, p. 574.

toms requiring medical intervention. This large group consists of women with either no discernible pathology or with normal anatomic or physiologic variants who can be diagnosed by history, physical examination, and mammography. The next larger category representing approximately 8% of the thousand women were patients who had some abnormal physiology requiring medical intervention. Most of these women had excessive, unusual, or irregular, engorgement with painful nodularity and changing densities on the physical examination. Approximately 10% of the group of "typical" women had benign pathological findings of fibrocystic change discovered at the time of biopsy of a dominant mass. Only 18% of these patients out of these 1000 adult women had carcinoma based on biopsy of a suspicious physical finding. Now one would expect that 10% to 30% of surgically biopsied masses would, harbor carcinoma. Successful diagnosis of symptomatic breast disease hinges on the identification of this small subgroup of patients harboring serious pathology among the much larger group of patients presenting with relatively innocuous complaints of no great pathologic significance. It is recommended further that a Breast Profile be established and, made an integral part of the medical record on all female patients that includes all of the following items:

BREAST PROFILE

1. History stressing risk factors and symptoms
2. Physical examination with diagramatic recording of findings
3. Previous biopsies with specific histopathologic patterns
4. Baseline and subsequent mammographic patterns

Inclusion of the Breast Profile in the routine gynecologic history will integrate breast-related health concerns into routine gynecologic office practice.

Pain

Pain in the breast is exceedingly common, occurs in most women sometime during their menstrual life, and represents the largest group of patients with breast symptoms. In most women, it is mild, cyclical, and in phase with their menstrual cycles. In such patients, the history of bilateral, cyclical breast engorgement and nodularity that wanes soon after the onset of menses allows the diagnosis to be made of an event of physiologic rather than pathologic origin. The diagnosis can largely be determined by the history and no treatment is usually necessary. Breast pain, however, often does not conform to this common pattern and may be unilateral, confined to one or more specific quadrants of a given breast, and may be prolonged and/or not in sync with the menstrual cycle. A careful physical examination should be performed to exclude the possibility of an acutely erupting cyst, a benign inflammatory process, or even a carcinoma with some associated tenderness. It is never safe to assume that cancers are usually or always painless. A careful physical examination must always be performed with special attention to the specific area of tenderness. The first priority in the physical examination of the patient with breast pain is to exclude the possibility of serious underlying pathology. Concern is always greatest in the patient with unilateral, persistent, localized pain and tenderness. Only when the physical examination and mammogram are negative can such a patient be reassured but close follow-up should still be provided.

Although the influence of diet on breast symptoms such as pain has been described (Xanthenes, dietary fat, micronutrients, and vitamins), there is no hard scientific data at the present time to support any specific dietary interventions to control such symptoms. For most patients, breast pain is mild and no treatment is required. For patients with more severe pain, reassurance that serious pathology has been ruled out by careful physical examination and mammography will allay anxiety. Often the symptoms can be made more manageable and acceptable with mild analgesics and other symptomatic measures such as local heat. It is the very rare patient, indeed, with pain sufficiently severe and persistent who requires any pharmacologic or surgical intervention. The problem of the differential diagnosis of the patient with breast pain is typical of the problem of differential diagnosis in breast disease in general, wherein a very large number of patients with a physiologic aberration are harboring a small number of patients with a truly pathologic finding.

Lumps

Lumps in the breast are exceedingly common and second only to breast pain in frequency of presenting complaints. The problem again posed in the differential diagnosis of patients with breast lumps is in isolating the small subgroup of patients with serious pathology from the much larger group of patients with anatomic variants or evolving and changing areas of "physiologic nodularity." This distinction may be difficult or impossible in some patients which presents another common pitfall in diagnosis. The sine qua non for the accurate diagnosis of patients with breast lumps is that once a physical finding is described as a lump, it must be diagnosed (definitive pathologic diagnosis) by one method or another. Most patients with solitary breast lumps may be diagnosed easily, accurately, painlessly, and cost effectively by fine needle aspiration cytology in the office. An algorithm is provided in Figure 14-2 that describes the author's method for fine needle aspiration cytology (FNAC) as a means of office triage of all solitary breast lesions. If a careful decision tree is followed the rapid diagnosis of all dominant masses is readily available without unnecessary delays that invariably increase patient anxiety. Fully 50% of dominant breast masses discovered in most office settings are benign cysts which can be dealt with effectively, diagnostically, and therapeutically by needle aspiration in the office. This relieves the inevitable attendant anxiety and definitively solves the problem in short order. Appropriate follow-up and subsequent 'mammography are described in the algorithm.

A cytologic preparation is created for all solid masses. Any lesions that are found on cytologic examination to be unequivocally malignant may then be further evaluated and treated accordingly. A corroborating histopathologic biopsy may be advisable under some circumstances prior to definitive surgical treatment. Equivocal or negative cytologies in the face of a persistent solitary mass obligate open surgical biopsy. All solitary dominant masses of the breast must be diagnosed without delay. The purpose of mammography in the face of a dominant mass is to screen the opposite breast and *not to diagnose the lump in question* which must be removed regardless of mammographic appearance. Another common pitfall in the diagnosis of breast lumps is the acceptance of a normal or negative mammogram in the presence of a palpable mass. Mammography, depending on technique and breast density, may have as high as 15% to 20% false-negative rate and a negative mammogram should never delay or negate the need for histologic diagnosis, of all breast masses.

The consistent premise that all breast masses must have an accurate cytologic or histologic diagnosis will avoid the pitfall of delay or misdiagnosis in clinically apparent breast cancer. The most difficult clinical problem in carrying out this simplified approach for all women with breast lumps is that large numbers of women with enhanced breast nodularity that is localized or generalized may be problematic on physical examination. There are many women in whom a solitary firm lesion in an otherwise unremarkable breast leaves no doubt in the clinician's mind that a dominant mass exists. Once this decision is made, a careful recording of the characteristics of the mass is incorporated in the medical record with an appropriate diagram (Fig. 14-3).[7] Characteristics of a breast mass that should be included in its description are its size, shape, delimitation (degree of sharpness of the edges), consistency, movability within the breast, and fixation, if any, to the skin or chest wall. Given the unique anatomic and physiologic variations in a given patient, however, the question of

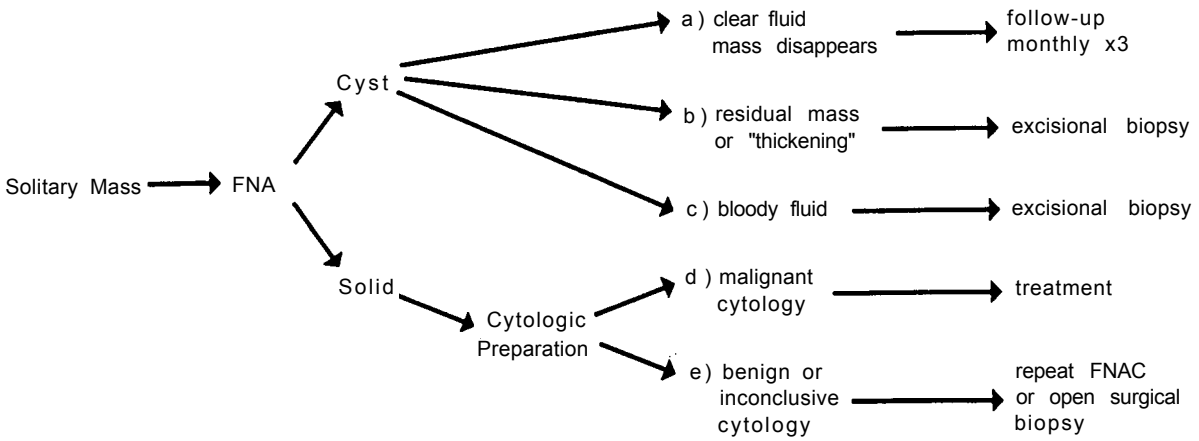

Figure 14-2. Algorithm for the use of fine needle aspiration (FNA) and fine needle aspiration cytology (FNAC) for office triage of breast lumps.

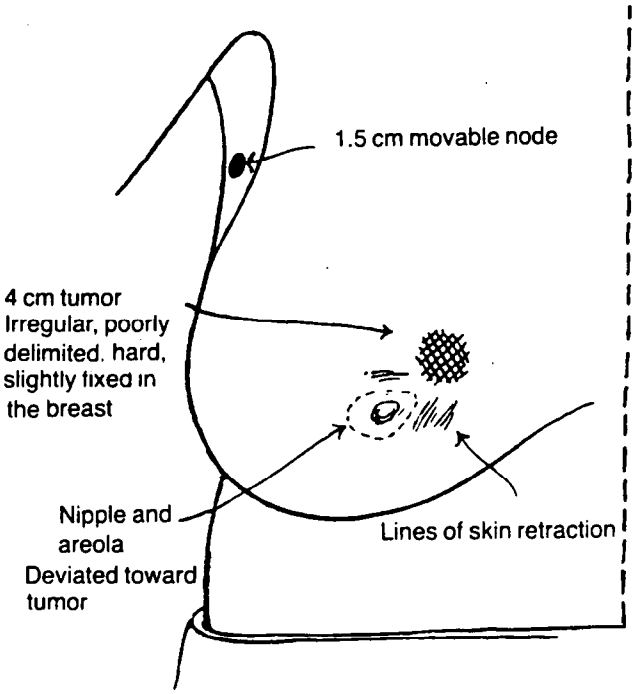

Figure 14-3. Method of recording physical finding found on examination. *(Borrowed with permission, Haagensen CD: Diseases of the Breast WB Saunders, 1971.)*

whether an area of nodularity is physiologic or pathologic may be unanswerable. The differentiation between exaggerated nodularity of the breast and a true dominant mass may be difficult or impossible to do on physical examination alone and may require further investigation including mammography, surgical consultation, and fine needle cytology or open surgical exploration. The differentiation between enhanced nodularity and a dominant mass is one of the fundamental obstacles to accurate physical examination of the breast and one of the major pitfalls and causes of error in diagnosis. As already stated, the basic anatomic structure of the breast lobule is compounded by the normally occurring physiologic events of proliferation and edema. This often creates a finely nodular character on palpation that may become exaggerated periodically in some women and be so marked at times as to make accurate physical examination difficult or impossible. Repeat physical examinations at close intervals in some patients are helpful

In doing breast physical examination it is useful to examine patients in multiple positions (supine, sitting, arms raised, hands on hips with squeeze for pectoralis contraction) to maximize the ability to discern the three-dimensionality of any physical finding. The finding of enhanced background nodularity in all quadrants of both breasts and of a confluent nature in a given quadrant increases the likelihood of a benign finding but does not eliminate the possibility of a small occult cancer being present. Confusing nodularity is particularly common in the inframammary folds, peri-areolar location, and the axillary tail regions. Close surveillance, repeated physical examinations, mammography, and ultimately biopsy are the only ways to avoid missing small carcinomas in the difficult breast. Given the ease and availability of fine needle aspiration cytology in most clinical settings, it is usually safer to err on the side of investigating equivocal physical findings than deferring for future clarification. It is only by persistence in pursuing the diagnosis in patients with subtle or equivocal findings that the clinician and the patient will be rewarded by the discovery of early and eminently treatable breast cancers.

Nipple Discharge

Nipple discharge is the third most common symptom of breast disease and again is largely physiologic and harmless. It is the clinician's task to find the small subgroup of patients with this mainly harmless and innocuous symptom who are harboring serious pathology. There are at least seven different types of nipple discharge: milky, multicolored, purulent, clear (watery), serous (yellow), serosanguinous; and, bloody. Many women will describe, when asked, that nipple discharge of one type or another has occurred at some time during their adult lives. Most women can elicit nipple discharge by breast or nipple compression. Only 8% to 10% of patients with nipple discharge are harboring serious lesions of pathologic significance. The critical features of pathologic nipple discharge can be elicited from the history and the remainder from the physical examination. Patients with discharge from multiple duct openings in both breasts have a systemic cause such as hyperprolactinemia (pituitary adenoma) or estrogenic overstimulation (pregnancy or prolonged oral contraceptive use). By virtue of the discharge emanating from multiple duct openings in both nipples the safe conclusion can be drawn that some systemic influence or organ-wide influence is affecting both breasts. Fibrocystic change of various types may also be a benign cause of such a symptom that involves both breasts. On further questioning, the patient may describe episodes of serous or bloody nipple discharge that consistently occurs without breast compression or stimulation and is only elicited from a single duct opening of the nipple of only breast. This implies local duct pathology rather than an organ-wide or systemic influence that involves both breasts, and this subgroup, which is quite small, deserves follow-up. A number of exceptions should be mentioned. Bloody discharge from both engorged breasts late in pregnancy may occur.

Bloody discharge may accompany the onset of menses in young proliferating breasts. Clear or bloody discharge may occur from one or both breasts after long-term oral contraceptive use. "Pseudodischarge" may be caused by benign or malignant skin eruptions involving the nipple.

In summary, the subgroup of patients with nipple discharge of pathologic significance is characterized by being

1. Nonlactational
2. Spontaneous
3. Single-duct in origin
4. Unilateral
5. Persistent
6. Serous or bloody

This subgroup of patients should be evaluated thoroughly by all available means including careful physical examination, mammography, and usually surgical duct exploration and biopsy. Eighty-five percent of such patients will have benign intraductal papillomas but approximately 10% to 15% of such patients will have small, occult intraductal carcinomas.

Skin Changes and Retraction Phenomena

A host of more subtle and less frequently reported symptoms and physical findings of breast disease also regularly occur. Dilated subcutaneous veins, redness of the skin, edema of the skin, erosions and ulcerations of the nipples, and skin retraction or dimpling should always be sought in a careful physical examination of the breast. Careful inspection of the breast in multiple positions can always be performed in a manner that allows the physician to gain the maximum information and allows the patient to retain maximum dignity during what can otherwise be a stressful and embarrassing experience for some patients. The physician needs to be sensitive to this, be dignified in approach, and appropriately drape and position patients to achieve all of these objectives. A four-position examination should always be part of the complete examination of the breast. Examination supine with the arm abducted and the opposite breast draped is the first maneuver. Examination supine of the opposite breast with redraping of the first breast is the next maneuver. Examination sitting with the arms at the side, then over the head, then on the hips with pectoralis contraction (hip squeeze) are all then performed. Special attention is given to areas of question noted during the initial supine examination. The axilla is always examined with the patient in the sitting position with the physician's hand opposite to that of the patient's axilla while the opposite hand supports that arm. Careful inspection of the breasts in multiple positions, with arms raised, and with pectoralis contraction, and sometimes with gentle molding of the breast may demonstrate a subtle tethering or skin retraction that might otherwise go unappreciated. Understanding the anatomy of Cooper's ligaments of the breasts is important in maximizing the return of information during this examination. The suspensory ligaments of the breast described by Sir Astley Cooper and shown as a corrosion preparation in the accompanying diagram (Fig. 14-4)[8] demonstrates how these suspensory ligaments ramify throughout the breast and connect all of the parenchyma of the breast to the skin and pectoralis fascia of the chest wall. Anything that impinges on one of these structures in the breast-whether inflammatory or neoplastic-can usually be discovered on physical examination by tethering or dimpling of the adjacent skin. This may even be true when no palpable mass is present and may be the only clue of a small, occult, otherwise unsuspected malignancy. Careful attention to this often neglected part of the physical examination may be frequently rewarding for the physician in seeking to diagnose early disease.

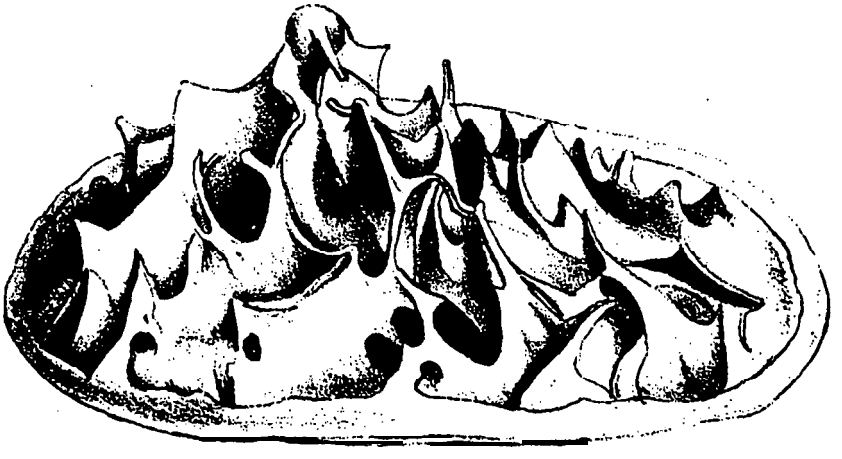

Figure 14-4. Cooper's ligaments of the breast. *(Borrowed with permission, Haagensen, CD: Diseases of the Breast, WB Saunders, 1971.)*

TNM* Classification of Breast Cancer

T Primary tumors

TIS Paget's disease of the nipple with no demonstrable tumor

T1 Tumor <2 cm T1a, T2a, T3a, with no fixation

T2 Tumor 2-5 cm T1b, T2b, T3b with fixation to underlying pectoral fascia or muscle

T3 Tumor >5 cm

T4 Tumor of any size with direct extension to chest wall or skin

- **T4a** With fixation to chest wall (including ribs, intercostal muscles, and serratus anterior muscle but not pectoral muscle)
- **T4b** With edema (including peau d'orange), ulceration of skin of breast, or satellite skin nodules on same breast
- **T4c** Both T4a and T4b
- **T4d** Inflammatory cancer

Dimpling of the skin, nipple retraction, or any other skin changes except those in T4b may occur in T1, T2, or T3 without changing the classification

N Regional lymph nodes

N0 No palpable ipsilateral axillary nodes

N1 Movable ipsilateral axillary nodes

- **N1a** Nodes not considered to contain growth
- **N1b** Nodes considered to contain growth

N2 Ipsilateral nodes considered to contain growth and fixed to one another or to other structures

N3 Ipsilateral supraclavicular or infraclavicular nodes considered to contain growth, or edema of the arm

M Distant metastasis

M0 No known distant metastases

M1 Distant metastases present

Definitions of Clinical Stages I to IV Using TNM Classification

Stage I	T1a	N0 or N1a	M0
	T1b	N0 or N1a	M0
Stage II	T0	N1b	M0
	T1a	N1b	M0
	T1b	N1b	M0
	T2a	N0, N1a, or N1b	M0
	T2b	N0, N1a, or N1b	M0
Stage III	T3	Any N	M0
	Any T	N2	M0
Stage IV	T4	Any N	Any M
	Any T	N3	Any M
	Any T	Any N	M1

*Tumor-Node-Metastasis

Staging system of International Union Against Cancer and American joint Commission on Cancer Staging and End Results Reporting

Figure 14-5. TNM classification of breast cancer.

All new or unusual physical findings in this category-especially redness of the skin, edema of the skin or nipple, and certainly all changes in the epithelium of the nipple-must be evaluated by mammography and surgical consultation.

CLINICAL STAGING

After completion of the physical examination of the breast and the recording of the findings with a diagram in, the record, assessment of clinical disease stage should be undertaken and recorded. Figure 14-5 describes the currently accepted clinical staging scheme based on the TNM system of the IUAC (International Union Against Cancer). The TNM staging system combines an assessment of tumor size, clinical axillary nodal status, and presence or absence of metastases. Clinical staging is important for precise individualized treatment planning, estimation of prognosis, and end results comparison with pathologic stage which is determined after definitive surgery.

COUNSELING AND SUPPORT

All patients with symptoms of breast disease fear the diagnosis of cancer. Most women are knowledgeable about breast cancer from the public press and from experiences with relatives, friends, or neighbors. The timely response to symptomatic women and the expeditious diagnosis of their complaints assuages much of the initial fear and anxiety. Compassion and adequate time to establish rapport and to discuss therapeutic options and concerns add to the healing process. These help in beginning the rehabilitation of the breast cancer patient long before treatment even starts. The stage is thus set for total rehabilitation-physical, emotional, and psychosocial-at the very first office visit. A team composed of an enlightened clinician (gynecologist), referral surgeon, mammographer, medical oncologist, oncology nurse clinician, and former patients as lay support, optimizes the necessary multidisciplinary approach in a supportive and successful attack on the disease.

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Breast Cancer Risks

Judging Breast Cancer Risk

There are a number of ways to identify risk. People often are keyed in to one way of talking about it. A good strategy is to select an explanation which most suits your individual patient.

1. Lifetime Risk: 1 in 8 women

   These are the figures given by the American Cancer Society Statistics Office. Recently, the Secretary of Health & Human Services, Donna Shalala, announced that the risk of an American woman developing breast cancer if she lived to be 90 was 1 in 8. (The risk was 1 in 20 in 1950!) Many people do not relate to lifetime risk principally because there is too much time in the distant future to worry about it.

Table 1

Lifetime Breast Cancer Risk For Women

Risk of Developing Cancer

By Age	**The Risk Is:**
25	1 in 19,608
30	1 in 2,525
35	1 in 622
40	1 in 217
45	1 in 93
50	1 in 50
55	1 in 33
60	1 in 24
65	1 in 17
70	1 in 14
75	1 in 11
80	1 in 10
85	1 in 8

Information taken from the American Cancer Society

2. Relative Risk: (e.g. "You are at three times the average risk.")

It is often helpful to talk about risk by comparing one person to others. The usual way of doing this is to compare people of similar age. If a 40 year old woman has twice the risk of developing breast cancer because of a positive family history, that translates to twice the risk of an ordinary 40 year old woman. That risk is usually given as what will happen in the next 5 or 10 years (not twice the lifetime risk). Most people can understand the concept of "risk over the next 10 years" fairly well and be motivated by it. **NOTE: saying a woman is 10 times the risk does not mean 10x the average lifetime risk, it means 10x the risk over a brief (5-10 years) period compared to other women her age.**

Defining relative risk by reviewing a patient's personal history or family history, is one of the most common ways of talking about risk with patients. This way of talking about risk gives a person a way to peg themselves among their peers, and gives them a certain relative perspective. Table 2 shows the most common risks.

Table 2

Patients' Situations

Risk Factor	Increase In Relative Risk (times)
Family history (overall risk)	2
Premenopausal relative	4
Postmenopausal relative	1.5
Breast Pathology	
Atypical hyperplasia	5-11
Proliferative disease without atypical hyperplasia	2
Reproductive history	
Menarche before age 12	1.5
First live born after age 30	2
Menopause after age 55	1.5
Long term estrogen replacement (>15 yrs)	1.5-2

Another way to discuss risk is by categorizing how great the risks are. Some risks are "weaker" than others. Only a few risks really raise one's chances of developing breast cancer very much. Table 3 lists risks by their strengths. Note that most risks are in the weakest category (only 1-2 times).

Table 3

Established Risk Factors For Breast Cancer In Women By Strength Of Risk Factor

A. Strong Risk: Relative Risk > 4.0

	High-risk group	Low-risk group
Age	Old	Young
Country of birth	North America, Northern Europe	Asia, Africa
Mother and sister with history of breast cancer, especially if diagnosed at an early age	Yes	No
Atypical hyperplastic epithelial cells	Yes	No

B. Intermediate Risk: Relative Risk = 2.1-4.0

Factor	High-risk group	Low-risk group
History of cancer in one breast	Yes	No
Mother or sister with history of breast cancer	Yes	No
Biopsy-confirmed benign proliferative breast disease without atypia	Yes	No
Radiation to chest in moderate to high doses	Yes	No

Table 3

Established Risk Factors for Breast Cancer In Women By Strength Of Risk Factor (Cont.)

C. Weak Risk: Relative Risk = 1.1-2.0

Factor	High-risk group	Low-risk group
Socioeconomic status	High	Low
Marital status	Never married	Ever married
Place of residence	Urban	Rural
Place of residence (within United States)	Northern	Southern
Race/ethnicity	Caucasian	Asian
Religion	Jewish	Seventh-day Adventist, Mormon
Removal of ovaries before age 40	No	Yes
Nulliparity	Yes	No
Age at first full-term pregnancy	$\geq$ 30 years	< 20 years
Age at menarche	$\leq$ 11 years	$\geq$ 15 years
Age at menopause	$\geq$ 55 years	< 45 years
History of primary cancer in endometrium, ovary	Yes	No

Adapted from: Kelsey, J. Breast Cancer Epidemiology: Summary and Future Directions. Epidemiologic Reviews: 1993 15:256-263.

Table 4
Relative Risk = 1.1 - 2.0

Factors Found To Be Risk Factors For Breast Cancer In Many Studies, But For Which Some Uncertainty Still Exists

Factor	High-risk Group	Low risk Group
Time between menstrual periods	≤ 21 days	≥ 30 days
Breast feeding	None	Several years
Oral contraceptives before age 20	Yes	No
Long-term use of estrogen replacement therapy	Yes	No
Diethylstilbestrol use during pregnancy	Yes	No
Height	Tall	Short
Alcohol consumption	Yes	No
High Fat Diet	Possibly	No

Adapted from: Kelsey, J. Breast Cancer Epidemiology: Summary and Future Directions. Epidemiologic Reviews: 1993 15:256-263.

An Example Of looking At What An Increase In Relative Risk Means

Remember 2 times the usual risk does not mean 2 times 1 in 8 (2/8 or 25% risk)! Rather 2 times the usual risk means 2 times the risk of a woman of a given age over the next 5-10 years. (This is because the relative risk numbers are all derived by comparing specific age cohorts, not lifetime risk). To make relative risk more realistic, one can convert the relative risk to a specific percent chance of developing cancer in the next 10 years. Table 5 gives the chances of developing breast cancer by decade of age for the average American woman.

Table 5

The Average American Woman's Chance Of Developing Breast Cancer In The Next 10 Years

Current Age	Approximate Chance
20	0.05%
30	0.5%
40	1.5%
50	2.0%
60	2.5%
70	2.2%

Now let's work out a specific example.

Your patient is a 60 year old woman who has a first degree relative who developed breast cancer when she was postmenopausal. From Table 5, you find that the average 60 year old American woman has a 2.5% chance of developing breast cancer in the next 10 years. From Table 2 you note that having a first degree relative who developed breast cancer when she was post-menopausal increases your patient's relative risk 1.5 times multiplying 2.5% x 1.5 times = 3.8%. Therefore, your patient has a 3.8% chance of developing breast cancer in the next 10 years. If her relative had developed breast cancer when she was pre-menopausal, your patient's relative risk in the next 10 years would be (2.5% x 4) or 10%. Remember however, that these numbers are only "guestimates".

3. Individualized Risk or "Added" Risk

This type of risk discussion assesses multiple risks in a woman's personal and family history and addresses the issue of "added" risks. Most patients will not want to be so specific. Those who will are usually women with a positive family history of breast cancer.

As a rough estimate of individual risk, you might want to use the risk model developed at the National Cancer Institute (The Gail Model). This statistical model estimates the chances of developing breast cancer in the next 10 years. This model uses 5 established risk factors:

Table 6

The Gail Model: Risk Factors

- Current Age
- Age at menarche
- Age at first live birth
- Number of first degree family members with breast cancer (mother, sister, daughter)
- Number of breast biopsies (with/without atypical hyperplasia)

The Gail Model is based on the Breast Cancer Demonstration and Detection Project (BCDDP) data and tends to overestimate risk, especially for younger women. This method is good to use for women with a number of risk factors (e.g., family history, multiple biopsies, increased risks from reproductive history).

The Gail Model: How To Use It

Step 1

Enter Associated Relative Risk in Box 1a - 1c

1a Age at menarche

if:	Associated relative risk
≥ 14 yo	1.000
12-13 yo	1.099
<12 yo	1.207

Menarche Risk ☐ **1a**

1b Number of Breast Biopses:

If current age is: <50 yo

0	1.000
1	1.698
≥ 2	2.882

If current age is: ≥ 50 yo

0	1.000
1	1.273
≥ 2	1.620

Biopsy risk ☐ **1b**

1c Pathology of Biopsy

No Atypical Hyperplasia	0.93
Atypical Hyperplasia	1.82
No Biopsy	1.00

Pathology Risk ☐ **1c**

Step 2

Enter Associated Risk Factor in Box 2

Reproductive & Family History

Age at 1st Live Birth	Number of 1st Degree Relatives With Breast Cancer	Risk Factor	
<20 yo	0	1.000	
	1	2.607	
	≥ 2	6.789	
20-24 yo	0	1.244	Reproductive and
	1	2.681	Family History Risk
	≥ 2	5.775	
25-29 yo	0	1.548	2
or nulliparous	1	2.756	
	≥ 2	4.907	
≥ 30 yo	0	1.927	
	1	2.834	
	≥ 2	4.169	

Step 3

To Calculate Current Cummulative Risk Factor, Multiply Risks and Enter in Box 3

	x		x		x		=	
1a		1b		1c		2		3

Current Cumulative Risk

Step 4

Using Current Age of Patient, Identify Cumulative Risk From Box 3 and Find Risk in Last Column

Current Age of Patient	Future Age	Relative Risk From Box 3	Risk of Developing Breast Cancer In Next 10 Years
20 yo	30 yo	1	0.0
		2	0.1%
		5	0.2%
		10	0.5%
		20	1.0%
		30	1.4%
30 yo	40 yo	1	0.5%
		2	0.9%
		5	2.3%
		10	4.4%
		20	8.7%
		30	12.8%
40 yo	50 yo	1	1.2%
		2	2.5%
		5	6.1%
		10	11.8%
		20	22.2%
		30	31.3%

Step 4 (cont.)

Using Current Age of Patient, Identify Cumulative Risk From Box 3 and Find Risk in Last Column

Current Age of Patient	Future Age	Relative Risk From Box 3	Risk of Developing Breast Cancer In Next 10 Years
50 yo	60 yo	1	1.6%
		2	3.1%
		5	7.6%
		10	14.6%
		20	27.1%
		30	37.7%
60 yo	70 yo	1	1.8%
		2	3.6%
		5	8.6%
		10	16.5%
		20	30.1%
		30	41.5%
70 yo	80 yo	1	1.4%
		2	2.7%
		5	6.7%
		10	12.9%
		20	24.1%
		30	33.7%

These tables derived from: Gail, M.H., Brinton, L.A., Byar, D.P., Corle, D.K., Green, S.B., Schairer, C., Mulvhill, J.J. Projecting Individualized Probabilities of Developing Breast Cancer for White Females Who Are Being Examined Annually. JNCI 1989 81: 1879-1886

4. Genetic Risk

Exciting recent developments in molecular biology have revealed the existence of a specific gene responsible for a rare type of hereditary breast cancer: the Breast Cancer gene (BRCA-1). The women at risk for carrying this gene have a striking family history.

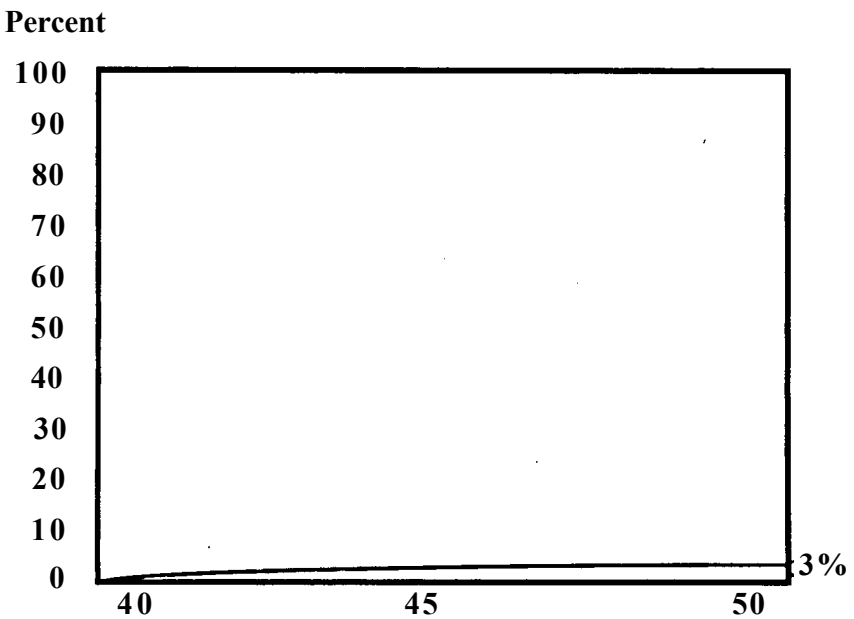
BRCA-1 Patient Profile

- A number of 1st and 2nd degree relatives with breast cancer.
- Most of the breast cancers occurring before age 40.
- Many of the family with bilateral breast cancer.
- Ovarian cancer in family occuring before age 50.

If a woman carries the BRCA-1 gene, she has more than an 85% chance of developing breast cancer by the age of 75. The gene however is rare. Only 1 in 200 women may have it; and it is responsible for only 5% of all breast cancers. Because of the many psychological and ethical issues associated with genetic testing, women who appear to be likely carriers should be referred to high risk breast cancer clinics.

5. Picturing Risk

Sometimes a picture is worth a thousand words. Graphing a risk can put it in perspective in a dramatic and understandable way. This may be particularly helpful when dealing with a patient who feels doomed. Often this is a patient who has only 1 family member with the disease - a mother who died from it. The patient may feel overwhelmed and will typically have greatly overestimated her chances of developing the disease. Graphing the risk should be very reassuring.



Example A 40 year old woman with double the usual risk because of family history. (Refer to Breast Cancer Risk Factors - Table 2. A 40 year old has 1.5% risk (2) = 3% of developing breast cancer in the next 10 years.)

Misdiagnosis Liabilities

Date: _____

Problem-Oriented Clinical Breast Exam

Name: _____ Referring MD: _____ D.O.B. _____
G: _____ P: _____ Menses Onset: _____ Breast Feeding: Y N How long: _____
Premenopausal: _____ Perimenopausal: _____ Post Menopausal: _____ Natural: _____ Surg: _____
Medications taken in past: _____
Current medications: _____
Birth Control Pills: Y N How long? _____ Replacement Therapy: Y N How Long? _____

Previous History

Family Hx of Breast Cancer: Y N Who: _____ Family Hx of Cancer: Y N Type: _____
Mother ❑ Age _____ Sister ❑ Age _____
Personal Hx of Breast Cancer: Y N Type: _____ Personal Hx of Fibrocystic Disease: Y N
Previous Mammogram: Y N Where: _____ When: _____ Findings: _____
Radiation to Breast: Y N Site: _____
Previous Biopsy: Y N Site: _____

Physical Breast Exam

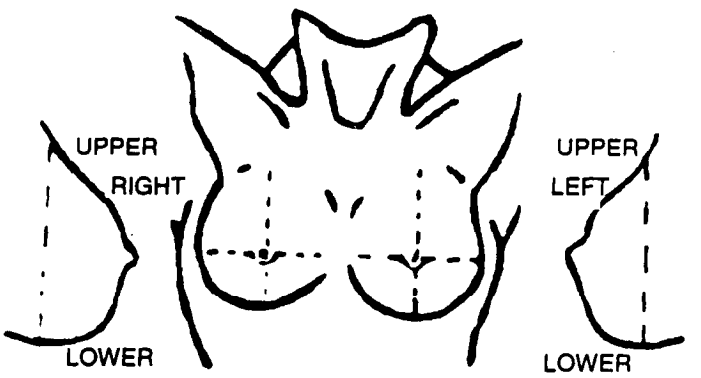
Chief Complaint: _____

Clinical Mass Size: _____ cm

Mass Location:
- ❑ Right Breast
- ❑ Left Breast
- ❑ Sub areolar
- ❑ Other

Multiple: ❑
- ❑ UOQ
- ❑ UIQ
- ❑ LOQ
- ❑ LIQ

Length of time present _____
Charge noted in mass _____
Lying ❑
Sitting ❑
Lump noted in R L side



Associated Findings

Nipple Discharge: Y N
Bloody: Y N
Yellow: Y N

Nipple Retraction: Y N
Nipple Erosion: Y N
Nipple Discoloration: Y N

Lymph Nodes Palpable: Y N
Axillary: Y N
Supraclavicular: Y N
Other: _____

Referrals

Radiology ❑
- ❑ Mammogram
- ❑ Ultrasound
- ❑ Needle Localization

General Surgery ❑

Pathology ❑
- ❑ Needle Biopsy
- ❑ Excision Biopsy
- ❑ Aspiration Cyst
- ❑ Needle Localization

Diagnosis: _____
Evaluation: _____
Next Visit: _____
Comments: _____

Pt. Teaching:
- ❑ SBE
- ❑ Mammogram Guidelines

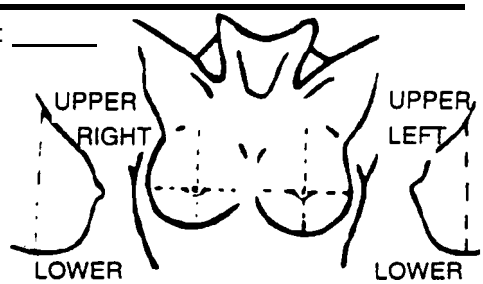
Signature: _____ MD Signature _____ (other)

Follow-Up - First Visit

Date: _____
Findings of Referral: _____
Recommended Rx: _____
Risks, Benefits, Alternatives Discussed: _____

Date: _____
Any change in previous Hx: Y N
Comment: _____

Clinical Mass Size: _____



Mass Location:
- ❑ Right Breast
- ❑ Left Breast
- ❑ Sub areolar
- ❑ Other

Multiple: ❑
- ❑ UOQ
- ❑ UIQ
- ❑ LOQ
- ❑ LIQ

Associated Findings

Nipple Discharge:	Y	N	Nipple Retraction:	Y	N	Lymph Nodes Palpable:	Y N
Bloody:	Y	N	Nipple Erosion:	Y	N	Axillary:	Y N
Yellow:	Y	N	Nipple Discoloration:	Y	N	Supraclavicular:	Y N
						Other: _____	

Referrals

Radiology ❑
- ❑ Mammogram
- ❑ Ultrasound
- ❑ Needle Localization

General Surgery ❑

Pathology ❑
- ❑ Needle Biopsy
- ❑ Excision Biopsy
- ❑ Aspiration Cyst
- ❑ Needle Localization

Diagnosis: _____
Evaluation: _____
Next Visit: _____

Pt. Teaching:
- ❑ SBE
- ❑ Mammogram Guidelines

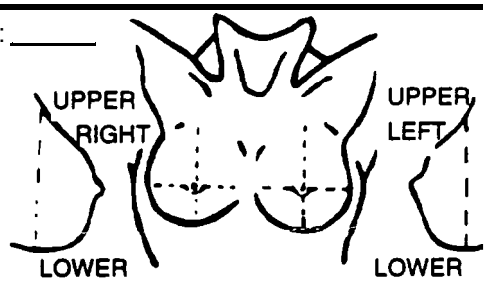
Signature: _____ MD

Signature _____ (other)

Follow-Up - Second Visit

Date: _____
Any change in previous Hx: Y N
Comment: _____

Clinical Mass Size: _____



Mass Location:
- ❑ Right Breast
- ❑ Left Breast
- ❑ Sub areolar
- ❑ Other

Multiple: ❑
- ❑ UOQ
- ❑ UIQ
- ❑ LOQ
- ❑ LIQ

Associated Findings

Nipple Discharge:	Y	N	Nipple Retraction:	Y	N	Lymph Nodes Palpable:	Y N
Bloody:	Y	N	Nipple Erosion:	Y	N	Axillary:	Y N
Yellow:	Y	N	Nipple Discoloration:	Y	N	Supraclavicular:	Y N
						Other: _____	

Referrals

Radiology ❑
- ❑ Mammogram
- ❑ Ultrasound
- ❑ Needle Localization

General Surgery ❑

Pathology ❑
- ❑ Needle Biopsy
- ❑ Excision Biopsy
- ❑ Aspiration Cyst
- ❑ Needle Localization

Diagnosis: _____
Evaluation: _____
Next Visit: _____

Pt. Teaching:
- ❑ SBE
- ❑ Mammogram Guidelines

Signature: _____ MD

Signature _____ (other)

A Statistical Model for Predicting the Outcome in Breast Cancer Malpractice Lawsuits

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Objective: **To analyze specific medical, legal, and cost factors that predict the probability of successfully defending lawsuits filed because of failure to diagnose breast cancer.**

Methods: **Seventy-six malpractice cases handled by the Massachusetts Medical Professional Insurance Association between June 29, 1983 and December 30, 1993 were abstracted and analyzed using univariate analysis, multivariate stepwise logistic and least-squares regression analysis, and the Cox proportional hazards model to identify statistically significant associations between clinical factors and medicolegal outcomes.**

Results: **Obstetrician-gynecologists were defendants in the largest number of cases (38) and incurred the highest total indemnity ($7,629,570). The probability of defending a suit successfully increased with smaller tumor size and younger patients (less than 40 years of age). The failure to perform a biopsy was associated with a decreased probability of successful defense. Variables predicting high case cost included younger patient age, an increased length of delay in diagnosis, and the failure to perform a biopsy. The presence of metastasis at diagnosis was associated with an increased interval from diagnosis to the initiation of a suit.**

Conclusion: **Statistical models that use medicolegal and cost factors can predict both the probability of a successful defense and the total cost of a breast cancer malpractice case.** ***(Obstet Gynecol 1994;84:392-8)***

The National Cancer Institute has reported that the incidence of breast cancer in the United States increased 32% between 1982 and 1987, and it is now the most common malignancy and the leading cause of death for women ages 35-50.[1] At least one of every nine women born in the United States and living to age 85 will develop breast cancer, and of those who do, one in four will die of it. A common public perception is that the cure for breast cancer is simply a matter of early diagnosis. However, Spratt[2] reviewed the limitations of our ability to control breast cancer by early diagnosis and concluded: "Any alleged delay associated with a non-curative outcome leads to a disillusioned patient and a physician being sued, even when alleged delay is not the proximate cause of the outcome."

It is likely that a woman's perception that there was a delay in the diagnosis of her breast cancer is responsible for at least a portion of the successful 'suits against physicians. However, if a medical malpractice action is to be successful, the patient must prove that the physician breached his or her duty to the patient. The legal concept of "breach of duty" can be supported by the failure of the defendant physician to perform a timely and appropriate diagnostic procedure. The medical consequences of the patient's tumor and the degree to which the chances for a normal life-style have been compromised because of the perceived delay in diagnosis often determine the size of the awards to the plaintiff.

This descriptive study focuses on a population of women who brought legal claims because of their perception of medical malpractice. The purpose was to determine whether the medical and legal records of these cases could be used to identify factors that resulted in an increased malpractice risk for the defendant physician. Models were developed that illustrate significant associations within this high-risk population. It is hoped that those profiles that predict an unsuccessful outcome for the defendant physician can lead to useful risk-management strategies.

Materials and Methods

The Massachusetts Medical Professional Insurance Association (formerly the Medical Malpractice Joint Underwriting Association of Massachusetts) provides malpractice coverage for over 70% of all private practitioners of medicine in the state of Massachusetts. (A

From the Department of Obstetrics and Gynecology, University of Massachusetts Medical School, Worcester: the Medical Malpractice Joint Underwriting Association of Massachusetts, Boston; and Keyes and Donnellan, P.C., Springfield, Massachusetts.

majority of the academic institutions are covered by self-insurance trusts.) Between June 29, 1983 and December 30, 1993, there were 76 malpractice cases handled by the Association that included questions about the diagnosis or treatment of breast carcinoma. These cases represent the material for this project.

The medical and legal information available for each case was reviewed and abstracted. In most cases, this. review included detailed history, physical examination, mammography, and pathologic data. Plaintiff and defense presentations were reviewed. To determine "clinical delay of diagnosis," we considered both the delays documented by objective information and those speculated by the plaintiff and defense experts. Case costs were those directly involved with the evaluation and defense of each case.

Logistic regression was used to assess the relation between various clinical factors and successful defense of the suit. Those factors with a suggestion of association were then used in a multivariate logistic regression analysis using a stepwise selection procedure. The multivariate stepwise logistic regression, computing the maximum likelihood estimates of indices of the logistic model, was performed on BMDP statistical software.

Multiple regression analysis was used to identify the clinical factors relevant to predicting the total cost of a suit. This was performed using the REG procedure of SAS (SAS, Inc., Cary; NC), which fit linear regression models by least squares for the factors associated with predicted total cost among those cases lost. Variables potentially affecting the time interval from the diagnosis to the initiation of the suit were evaluated using the PHREG procedure of SAS by analyzing survival data based on the Cox proportional hazards model.

Results

Seventy-six cases were initiated. At the time of cancer detection, the patients ranged in age from 26-59 years, with a mean of 41.4. Nine patients had not been pregnant, and the range of gravity was 0-8. The menstrual status was identified in all 76 cases; 50 patients (65%) were premenopausal, ten (13%) were perimenopausal, and 16 (21%) were postmenopausal. Thirty-one patients (40%) had a family history of breast cancer: 11 had affected first-degree primary relatives (mother or sister), ten had only second-degree relatives (grandmother or aunt), and the family relationship was not known in ten cases. Seven of the 11 with primary relatives also had secondary relatives with a history of breast cancer. A history of "fibrocystic disease" was found in 32 (42%), fibroadenoma in six (8%), and cancer associated with pregnancy in six (8%).

The most common presenting symptom was a painless mass in 35 women (46%). However, 30 (39%) presented with a painful mass and seven (9%) with nipple discharge; eight (10%) were asymptomatic. No association was identified between the presenting symptom and case outcome.

The patient herself discovered the breast lesion in 65 cases (86%). An average of 15.7 months followed this discovery and the diagnosis of cancer. A physician discovered the lesion in only seven (9%) of the cases, and an average of 21.8 months passed before the cancer diagnosis. Two lesions were discovered by the radiologist on a self-referred mammogram, and two lesions were found incidentally while the patient was 'being evaluated for another medical problem.

The sizes of 25 lesions were documented; the average diameter estimated at clinical breast examination was 3.1 cm (range 0.25-7). Cases with diagnostic studies included mammography (42) ultrasonography (nine), needle aspiration (131, and needle biopsy (12). Tests to detect metastasis were performed in a number of cases: bone scan (11) liver scan (six), x-ray of painful bony areas (three), computed tomography scan (three), and brain scans (three). Fifty-three patients underwent excisional biopsy as the initial diagnostic procedure. Forty-six received modified radical mastectomy as either a primary or secondary procedure. As expected, the majority of lesions (60%) were located in the upper, outer breast quadrants. In six patients, the lesions were multicentric in either the ipsilateral or contralateral breast. It was possible to assign a stage of disease to all 76 cases, and advanced disease was found in all (49% stage II, 14% stage III, and 37% stage IV). Twenty-one of the 76 plaintiffs were dead before closure of their case.

The histologic tumor type was documented in 74 cases (97%). Infiltrative ductal carcinoma was found in 62 (84%), intraductal carcinoma in 13 (17%), inflammatory carcinoma in five (7%), lobular carcinoma in situ in three (4%), and Paget disease in one (1%). Multiple primaries were found in 17 of the 74 patients (23%).

Only some charts documented breast cancer screening. Within the charts, a clinical breast examination was recorded in 46 (60%), prior screening mammography in 34 (45%), and patient instruction in breast self-examination in only 12 (16%). Over 40% of the patients had at least one negative mammogram before diagnosis.

In 46 patients (60%), the apparent reason for delay of diagnosis was a negative clinical examination. In all cases, it was possible to estimate this delay. Table 1 presents the mammographic and examination findings in breast cancer cases with alleged delay in diagnosis.

At the time of writing, ten cases remain unresolved and 66 have been closed (litigation completed). Fourteen closed between 1985 and 1988 and 52 closed

Table 1. Mammographic and Examination Findings in 76 Breast Cancer Cases*

Mammogram	*N*	Physician	*N*
Negative	31	Negative examination	46
Test not ordered	17	Failure to biopsy	29
Failure to react to suspicious results	9	Failure to react to patient-identified mass	13
Suspicious report filed without physician review	5	Record-keeping errors	12
Technically defective study	3	Failure to provide follow-up instructions	10
Misinterpretation	2	Delayed consultation	8
		Inadequate physician-to-physician communication	4

*Some cases had more than one reason for delay in diagnosis, and others had none.

Table 3. Indemnity on Closed Breast Cancer Cases*

Specialty	No. of cases without indemnity	Cases with indemnity		
		No. of cases	Indemnity†	Indemnity total
Obstetrics-gynecology	20	18	$423,865 ($18,000-900,000)	$7,629,570
General surgery	7	16	$349,640 ($18,000-1,500,000)	$5,594,240
Internal medicine	5	2	$722,500 (695,000-750,000)	$1,455,000
Family practice	3	4	$301,375 (150.000-530,500)	$1,205,500
Radiology	6	2	$557,500 (413,000-700,000)	$1,115,000
Total	27	39	$435,623 (12,500-1,500,000)	$16,989,310

*Some cases had more than one specialty included in the suit.
†Mean (range).

between 1989 and 1993. Seventeen cases were tried in court, and only two of the verdicts favored the plaintiffs. Thirty-seven cases were settled with indemnity, five were closed without payment, and in seven cases no formal claim was made.

Table 2 lists the case expenses for the closed cases. As expected, the highest costs were associated with verdicts for the plaintiff. The cases closed with indemnity payment ("settled out of court") were approximately one-third as expensive per individual case, but resulted in a larger total payment because of the larger number of cases. The average indemnity by 5-year age intervals demonstrated that the highest payout was in the 40-54-year age group.

Table 3 shows the indemnity payments on the closed cases grouped by physician specialty. The total liability for all cases closed was $16,989,310. The awards for individual cases ranged from $18,000-$1.5 million. Obstetrician-gynecologists were involved in the highest number of cases (38) and had the highest total indemnity ($7,629,570).

Stepwise logistic regression analysis was performed on the 66 closed cases in an attempt to relate the probability of defending a case successfully (defense verdict) to a series of variables that were found to be associated by univariate analysis. The resulting model predicts the probability of successful defense as follows:

Log odds = LN (Pwin/1 - Pwin);

Log odds = 2.224 - 1.198 age - 1.103 no biopsy

- 0.8151 tumor size;

Probability of successful defense = Exp (log odds)/1

+ exp (log odds).

The variables in the multivariate model (P = .049) were patient age, tumor size, and the failure to perform a

Table 2. Expenses for 66 Closed Breast Cancer Cases

	No. of cases	Indemnity	Expenses	Total expenses
Verdict: plaintiff	2	$1,112,635 (725,270-1,500,000)	$93,448 (91,004-95,892)	$1,206,083 (821,163-1,591,004)
Settled with indemnity	37	$388,370 (18,000-1,200,000)	$29,387 (450-119,914)	$417,754 (18,450-1,311,011)
Verdict: defense	15	0	$44,989 (533-89,728)	$44,989 (553-89,728)
Settled without indemnity	5	0	$12,228 (0-31,964)	$12,228 (0-31,964)
No formal claim	7	0	$14,696 (0-50,166)	$14,696 (0-50,166)

Data are presented as mean (range).

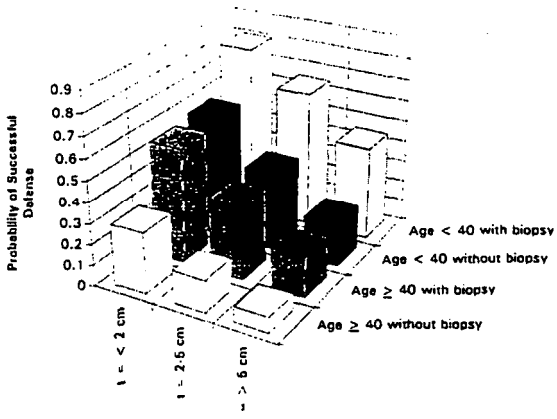

Figure 1. Predicted probability of successful defense based on stepwise logistic regression analysis of the 66 closed cases. T = tumor.

biopsy. Figure 1 illustrates the significant variables associated with the probability of successful defense of the suit. Small tumor size and younger patient age (less than 40) appear to be significantly related to the successful defense of cases. The failure to perform a biopsy made cases less defensible. A "family history" of breast cancer, patient death before closure of the case, "benign" fibrocystic breast disease, documentation of breast self-examination, the presence of metastasis or positive nodes, and time from diagnosis to initiation of the suit were also entered into the stepwise selection procedure but failed to enter from the final model because of lack of statistical significance.

Predictors of total cost of the suit were identified by regression analysis performed on the 39 lost cases. Univariate regression found the following factors to be sufficiently associated to warrant inclusion in the stepwise procedure: the failure to biopsy, patient age, length of delay, and documentation of breast self-examination. After performing stepwise selection, we included patient age, length of delay, and the failure to perform biopsy in the final model ($P = .0174$, $R^2 = 0.25$). The predicted total cost was calculated as follows:

$$\text{Total cost} = 694{,}584 + 368\ \text{delay} + 181{,}657\ \text{no biopsy} - 10{,}670\ \text{age}.$$

The model is illustrated in Figure 2. As women with breast cancer aged, the predicted total cost per case diminished, with other factors in the model being constant. Similarly, the predicted total cost per case increased as the delay in diagnosis lengthened or a failure to biopsy occurred, with other factors held constant.

The additional variable of documentation of breast self-examination tended to be associated with an increased predicted total cost ($P = .0724$) but was not allowed to enter the selection process. Only five of the lost cases contained such documentation. Review of these five cases showed that each was associated with young age and palpable lesions, and a biopsy had not been performed in four of the five. It appears that documentation of breast self-examination appears only in such records, but is not routinely documented in the other charts. Such documentation appears not to be a

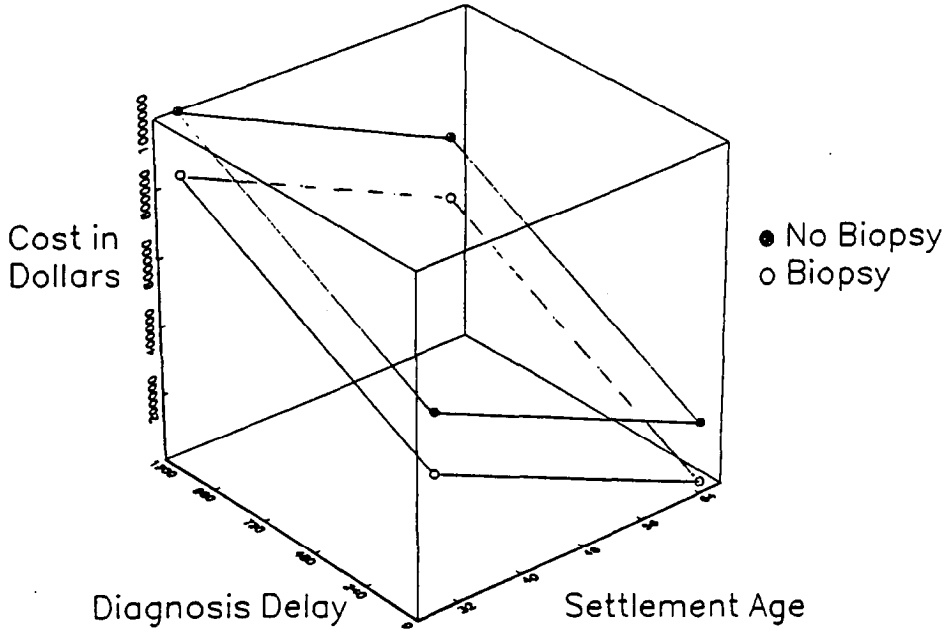

Figure 2. Predicted total cost of suits in the 39 closed cases based on stepwise logistic regression analysis of patient's age, failure to perform a biopsy, and length of delay in diagnosis.

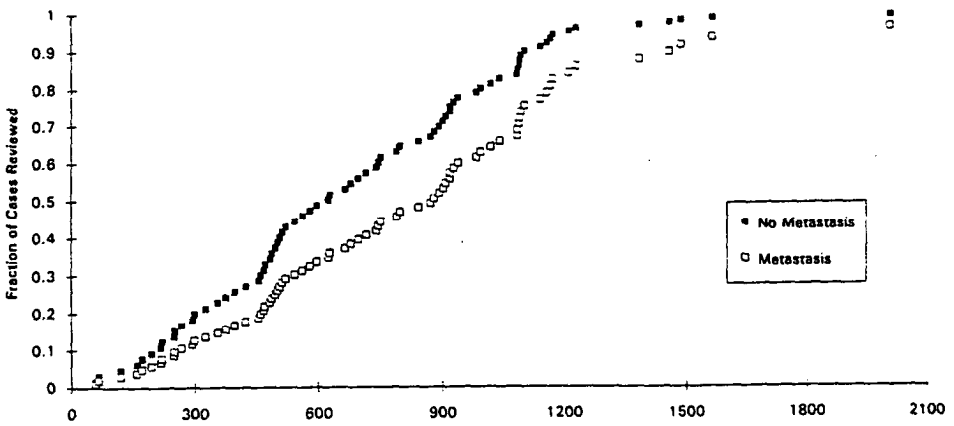

Figure 3. Effect of the presence of metastasis on the time involved (in days) from the diagnosis to initiation of a lawsuit for the 76 breast cancer cases.

substitute for biopsy of palpable lesions, especially in younger women. A family history of breast cancer, "benign" fibrocystic breast disease, the presence of nodes or metastasis, tumor size, patient death before closure of the suit, interval from diagnosis to initiation of the suit, and interval from initiation of the suit to closure of the case were all entered into the stepwise selection process but failed to enter the final model because of lack of significance.

The variable of age at loss (time at which the cancer should have been diagnosed) and biopsy diagnosis, history of "benign" fibrocystic disease, family history of breast cancer, documentation of breast self-examination, tumor size, failure to biopsy, presence of nodes and metastasis, and time from loss to diagnosis (delay) were all evaluated by analysis of survival data using the Cox proportional hazards model relating to the interval from diagnosis to initiation of the suit. Using stepwise regression analysis, the presence of metastasis (P = .0454) was found to be associated with an increased interval from diagnosis to initiation of the suit. The other clinical indices were allowed to enter the analysis, but none remained in the model because of lack of statistical significance. The model is illustrated in Figure 3. Patients tended to initiate a suit more slowly if they had metastasis at the time of diagnosis.

Discussion

Attorneys commonly believe that one of the major risks in defending a physician successfully against an allegation of failing to diagnose breast cancer in a timely manner is the public's perception of the significance of any delay in the diagnosis.[3] The American Cancer Society consistently tells the public that earlier detection increases the likelihood of a complete cure.[4] However, medical evidence does not wholly support this premise for breast cancer. Fisher et al[5] concluded as early as 1977 that the designation of "early" with regard to the diagnosis of breast cancer may be fallacious in some cases.

The past decade has seen ever-increasing emphasis on the early detection and treatment of breast cancer in the United States. Massachusetts was the first state to declare publicly a breast cancer epidemic, according to a recent Forum article.[6] This same decade has also seen an increase in the number of lawsuits filed for delay in diagnosing breast cancer.[2] In 1990, the Physician Insurer's Association of America[7] reported that an 'alleged delay in breast cancer diagnosis is the single most expensive and second most common cause of medical malpractice litigation in the United States, accounting for 27% of all cancer-related claims at an average cost of $210,000 per claim (273 cases totaling $60.5 million). This suggests a need for careful scrutiny of the associated medicolegal risk factors and deliberate incorporation of risk-management principles into the practice of clinical medicine.

In medical malpractice law, to be held liable, the physician must breach a duty owed to a patient, and that breach must be the proximate cause of the patient's injury. The physician must exercise the same degree of skill and care as is exercised by the average qualified practitioner. Consequently, as Brenner[8] pointed out in reviewing the fundamentals of negligence law; "duty" is a dynamic concept dependent upon the goals, circumstances, and nature of a given practice. As an example, the decision of an imaging facility to accept a self-referred patient imputes a duty not only to provide imaging services but also to evaluate the patient clinically.[8]

Previously in medical malpractice law, the appropriate physical examination has been predicated upon a community standard. However, as Brenner[8] recog-

nized, the evolving trend in the majority of jurisdictions is toward a national standard, which does not distinguish between primary care physicians and specialists. For example, evaluation of a suspicious mammogram-detected lesion may require fine-needle aspiration, open biopsy, or both. If the primary care physician does not perform these procedures, he or she is responsible for making a timely referral to an appropriate specialist.

Kern[9] and others[10,11] have analyzed the reasons for and clinical impact of a delay in the diagnosis of breast cancer. However, Kern's analysis included only those cases that were actually tied in the federal and state court systems. He did not include settled cases. Kern was unable to demonstrate a correlation between the length of delay in diagnosis and the staging or tumor size. Dennis et al[12] failed to show a correlation between diagnostic delay and recurrence or survival rate in patients with breast cancer.

More recently, Mitnick et al[13] reviewed 34 cases from New York state between 1985-1991 and found purported delay in the diagnosis of younger patients to be a common reason for indemnity suit. This was based on the emphasis on early diagnosis and the belief that delay in diagnosis would change the chance of survival. The highest awards listed by Mitnick et al were given to younger patients, and the most frequent specialists were obstetrician-gynecologists.

Using multivariate regression analysis to determine the probability of defending a breast cancer case successfully and to predict its cost, we produced models that illustrate factors associated with failure. For example, Figure 1 shows the importance of the patient's age, tumor size, and the failure to biopsy as they relate to the probability of winning a suit. From the model, younger patients with small tumors are relatively defensible, but cases are generally lost if the patients are beyond 40 years of age, the tumor size is 2 cm, or the Physician failed to perform a biopsy. Longer delay of diagnosis, younger patients, and the failure to biopsy lead to a significant increase in total costs among those cases lost (Figure 2). In addition, the presence of metastasis at diagnosis in this select population appears to delay suit initiation, as seen in Figure 3. The presence of metastasis may reflect patients who are very ill or who die before closure of their case.

To provide optimal medical care, as well as to decrease the potential for an adverse legal outcome, it is incumbent on physicians, especially obstetrician-gynecologists, to diagnose breast cancer as early as clinically possible. Although the premise that early detection improves breast cancer cure remains controversial, a delay in either detection or treatment will likely be viewed as inappropriate by the patient and the legal system. This "loss of chance" permits compensation to the plaintiff in many jurisdictions if, in the court's opinion, the physician's negligence significantly reduces the chance of survivability or the patient's life expectancy.

It is essential that physicians respond to patients with breast lesions. The likelihood of a lawsuit increases significantly if the patient has discovered a lesion but the physician delays the diagnosis. The clinician must provide those examinations and tests that can, with a high degree of certainty, distinguish a likely benign lesion from a malignancy. The physician also must understand the limitation of mammography as a reliable diagnostic tool. Although an effective screening measure to assist in early detection, mammography does not always provide a precise characterization or diagnosis of a palpable mass. Therefore, in patients with a mass and a high risk for breast cancer, strong consideration should be given to biopsy or excision. When an increased risk is not present and clinical evidence with or without a mammogram supports the diagnosis of a benign lesion, the physician should institute an appropriate mechanism for follow-up evaluations and provide patient education. Recent changes by the National Cancer Institute delaying screening mammography to age 50 may have increased medicolegal liability over that which may have resulted from an earlier diagnosis.

A risk-management strategy is evolving that includes an integrated multidisciplinary approach to patients and addresses their fears and concerns. This approach should ensure a thorough, timely, and well-documented evaluation. Such a strategy in association with modified appraisal of legal negligence, should improve the medicolegal climate for the practicing physician involved in the diagnosis and treatment of breast cancer.

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Fine Needle Aspiration

Writing about the results of their method, Martin and Ellis[35] stated, "During our earlier experience, we were able to secure tissue by aspiration in about 80 per cent. Of the cases attempted, the failures usually being in the harder fibrous tumors. With more experience and by more careful attention to the technique of aspiration, we practically always secure tissue. Where tissue was obtained, we have been able to distinguish between its malignant and benign nature in all cases. . . ." Of the 6 tumors of the breast they reported, 5 were carcinoma (confirmed by open biopsy) and 1 was a sarcoma.

The fine needle aspiration cytology experience at Memorial Hospital, New York, was summarized by Goodwin in 1956.[39] About 2500 aspirations of all types were performed annually by the technique originally described by Martin.[35] Goodwin described the procedure as time saving, efficient, relatively painless, safe, and inexpensive. It was noted that experience and a sufficient number of cases were necessary for highly reliable results and functional efficiency of both the clinician and the pathologist. With a definite cytologic diagnosis of cancer of the breast, the author advised proceeding with definitive surgery ". . .thereby obviating a local excision, lengthened anesthesia time, and redraping." However, a cytologic report of atypical cells required a frozen section histologic diagnosis. In a five-year period there were 1579 breast cancers of which 806 had aspirations performed by experienced residents with a diagnostic accuracy of 90%. The other smears were inadequate for cytologic diagnosis. In 7_73 aspirations done on women with cancer of the breast by less experienced residents, the diagnostic accuracy was 80%. False-positives were "nearly nil."

In 1973 Hajdu[40] reported a two-year experience at Memorial Hospital for Cancer and Allied Diseases, New York, covering 996 aspirations of eight body sites. Forty-six percent were fine needle aspiration cytologies of solid breast masses, 83% of which were cancer by definitive fine needle aspiration cytology or open biopsy histology. [This very high percentage of cancer probably represented the selected patient population referred to Memorial Hospital.] The technique for fine needle aspiration cytology was essentially the same as described by Martin.[35] Sixty-nine percent of the fine needle aspiration cytologies of the breast were positive for cancer. The sensitivity was 83%. However, Hajdu reported, "For simplicity, aspiration smears which were originally diagnosed as suspicious, atypical, or unsatisfactory are reclassified in this study as negative." There were no false-positives for cancer of the breast. For cancers of all types and sites, fine needle aspiration cytology was 16% inadequate ("too scanty") for cytologic diagnosis. All patients with breast cancer diagnosed by fine needle aspiration cytology had subsequent mastectomies without open biopsy or frozen section.

In 1983, while on the cytology service at Memorial Sloan-Kettering Cancer Center, New York, Bell[41] reviewed 1680 aspiration cytologies of palpable breast masses obtained in office practice from 1977 to 1981. The accuracy of fine needle aspiration cytology was 87% for cancer of the breast. She states that "Aspiration cytology is accurate, rapid and of value in the assessment and management of patients in office practice. Aspiration of minimally suspicious lesions often is helpful in initiating excisional biopsy in some occult, clinically unrecognized breast cancers."

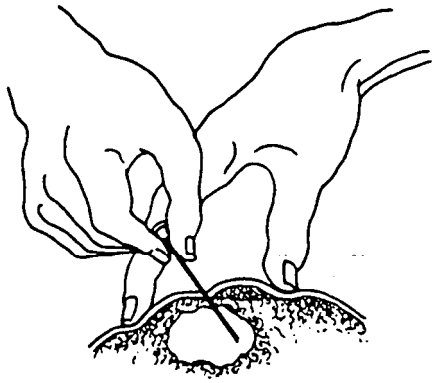
Interest in fine needle aspiration cytology spread to Europe where its recorded history dates back to 1919.[42] Thin needles were utilized in 1931.[43] Subsequently, fine 'needle aspiration cytology was extended to virtually every tumor site which could be reached with a needle. Results of large series were reported. In 1954, Dr. Cardozo, a hematologist, published a book on fine needle aspiration cytology."

The Radiumhemmet in Stockholm became a leading center for fine needle aspiration cytology. In the late 1940s, Franzen at the Karolinska Institute developed a single hand glass syringe holder. Franzen, a radiotherapist-oncologist, was followed in this work with fine needle aspiration cytology by Josef Zajicek[2] and later by Esposti, Loewhagen, and Willems in Stockholm. In addition to these authors, working mostly at the Karolinska Institute in Sweden, similar large series of fine needle aspiration cytology were developed in other European centers. Zajdela reported a large series at The Curie Institute in Paris.[9] Recently, Zajdela[45] published the technique of cytologic diagnosis by fine needle sampling without aspiration (see Fig. 8-1).

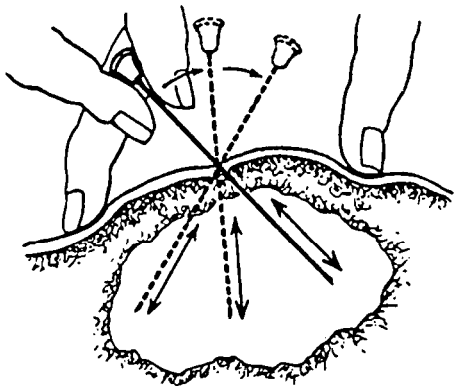
Extensive experience with fine needle aspiration cytology eventually was reported in the United States by Frable,[46] Kline,[47,48] Koss,[49] and others. Articles appeared in the US Ob-Gyn literature by Bibbo[3] and Kline' in 1975, and Hindle[50] in 1983.

TECHNIQUE OF FINE NEEDLE ASPIRATION CYTOLOGY

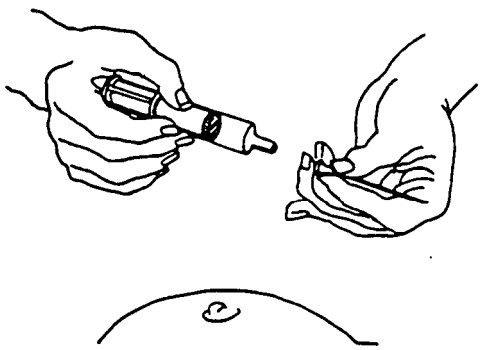
A palpable distinct dominant mass must be present in order to obtain high sensitivity and high specificity in the diagnosis of a benign or malignant lesion of the breast by fine needle aspiration cytology. Though cytologic diagnoses can be obtained from vague indistinct masses, areas of thickening, and clinically indistinct lesions of the breast, the diagnostic cytologic yields are very low. Sampling of a vague mass is an extended indication for fine needle aspiration cytology, and should be reserved for teaching, investiga-



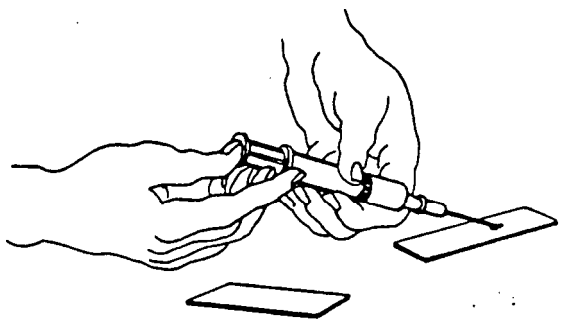
Step 1. The tumor is immobilized with one hand. The fine needle is introduced into the tumor with the other hand.



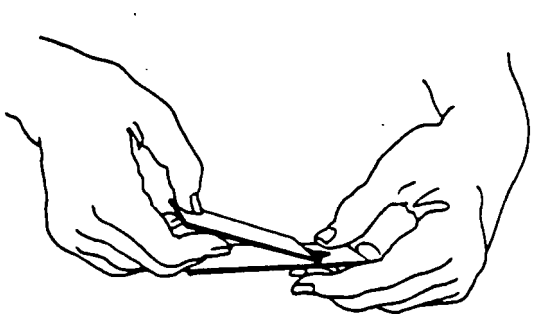
Step 2. The needle is moved back and forth very slightly as it is angled in different depths of the tumor before it is withdrawn.



Step 3. The needle is removed and connected to a syringe filled with air.



Step 4. The cellular material is expelled onto a glass slide.



Step 5. The smear is spread gently with a glass slide inclined at an angle of 10°.

Step 6. The smear is fixed in ethylalcohol Other smears are air dried.

Figure 8-1. Technique of fine needle cytology of a breast mass *without* aspiration *(Zajdela A, Zillhardt P, Voillemot N: Cancer 1987;59:1201. Reproduced by permission).*

tive, and research purposes. In cases of vague lesions of the breast, definitive diagnostic cytology results are rarely obtained, except in high volume centers where the fine needle aspiration cytologies are done by a single physician or a few highly skilled physicians.

The clinical application of the technique of fine needle aspiration cytology of the breast is described in Table 8-1. The skin over the dominant mass is prepared with an antiseptic such as alcohol or povidone-iodine (Betadine). Utilizing either the index and middle finger or thumb and index finger, the mass is stabilized with one hand. The mass should be moved over a rib, if possible. Gloves are not necessary as part of the procedure, but with concern about AIDS many aspirators choose to wear gloves in an effort to protect themselves. If the patient is apprehensive or for other reasons local anesthesia is desired, a small amount (e.g., 0.25 cc) of 1% lidocaine (Xylocaine) can be injected slowly into the skin with a 25-gauge or smaller 5/8" needle forming a small skin weal. Care must be taken not to obscure the outline of the dominant mass. With firm downward pressure on the skin over the mass, the mass is compressed against the rib and stabilized (Fig. 8-2). Utilizing a needle alone, or a needle on a syringe (a three-finger control syringe or a standard syringe), or a pistol syringe holder with a syringe and needle, the needle is sharply introduced through the skin to the level of the dominant mass. The choice of technique and equipment is based on the personal preference of the physician doing the aspiration. In reviewing published articles, it is of interest to note that many radiologists and pathologists utilize pistol syringe holders, whereas many surgeons use standard syringes.

The recently described fine needle cytology without aspiration[43] (Fig. 8-1), by providing direct tactile perception of the fingers on the needle, allows (1) sensitive contact, (2) assessment of the capsule of the mass, and (3) a sense of the consistency of the mass itself. With extensive experience and tactile sensitivity, the aspirator can reliably base a clinical impression on the feel of the needle, particularly in differentiating benign from malignant lesions. This impression is usually confirmed by the cytologic analysis. The sensation of the needle popping into a distinct mass is usually associated with benign lesions. A sensation of rubbery resistance is associated with

TABLE 8-1. TECHNIQUE OF FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Prep the skin with antiseptic.
2. Gloves are NOT necessary.*
3. Stabilize the mass between the fingers of one hand (index and middle fingers or thumb and index fingers).
4. Move the mass over a rib if possible.
5. Compress the mass with downward pressure on the skin.
6. Local anesthesia is NOT necessary (optional).
7. Using the other hand to hold the syringe with needle attached, insert the needle through the skin.
8. Gently insert the needle into the mass.
9. Create suction (negative pressure) in the syringe.
10. Move the needle briskly back and forth within the mass at least ten times.
11. RELEASE ALL THE SUCTION IN THE SYRINGE.
12. Gently withdraw the needle from the mass.
13. Gently withdraw the needle from the skin.
14. Have assistant apply firm pressure with a 2 x 2 gauze on aspiration site for two minutes.
15. Detach the needle.
16. Fill the syringe with air.
17. Reattach the needle.
18. Touch the needle tip at a 45° angle on a cytology slide.
19. Forcibly eject the air in the syringe through the needle.
20. Repeat steps #15-19 (optional).
21. Avoid drying-unless using air-dry technique.
22. Smear the drop of tissue juice on the slide (labeled with patient's name).
23. Place cytology fixative on the slide (or place slide in alcohol fixative).
24. Look for specks of tissue on the slide (repeat aspiration if no tissue fragments are seen).
25. Label the slide container.
26. Send to cytology for reading.
27. Place a bandaid over the skin puncture site, if needed.

*Many aspirators now prefer to wear gloves for their own protection since the increased prevalence of AIDS.

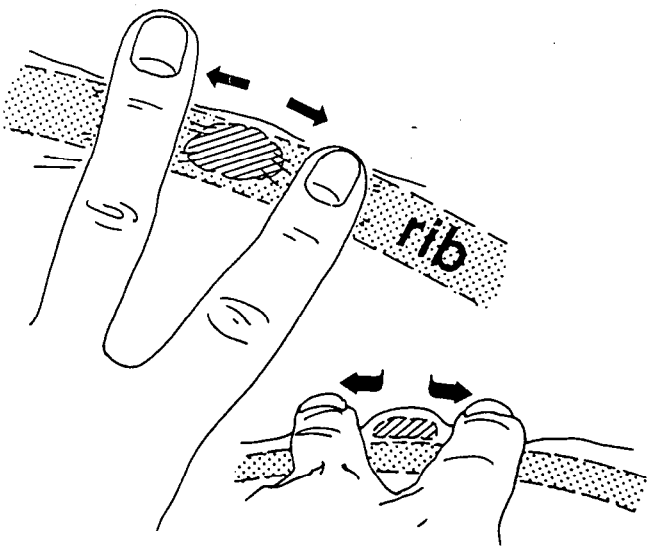


Figure 8-2. Technique of stabilizing a dominant breast mass over a rib with firm downward pressure on the skin using the index and middle fingers. The finger pads should be parallel to the mass which requires bending (flexing) the middle finger.

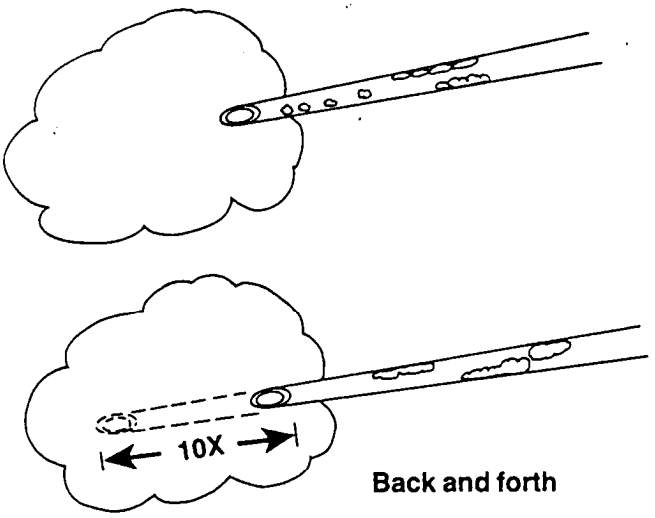


Figure 8-3. Position of the needle in the breast mass with cellular material in the barrel of the needle. At least ten back and forth sharp motions *within the mass* are necessary for an abundant harvest of cellular material.

fibroadenomas. A grating or gritty sensation is associated with malignancies.

Once the needle is within the mass, then (and not before) negative pressure (suction) is created within the syringe by pulling back the plunger. Moving the needle gently side to side when the needle tip is within the mass moves the mass like a toothpick in an olive, confirming the position of the needle tip within the mass. The needle is sharply moved back and forth, to and fro, with short brisk strokes within the mass. The aspiration technique of multiple distinct repeated up and down motions greatly increases the cellular yield. These brisk, short back and forth, to and fro needle strokes within the mass should be done at least 10 times (Fig. 8-3). Some aspirators repeat the short strokes more than 20 times within the mass. *Suction should be completely released before the needle tip is removed from within the dominant mass.* The needle is gently withdrawn from the mass and then gently withdrawn from the breast. The six basic steps of the aspiration technique are illustrated in Figure 8-4.

Hemostasis is important. It is more comfortable and less stressful for the patient and allows fine needle aspiration cytology to be repeated at any time without hematomas. Also, mammograms are more accurate and reliable without hematomas.

To limit hematoma formation and skin bleeding, an assistant can place firm pressure with a 2 **x** 2 gauze or a cotton ball on the aspiration site. If an assistant is not available a cooperative patient can hold the gauze in a similar manner. Patients often do not press firmly enough and frequently are not accurate in pressing on the exact aspiration site. Two minutes of firm pressure will usually completely control the bleeding. When bleeding occurs, it is usually from blood vessels immediately below the skin surface. Aspiration of blood from subcutaneous vessels is minimized by avoiding any suction in the syringe both when the needle enters the breast tissue and when it is removed from the breast. Hematomas and ecchymosis are minimized by an assistant applying precise firm pressure for an adequate time.

Prior to cytologic slide preparation, the needle is detached from the syringe. Air is sucked up into the syringe. The needle is then reattached to the syringe. With the bevel of the needle downward at a 45° angle touching the cytology slide, the air is forceably ejected down through the needle. This syringe detachment from and reattachment to the needle and forceable ejection of air can be repeated until no further. tissue juice comes from the needle. Usually about three drops are obtained and deposited on the slide. The amount of material (tissue juice) obtained varies considerably with the type of lesion being aspirated. The slides should have been previously labeled with the patient's name, the date, and the number of the aspiration if there are multiple aspirations. The slides should then be carefully smeared, utilizing the technique favored by the cytopathologist who will read the smears. Proper smearing techniques are de-

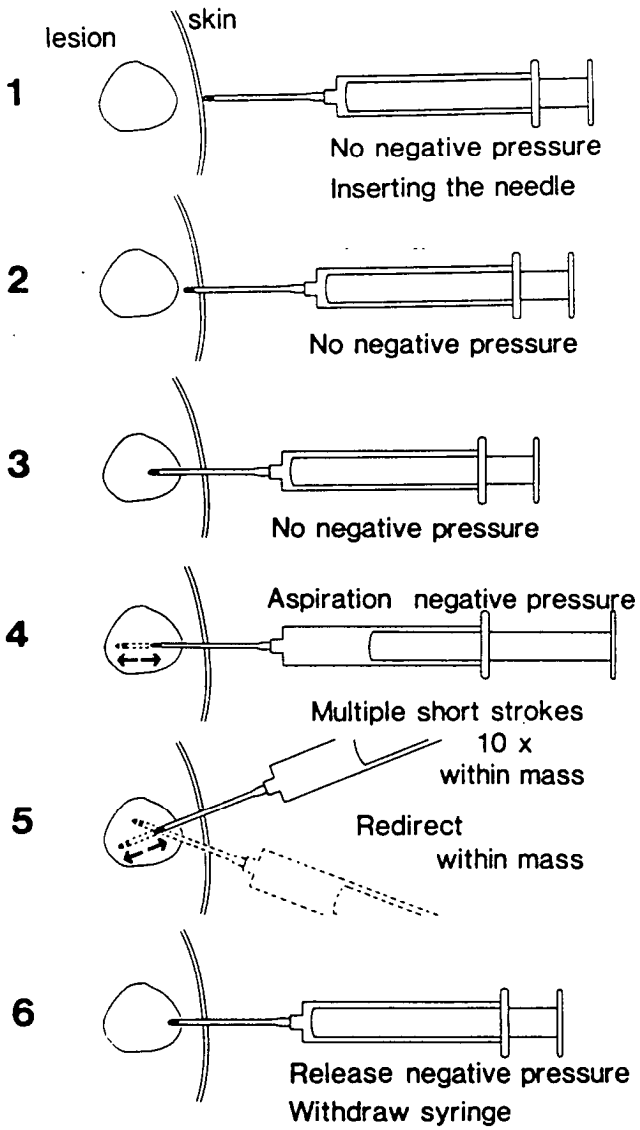


Figure 8-4. Six-step technique of aspiration of a dominant solid breast mass. Negative pressure (suction) in the syringe is only applied while the tip of the needle is within the mass. In step No. 5, to change the angle of the needle in the mass, the needle tip should be withdrawn to the surface of the mass and slightly redirected before repeating short thrusts within the mass.

scribed in detail by Glant in the next chapter and by Abele[51] in his 1985 article.

A fixative such as Carbowax* is then placed on the slide in the same manner as a Pap smear. Alternately, the slide can be placed in alcohol. Care is taken to avoid drying of the tissue juice unless an air-dried cytologic preparation technique is being used.

*Carbowax 4000 (polypropylene glycol), Union Carbide. Solution of 5% Carbowax and 95% reagent alcohol.

After the slide is fixed, careful inspection will usually show specks or fragments of tissue on the slide: If none are present, then a repeat aspiration can be done. With experience, after fixation, a visual impression of benign or malignant tissue can be made. Larger, more numerous specks of tissue are typical of cancer. The slides are then placed in a labeled container identified with the patient's name, site of the aspiration, and date obtained. It is important to smear and fix the slides *before* repeating an aspiration. Speed of technique from aspiration to fixation usually avoids clotting. Fixation should be done immediately after smearing.

If the cell harvest is inadequate, a repeat aspiration can be done. Usually the first aspiration of a mass gives the best cellular material. For lesions less than 1 cm, three aspirations should be the maximum. However, with large lesions such as distinct fibrocystic change over a 3 cm area, multiple aspirations are necessary for representative sampling.

The slides are then sent to cytology for reading. The type of slide preparation, fixation, and staining should have been prearranged and carefully coordinated with the cytopathologist who will do the final reading of the smears.

Finally, if needed, a small bandaid can be placed over the puncture site. The patient should be told there may be ecchymosis formation, which will usually resolve like bruises elsewhere in the skin. Before she leaves the office, the patient should know the specific arrangements for receiving the report of her fine needle aspiration cytology.

The advantages of fine needle aspiration cytology of the breast are summarized in Table 8-2. Fine

TABLE 8-2. ADVANTAGES OF FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Easy and quick for the patient and doctor
2. Efficient procedure
3. Cost effective
4. Rapid results
5. Reliable results
6. Office procedure
7. No special equipment required
8. Readily learned technique by the physician/aspirator
9. No anesthesia necessary
10. Usually no more painful than a venipuncture
11. Takes no more time than a venipuncture
12. Results similar to a Pap smear
13. High patient acceptance
14. Can Quick DIP* stain and check cellular material in exam room
15. Can be repeated immediately or at a later time
16. Can aspirate multiple lesions (each on a separate slide)

*Quick DIP. Mercedes Scientific, 676 Willis Avenue, Albertson, NY 11507

needle aspiration cytology of breast masses is relatively easy and straightforward for both the patient and the gynecologist. It is a very efficient procedure. The results can be obtained rapidly. Fine needle aspiration cytology is dramatically cost effective, even when positive reports are followed by one-step excision biopsies with frozen sections and mastectomies or lumpectomies.

If urgently needed, a cytopathology laboratory report can be obtained within one hour, or if appropriately set up by the cytopathologist, a quick stain such as Quick DIP or Diff Quik* can be read within 30 seconds. However, most cytopathology laboratories report fine needle aspiration cytology slides the following day. Ideally slides should be screened for adequate cellular material for cytologic evaluation while the patient is still in the examining room, so that a repeat aspiration can be done if necessary. Some cytopathologists prefer a fast stain with Toluedene Blue. Subsequently, this stain can be washed off with alcohol and the smear restained with Pap stain.

The results of fine needle aspiration cytology are very reliable with high specificity and high sensitivity of the cytologic diagnoses. False-negative reports are unusual. False-positive reports are rare. Fine needle aspiration cytology is an office or outpatient procedure which requires no special equipment. All the equipment required is generally present in the gynecologist's office. The technique is readily learned but requires proper instruction, appropriate patients, and frequent practice. Ideally, training in the technique of fine needle aspiration cytology should be taken at a referral medical center with a large volume of fine needle aspiration cytology of the breast, and under the direct supervision of a highly skilled physician/aspirator. Text can provide an introduction, but personal instruction and supervision followed by frequent careful practice of the technique is necessary to obtain consistent, reliable results.

No anesthesia is necessary, although a small amount may be useful with apprehensive patients. Fine needle aspiration cytology is usually no more painful or time consuming than a venipuncture. With dense fibrous tissue, especially cancers, the patient may experience pain. However, the entire procedure is of short duration, When patients are told this, they readily accept the procedure. The author has never had a patient refuse the procedure when the advantages were explained. The results of the cytology reports are comparable to Pap smears of the uterine cervix. The cytologic concept is the same, though cervical Pap smears are for screening and fine needle aspiration cytology of the breast is diagnostic. There is now wide patient acceptance of the fine needle aspiration cytology procedure, particularly when the results can be rapidly obtained and a definite cytologic diagnosis established. If for any reason the fine needle aspiration cytology is unsuccessful, it can be repeated immediately, or at a later time. Many physicians/aspirators prefer to do two or more separate aspirations of each mass as standard procedure. Others find a single careful aspiration adequate. In deference to patients who are progressively anxious, after three attempts repeat aspirations should be deferred to a later time if adequate cellular material has not been obtained. If the patient has gross bleeding into the breast tissue during an aspiration, a repeat aspiration should be deferred at least 10 days. Multiple aspirations of the same dominant mass or aspirations of multiple lesions (each on a separate slide appropriately identified) can be done at one sitting.

Complications of fine needle aspiration cytology of the breast are outlined in Table 8-3. Complications with this procedure are infrequent and usually not serious. The most common complication of fine needle aspiration cytology is bleeding, which can produce (1) gross blood in the aspirated specimen making the cellular yield very low, (2) blood at the skin surface requiring pressure for hemostasis, (3) subcutaneous blood with subsequent ecchymosis on hematoma formation. Hematomas generally resolve spontaneously with time. Bleeding can also occur in the deeper tissues with deep hematoma formation. Occasionally there is bleeding within a cyst with gross fresh bloody contamination of the fluid, making clinical and cytological evaluation unreliable. Some cysts are filled with dark old blood which gives a very poor yield of diagnostic cellular material. Hematoma formation within the breast can give false-positive cancer mammographic interpretations.[53-54] Such deep hematomas generally resolve spontaneously

TABLE 8-3. COMPLICATIONS OF FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Bleeding from skin edge
2. Hematoma-ecchymosis
3. Difficulty interpreting mammogram after hematoma
4. Infection–extremely rare
5. Pneumothorax–very rare with proper technique
6. Spread of tumor along needle tract-theoretical
7. No epithelial cells obtained-inadequate for cytologic diagnosis

*Diff-Quik, Harleco, Gibbstown, NJ Note: Dr. S.R. Orell (Flinders Medical Centre, Adelaide, South Australia) recommends: ". . .extend the fixation time in the pale blue fluid to at least one minute …15 seconds in solution 1 (red) and 25 to 30 seconds in Solution 2 (dark blue) . . ."[52]

within a two-week period, after which the accuracy of mammography is restored. If the mammogram cannot be done simultaneously with the fine needle aspiration cytology, the mammogram should be done prior to the fine needle aspiration cytology, or two weeks after the aspiration. The sequence of the diagnostic protocol for the evaluation of breast masses should be worked out with the cooperation and counsel of the mammographer.

Infections secondary to fine needle aspiration cytology are extremely rare. Shabot[32] reported one case of a superficial infection as a complication of the technique of fine needle aspiration cytology and tissue core needle biopsy. Pneumothorax has also occurred with tissue core needle (e.g., Tru-Cut) biopsy of the breast but is exceedingly rare with fine needle aspiration. If the mass to be aspirated can be manipulated to a position over a rib, then the possibility of pneumothorax should be eliminated.

The spread of tumor along the needle tract in the breast is a theoretical consideration with no documented validity.[8-10,55,56] The incidence of local recurrence of cancer and duration of survival are not affected by fine needle aspiration of the breast.[12,13,57]

When no epithelial cells are obtained and the cytology report comes back as "Inadequate for Cytologic Diagnosis," no clinical conclusion can be drawn. *This is not* a *negative report.* A repeat fine needle aspiration cytology or an open biopsy for a histologic diagnosis of the dominant breast mass should be done.

Contraindications to fine needle aspiration cytology of the breast are summarized in Table 8-4. There are no real medical contraindications to fine needle aspiration cytology. If there is not a distinct dominant mass but only a vague suspicious area, the cytologic yield is very low, as would be expected. As a general rule, gynecologists should only attempt fine needle aspiration cytology on dominant distinct breast masses. Extensive skin infection over the lesion with no clear clean window of skin for the aspiration, and far advanced proven metastatic disease, are relative contraindications. With advanced disease, if there is clinical value, fine needle aspiration cytology can be done on any mass or suspicious area. When there is no distinct dominant mass but only vague swelling, a specific cytologic diagnosis is usually not obtained. Clinical vascular tumors should be avoided unless the aspirator is experienced with the special techniques of aspirating vascular tumors. A clinically benign lymph node is a relative contraindication. If there is significant doubt as to the specific diagnosis of a palpable lymph node, fine needle aspiration cytology will usually resolve the doubt with a definite cytologic diagnosis. When clinically applicable, any suspicious or doubtful palpable node should be evaluated by fine needle aspiration cytology. Fine needle aspiration cytology need not be done if the diagnosis is already established.

Investigative and research protocols have extended the application of fine needle aspiration cytology. By using specialized mammography techniques and sophisticated stereotactic devices, nonpalpable lesions of the breast can be sampled by fine needle aspiration cytology. Sonography (ultrasound) directed fine needle aspiration cytology of occult lesions of the breast has been successful, and can be done in centers with enough volume of such lesions to permit the mammography/fine needle aspiration cytology team to gain adequate experience. These techniques are appropriately confined to research centers.

The equipment for fine needle aspiration cytology of the breast is outlined in Table 8-5. All of these materials are usually available in the gynecologist's office. It is convenient to set up a small tray with the antiseptic skin wipe, #22 sterile disposable 1½" needles with clear plastic hubs, syringes of the physician's choice, 2" x 2" gauze (for pressure on the aspiration site after the needle is withdrawn), cytology slides, cytology fixitive, and a small bandaid. The most commonly used needles are 22 and 23 gauge. Large-gauge needles produce more bleeding, more hematoma formation, and are more painful to the patient. The 18-gauge needle is no longer used for fine needle aspiration cytology. For aspirations of very

TABLE 8-4. CONTRAINDICATIONS TO FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. No real medical contraindications
2. No mass or even vaguely suspicious area
3. Florid skin infection over the mass-very rare
4. Far advanced metastatic disease (relative contraindication)
5. Swelling alone with no distinct mass
6. Clinical vascular tumor (relative contraindication)
7. Clinically benign lymph nodes (relative contraindication)
8. Diagnosis already established

TABLE 8-5. EQUIPMENT FOR FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Antiseptic skin wipe
2. #22 disposable 1½" needle *with clear plastic hub*
3. 10 cc syringe of the three finger control type, or a pistol syringe holder and fitted syringe (disposable)
4. 2" x 2" gauze for pressure after the aspiration
5. Cytology slide (frosted end for patient's name/label)
6. Cytology fixative
7. Small bandaid

small or very fibrous masses in the breasts 25-gauge needles are used. Some aspirators prefer 1" needles when the breast mass is not deep. A new needle and syringe should be used for each aspiration. Care must be taken to label the slides accurately and to correlate the site of the aspiration on a diagram of the breast placed in the patient's record.

Table 8-6 lists commercially available pistol grip syringe holders for fine needle aspiration cytology of the breast. The author prefers a 10 cc Multifit Luer-Lok three-finger control syringe which most gynecologists have in their offices. The author uses disposable 22-gauge needles 1½" in length (or longer needles when needed in large breasts with deep masses). Clear plastic needle hubs are very useful in the visual control of fluid or blood during fine needle aspiration cytology.

Zajdela,[45] at the Curie Institute in Paris, has published *Cytological Diagnosis by Fine Needle Sampling Without Aspiration* (Fig. 8-1). The results of this technique without aspiration were comparable to fine needle aspiration cytology.

The two major staining techniques used for fine needle aspiration cytology of the breast are summarized in Table 8-7. The wet fixed technique, which is identical to the technique used for Pap smears of the uterine cervix, is the most commonly used staining technique. The Pap stain gives clear nuclear detail, which is essential for evaluation of malignancy, but is relatively poor for cytoplasmic detail. The coloring is very similar in Pap cytology and in H&E histologic material and is familiar to gynecologists. The Pap stain can highlight early cancer changes in the nuclei of the aspirated cells.

Wright-Giemsa air-dried staining technique emphasizes metachromasia, cell size cytoplasmic features, and background material. The Wright-Giemsa stain shows cell variety which is particularly useful for large numbers of cells (e.g., cells in sheets or clumps). The air-dried technique such as with Wright-Giemsa stain retains more cells on the slide than immersion fixation does.

A separate slide can be prepared and stained by the Quick DIP staining method and checked for adequate cellular material within 30 to 60 seconds. Quick DIP does not give the detail of the nucleus as does the Pap stain or the cytoplasmic detail of the Wright-Giemsa stain. It can be methanol washed and restained.

The exact staining technique of the slides is the prerogative of the cytopathologist. A conference with the cytopathologist should be held to discuss, in detail, the smearing techniques, fixation methods, and slide preparations before doing any fine needle aspiration cytology. During the early learning phase of fine needle aspiration cytology, the gynecologist should review all of the slides with the cytopathologist so that both are in accord and the gynecologist can vividly see the results of the aspiration and smearing techniques. With practice, abundant cellular material should be obtained and a consistent high quality of cytologic material preserved on the slides with each aspiration.

The pitfalls to reliable results from fine needle aspiration cytology of the breast are outlined in Table 8-8. When no palpable mass or a vague mass is being

TABLE 8-6. SYRINGE HOLDERS AND NEEDLES AVAILABLE FOR FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

Syringe Holders-Pistol Type	
Aspiration Biopsy Syringe Gun	INRAD A Division of DLP, Inc. 620 Watson S.W. Grand Rapids, MI 49501
Aspir-Gun	The Everest Co, Inc 5 Sherman Street Linden, NJ 07036
Cameco Syringe Pistol	Precision Dynamics Corp. 13800 Delson Street San Fernando, CA 9 1340
R-H Reusable Syringe Holder	R-H Medical Products 11504 College View Drive Silver Spring MD 20902
Control Syringe	
Three finger control Multifit Luer-Lok syringe	Becton-Dickinson Division of Becton Dickinson & Company Rutherford, NJ 07070
Needles	
Disposable needles with clear plastic hubs	Scientific Products 1430 Waukegan Road McGraw Park, IL 60085

TABLE 8-7. FEATURES OF STAINING TECHNIQUES FOR FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

Papanicolaou–immersion wet fixed technique*
1. Clear nuclear detail
2. Limited cytoplasmic information
3. Similar information as acquired with H&E stain
Wright-Giemsa–air-dried technique
1. Metachromasia – gives additional information about cytoplasm and extracellular products
2. Retains more cells than immersion wet fixed technique

*Spray fixation can be used if an assistant is present to spray the slides immediately. However, even a short delay in the use of spray fixation can cause drying artifact especially with benign cells.

TABLE 8-8. PITFALLS TO RELIABLE RESULTS FROM FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. No mass
2. Vague mass
3. Gross blood into syringe
4. Scant cellularity in mass
5. Drying of aspirate after smearing (when not using air-dry technique)
6. Gross fluid in syringe (relative pitfall)
7. Scant or inadequate material on the slide
8. Aspirated material clotting before smearing

evaluated, the cytologic yield is low. Occasionally, a cytologic diagnosis of a vague mass can be made which does aid in the clinical management. Even when physical examination fails to find a distinct lesion in the suspected area, surgical consultation and open biopsy are indicated if there is clinical suspicion of cancer.

Masses with scant cellularity give a low yield of cytologic material. This is more common in benign lesions than in malignant lesions of the breast. When not using air-dry technique, delayed application of cytologic fixative to the slide after smearing results in marked distortion of the cells and difficulty in interpretation. Gross fluid or blood in the syringe dilutes the tissue juice specimen with resultant low cellular yield, which when smeared, often results in reports of inadequate for cytologic diagnosis. If there is a residual mass, a repeat fine needle aspiration cytology can be done from a different angle, in an attempt to avoid fluid or blood. If there is gross hematoma formation, up to two weeks is required for the absorption of the hematoma. A repeat fine needle aspiration cytology should be deferred until the hematoma is absorbed.

When there is gross fluid (not blood) in the syringe from a cyst, it can be spun down and smeared, or a cell button made if there is adequate cellular material. Other extraction/concentration techniques can be used on gross bloody fluid, but the incidence and reliability of a definite cytologic diagnosis are low.'

After the cytologic fixative has been applied to the slide, the slide should be inspected for tissue specks or fragments which indicate clumps of cells from the mass. These clumps are usually abundant in aspirations of cancer of the breast. If there is scant or inadequate material on the slide, a repeat fine needle aspiration cytology should be done. Aspirated material that clots before smearing traps and distorts the cells. It is important to smear the material quickly before it clots. Speed is particularly important when smearing bloody aspirates.

To be clinically useful, the cytologic reports of fine needle aspiration cytology must be reliable and consistent. Difficulties with cytology reports are listed in Table 8-9. False-positive fine needle aspiration cytology reports must be avoided. Strict adherence to cytologic criteria for malignancy is critical. If there is any doubt about the cytologic diagnosis of cancer, that specific diagnosis should not be made in the report. In a large series of fine needle aspiration cytologies of the breast, the incidence of false-positive reports should ideally be less than 1:1000 cancers. In smaller series, the incidence of false-positive reports should ideally be less than 1:1000 of all aspirations.

With cancer of the breast, there is usually abundant cellular material obtained by fine needle aspiration cytology. The cells are usually uniformly malignant and not mixed (benign and malignant) except in carcinoma in situ. Most cytology laboratories report fine needle aspiration cytology of carcinoma in situ as "suspicious" or otherwise qualified.

False-negative reports should be less than 5% of breast cancers diagnosed by fine needle aspiration cytology. Reviews of false-negative reports usually show more than 90% due to insufficient cells on the slides. This is primarily due to faulty aspiration technique, such as misplacement of the tip of the needle (not directly in the mass being evaluated), or inadequate up and down, brisk to and fro multiple needle strokes within the mass. Such faulty aspiration technique is often associated with smal1 palpable tumors. When there are too few cells present and the cytologic diagnosis is doubtful, no specific cytologic diagnosis should be reported.

"Inadequate for cytologic diagnosis," "no epithelial cells seen," and similar descriptions are appro-

TABLE 8-9. DIFFICULTIES WITH FINE NEEDLE ASPIRATION OF THE BREAST CYTOLOGY REPORTS

1. False-Positive-rare
   - Should be less than 0.1% of cancers diagnosed
   - Usually associated with attempted diagnosis on too few cells
2. False-Negative
   - Should be less than 5% of cancers diagnosed
   - Usually associated with too few cells
   - 90% due to faulty technique of aspiration
3. Inadequate for Cytologic Diagnosis
   - Too few cells
   - Should be less than 5% of aspirations of solid masses
   - May be as high as 25% with multiple aspirators
   - Usually associated with faulty technique of aspiration
   - High percentage often related to inexperienced aspirators
4. Abnormal, Atypical. Borderline, Suspicious
   - Should be evaluated the same as Positive.
   - Definitive diagnosis must be established-usually by open biopsy and histologic diagnosis

priate reports when there is insufficient cellular material on the slides for specific cytologic diagnoses. Such reports are fairly common when physicians are beginning fine needle aspiration cytology, particularly if there are multiple aspirators with a limited volume of cases. Though early series often report that as many as 25% of the smears have inadequate cellular material, with practice and a sufficient volume of cases the incidence of inadequate smears should be less than 5% of all aspirations of solid masses of the breast.

To re-emphasize, inadequate cellular smears are usually related to faulty technique of fine needle aspiration cytology. The needle tip must be in the mass and multiple (at least 10) brisk up and down, to and fro, strokes made within the mass. The mass must be stabilized and not allowed to move during the aspiration. Some very fibrous lesions of the breast have few epithelial cells present and may require repeated aspirations for definitive cytologic diagnoses. Elderly women with little glandular breast tissue may show only fat in their breast aspirations if there is not a definite dominant mass.

Any fine needle aspiration cytology report which does not give a specific diagnosis must be further evaluated and closely followed until a definitive diagnosis is made. Reports such as "abnormal," "atypical," "borderline," or "suspicious" should be evaluated and followed in the same manner as positive reports. All reports with any suggestion of malignancies must be presumed to be cancers until definite histologic diagnoses prove otherwise, usually by open biopsies.

Table 8-10 lists the difficulties of aspiration technique in fine needle aspiration cytology of the breast. The patient must be properly positioned so that the dominant mass in the breast can be easily palpated and stabilized for fine needle aspiration cytology. The patient must also be prepared not to move suddenly' or shift position during the aspiration. If the mass is not properly fixed in position between the fingers, with the aspirator utilizing either the index and middle finger or the thumb and index finger, the mass may slide around during the aspiration with resultant poor cellular yield. The tip of the needle may even become positioned outside the mass, thereby sampling an inappropriate area. Marked fibrocystic change of the breast in the surrounding area can lead to inappropriate positioning of the tip of the needle. If the needle tip is outside the mass, the tip must be repositioned within the mass or the aspiration discontinued.

TABLE 8-10. DIFFICULTIES OF ASPIRATION TECHNIQUE IN FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Patient not properly positioned for palpitation
2. Mass not fixed in position between fingers
3. Mass too small (less than 1 cm)
4. Mass too deep
5. Needle tip in adjacent area to the mass
6. Movement of the mass during aspiration (especially small masses)
7. Too few passes of needle within the mass

Breast masses of less than 1 cm are difficult to palpate. With such small masses in the breast, it is difficult to position the needle properly for adequate cellular sampling. However, if a definite small mass can be palpated, it can be aspirated. Particularly in large, pendulous breasts, the mass may be too deep to penetrate, even with an extended-length needle. Such deep masses are usually difficult to palpate. Even in a large breast with a deep lesion, if a definite mass can be palpated and stabilized, it can be aspirated. In those institutions that are set up to use the technique, sonography can be useful in the placement of the tip of the needle for fine needle aspiration cytology of a mass deep in the breast. This sonography technique requires considerable experience and patience.

After aspirating a cyst of the breast, the aspirator should *always* palpate for a residual mass, an adjacent mass, or a mass previously hidden by the cyst. Repeat fine needle aspiration cytology should be done on all such masses. A definitive cytologic or histologic (by open biopsy) diagnosis *must be established for any persistent residual mass.*

In the past, dull needle tips and inferior needle quality were significant problems in fine needle aspiration cytology and resulted in poor cellular yields. The current disposable needles have eliminated these problems. A needle should *never* be reused for fine needle aspiration cytology. Needles made with opaque hubs (that attach to the syringes) are of limited value in fine needle aspiration cytology. These impair visual control of blood or fluid rising in the bore of the needle up into the hub during the aspiration. Gross fluid or blood in the syringe dilutes the cellular material to such a degree that cytologic evaluation is usually nonproductive. When gross fluid or blood is in the hub of the needle or in the syringe, that particular attempt at fine needle aspiration cytology of a solid breast mass should be discontinued. A repeat aspiration should be done at a new site in the skin, utilizing a new needle and syringe and a different angle through the tissue into the dominant mass.

Gross swelling around the breast mass makes the mass indistinct and difficult to localize, and thus a poor target for fine needle aspiration cytology.

Lack of multiple (at least 10) passes often yields a paucity of cells for evaluation. The movement of the needle tip with repeated brisk short strokes to and

fro, back and forth *within the mass* is the best technique for obtaining an abundant cellular specimen for cytologic diagnosis.

Table 8-11 summarizes the difficulties of syringe/negative pressure technique with fine needle aspiration cytology of the breast. Techniques of fine needle cytology *without* aspiration have been developed using no syringe[45] (see Fig. 8-1). Even using the standard fine needle aspiration cytology technique *without any negative pressure* (suction), a moderate amount of cellular material can be obtained and a definite cytologic diagnosis can be made. Application of negative pressure will "suck up" gross fluid or blood when the tip of the needle at any time is located outside the mass being aspirated. Negative pressure applied before or after the tip of the needle is *in* the mass contaminates the specimen with other debris and cellular material and makes an accurate cytologic diagnosis of the mass less likely. It is difficult to harvest cellular material that is drawn up into the syringe. Some aspirators prefer a standard syringe to the Luer-Lok syringe because detaching and reattaching the needle takes less time with the standard type. Delay in emptying the needle causes drying of the cellular material in the bore of the needle. Sometimes Luer-Lok syringes can also trap cellular material.

During the aspiration technique, the needle must be securely attached to the syringe in order to establish negative pressure within the syringe when the needle tip is in the breast mass. Very little negative pressure (e.g., 3 cc) is required, although too little negative pressure may harvest insufficient cellular material for cytologic diagnoses. Many aspirators prefer to apply full negative pressure. Excess negative pressure is a significant problem if applied when the needle tip is *outside* the mass. Gross blood in the syringe will dilute the cellular material with low cytologic yield when smeared. Gross blood often yields smears which are inadequate for cytologic diagnosis. When the syringe and needle are detached and then reattached for ejection of the air through the needle, proper tight-fitting reattachment of the needle to the syringe is necessary. Moving the needle briskly back and forth, to and fro, at least ten times within the mass is the most important technique to obtain an abundant cell harvest.

Table 8-12 summarizes the difficulties with slide preparation in fine needle aspiration cytology of the breast. For optimum cytologic evaluation, 3 or more drops of tissue juice should be obtained and smeared on the slides. (When not enough cellular tissue juice is obtained by any aspiration technique, a repeat aspiration should be done immediately.) If the material dries on the slide before a cytologic fixative is applied (except when using the air-dried technique), poor results are obtained and the cytologic evaluation is difficult. Material rich in cells may be smeared too thick, making the slide difficult to read. Even when the tissue juice is spread very thin, if there is adequate cellular material, a definite cytologic diagnosis can be made. Too much pressure in spreading the slide can result in "cellular crush" and loss of distinct cellular detail. Slow spreading, particularly when large clumps of material are present, may produce thick layers of cells which are difficult to interpret. Too much' material (e.g., when a portion of the slide is crowded with stacks of cells) will decrease the accuracy of specific cytologic interpretation. If too much time elapses before smearing, bloody material will clot, interfering with the cytologic diagnosis.

New, clean slides (preferably with frosted ends for proper identification) should always be used. Unclean slides confuse the issue with too much artifactual material. Without a proper smearing technique, cellular material can collect on the edges of the slides and not be available for proper cytologic evaluation. The individual who prepares the slides should spend time in the cytology laboratory under the supervision of the cytopathologist, and practice smearing slides in the exact manner preferred by the cytopathologist. A close working relationship between the physician doing the fine needle aspiration cytology and the cytopathologist reading the slides is essential for meaningful results and a low level of inadequate smears.

TABLE 8-11. DIFFICULTIES OF SYRINGE/NEGATIVE PRESSURE TECHNIQUE WITH FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Negative pressure (suction) applied *after* the tip of the needle is withdrawn from the mass
2. Needle not properly attached to syringe
3. Inadequate negative pressure creates the possibility of low yield of epithelial cells
4. Too much negative pressure which theoretically can suck up gross fluid/blood into the needle/syringe (low cytologic yield)

TABLE 8-12. DIFFICULTIES WITH SLIDE PREPARATION IN FINE NEEDLE ASPIRATION CYTOLOGY OF THE BREAST

1. Not enough cellular tissue fluid
2. Dried material on slide (when not using air-dry technique)
3. Smear too thick-slide difficult to read
4. Spread too firmly-crushed cells
5. Accumulated material at slide's edges-cells not available for cytologic evaluation
6. Bloody material allowed to clot before smearing

CONCLUSION

Fine needle triage of dominant breast masses is an effective and efficient procedure. When gross fluid is obtained, the diagnosis of a cyst of the breast is established. If the fluid is clear or cloudy, it can be discarded. Bloody fluid (macroscopic or microscopic) should have cytologic analysis. When bloody fluid is present, a definitive diagnosis must be established. If there is a persistent palpable residual mass, fine needle aspiration cytology or open biopsy should be done to establish a definitive diagnosis. If the fluid obtained is not bloody and there is no residual mass, a biopsy is not necessary, but the patient must be followed. If a cyst recurs, it can be reaspirated once. Any further recurrence should be treated by excision biopsy.

Fine needle aspiration cytology is indicated for any palpable solid breast mass. By this technique, specific cytologic diagnoses of benign and malignant lesions can be obtained quickly in 90% of solid breast masses. True false-positive reports should be less than 0.1%. False-negative reports should be less than 5%. Smears that are inadequate for cytologic diagnosis should be less than 5%. Abnormal, atypical, suspicious, and unsatisfactory smears require definitive histologic diagnosis by open biopsy.

Fine needle aspiration cytology is a simple, reliable, cost-effective procedure. No special equipment is required. The technique is readily learned by clinicians and readily accepted by patients. Complications are rare. There are no medical contraindications to fine needle aspiration cytology. The combined use of physical examination (a systematic complete physical examination of the breasts, axillae, and supraclavicular areas by inspection and palpation with the patient both sitting and prone), mammography, and fine needle aspiration cytology can establish definitive diagnoses for almost all palpable breast masses. Mammography should be done prior to, or more than two weeks after, fine needle aspiration cytology of the breast. Hematoma formation after fine needle aspiration of the breast can give false-positive mammographic readings.

All patients with dominant masses of the breast deserve lifelong follow-up. A definitive histologic diagnosis must be established for any persistent or recurrent palpable breast lesion. Any breast lesion that is suspicious for malignancy by clinical impression, physical examination, mammography, or fine needle aspiration cytology requires a definitive histologic diagnosis by open biopsy.

The complete evaluation of breast masses by the gynecologist requires the close cooperation of a cytopathologist and a mammographer, both of whom are clinically oriented and dedicated. When a diagnosis of breast cancer is made, the gynecologist should coordinate the multidisciplinary team: the surgeon,

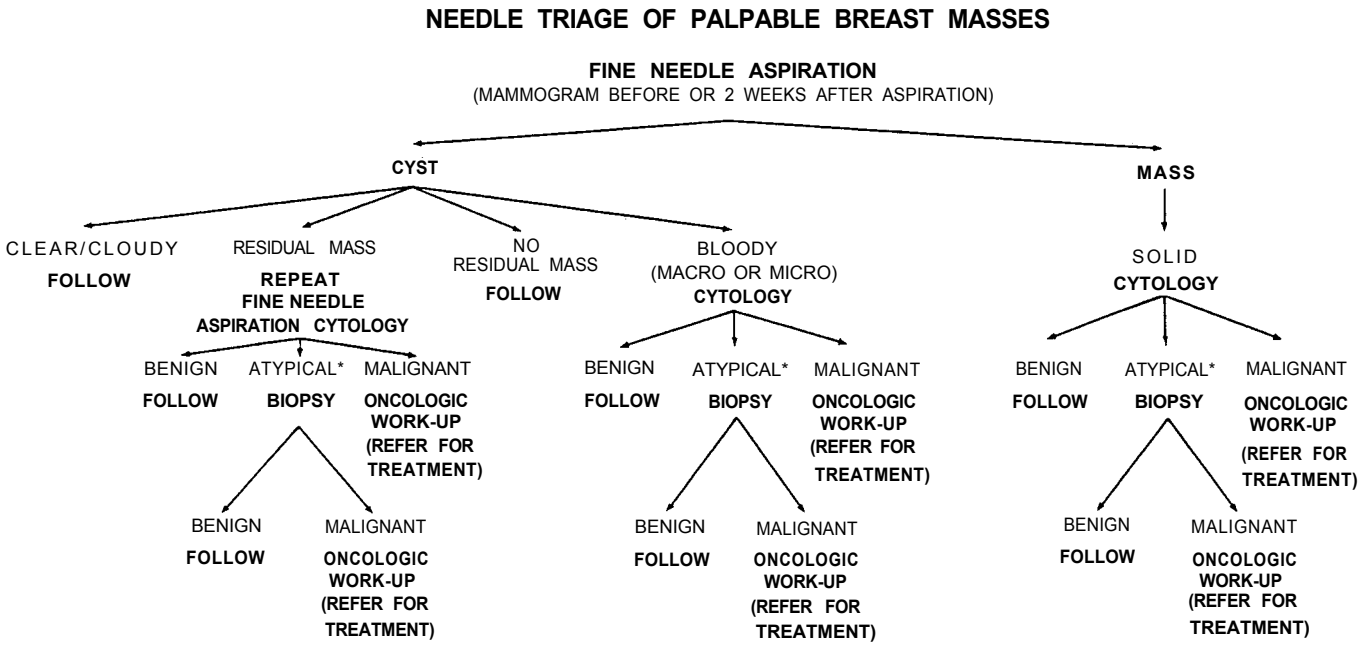


Figure 8-5. Clinical algorithm of needle triage of palpable breast masses with physical examination, fine needle aspiration cytology, and mammography. *(Atypical** includes *abnormal, borderline, inadequate, insufficient, suspicious, and any other category which is nor a definite benign or malignant diagnosis.)*

plastic surgeon, medical oncologist, radiation therapist, oncology nurse, counselors, and patient support personnel (especially immediate family). The therapeutic choices must be shared with the patient so that she can make her own informed decisions. Appropriately, there will be many questions which should all be discussed in clear, understandable language. A rewarding technique of obtaining valuable feedback is to ask the patient to explain what her understanding is of her current situation and future options. As the primary care physician for the patient with cancer of the breast, the gynecologist is responsible for the patient's lifelong follow-up and medical support.

The author's clinical algorithm for needle triage of palpable breast masses is illustrated in Figure 8-5.

The essential baseline laboratory tests for an oncologic work-up are: 1) complete blood count, 2) urinalysis, 3) chest film, 4) liver function tests. The alkaline phosphatase is particularly important. If the alkaline phosphatase is elevated, a liver scan and bone scan should be done. If the breast cancer is an advanced stage lesion, a serum calcium should be measured. Bilateral diagnostic mammography with special views as indicated is fundamental to the work-up of all breast cancers.

Fear is a powerful feature of all breast problems. Especially with cancer of the breast, the emotional aspects should be addressed openly and directly by both the woman and her physician. The physician must be particularly sensitive and caring in handling all varieties and facets of breast disease.

The reader is referred to Part Two for a chronological, selected review of the literature pertaining to fine needle aspiration cytology.

PART TWO
Chronological, Selected Literature Review

The following are brief and generally summarized findings about breast cysts, nipple discharge, tissue core needle (Tru-Cut) biopsy, and fine needle aspiration cytology reported in the English medical literature. These published articles are selected representative papers arranged chronologically by year and alphabetically by primary author within each year. The figures are general and the percentages are rounded off. Selected conclusions are noted. The reader should consult the original articles for the precise data and specific details. The appropriate citations are listed by numbers in the bibliography at the end of this chapter. When appropriate for clarity and consistency, the terms "fine needle aspiration cytology" and "inadequate for cytologic diagnosis" are used throughout, often in place of the various particular terms used in the original articles.

Chronological Selected Literature Review: Breast Cysts

1899 Bull[58] reported on 39 cystic tumors of the breast. These tumors were labeled "retention cysts." Sixty-seven percent were single cysts. The cysts were often painful and present by history for a short time. Bull wrote, "I believe the statement correct that bloody discharge indicates always papillary growth in the ducts and suggests malignancy, or at least such an approach to it as is found in the 'intra-canalicular epithelioma'." "The story that the tumor has disappeared and then reappeared makes the diagnosis probable. Puncture with needle and hypodermic syringe is the final diagnostic test, and this should never be neglected." Several of the cysts of the breast disappeared spontaneously during the follow-up observation. Though cancers were found, it was stated, "We have little evidence that this condition [cystic disease of the breast] degenerates into cancer, and it certainly may be slow in its development."

1903 Abbe[59] published his persona1 experience with 41 mammary cysts and 56 scirrhous tumors. The patients were referred to him with presumptive diagnoses of cancer of the breast. Needle aspirations established the diagnoses of mammary cysts. The cysts were located throughout the breast. Most of the scirrhous tumors were present in the upper outer quadrants of the breast. Of the mammary cysts, 75% were single cysts. The volume of fluid aspirated was "from one drachm to one ounce," and was usually opulescent, whitish, and turbid. In 2 cases, papillomatous ingrowths were noted. In a 21-year-old woman, a galactocele presented as 4 cysts, all of which cleared with single aspirations. In 2 women, repeat aspirations were necessary to empty cysts which had refilled.

1936 Mathews[60] reviewed 50 breast cysts treated by aspiration. He recommended that (1) if bloody fluid was obtained by aspiration of a breast cyst, excision should be done; (2) if a breast cyst refilled promptly, it should be excised; (3) after complete aspiration of a breast cyst, the patient should be examined and followed to be certain that there is no residual or recurrent mass, thickening, or induration; (4) all patients who had aspirations of breast cysts should be re-examined within one month and told to return immediately if a cyst refilled. One of the discussants, Dr. Adair,[60] agreed" . . . that simple cysts can and should be treated by aspiration and not by surgical extirpation." In Adair's series of 664 breast masses, local anesthesia, fine stab wounds, and 18-gauge needles were used for aspirations. Eight percent were solitary breast cysts. Single aspirations

Additional Materials

BARRIER-SPECIFIC COUNSELING

ADAPTED FOR INCREASING SCREENING MAMMOGRAPHY RATES

Barrier-Specific Counseling is a well-established health intervention often used by paramedical personnel. This strategy uses counseling techniques to identify the specific concerns or circumstances which prevent the desired health behavior. Once these "barriers" have been identified, the counselor then selects the appropriate responses which convey those messages or information which will help the respondent to overcome that barrier. This technique 'has been successfully used in suicide prevention, health counseling, smoking cessation counseling, and to encourage various medical tests. Several theories of health behavior have been used to develop this counseling intervention, including the Health Belief Model (Rosenstock, 1990), Prochaska's Transtheoretical Model (also called the Stages of Change Model) (Prochaska and DiClemente, 1982, 1983) and the Conflict Model of Decision Making (Janis 1982).

This counseling intervention has been successfully used by researchers to increase utilization of mammography and clinical breast exam among women aged 50-74 (Rimer et al., 1991).

Here we have adapted the techniques and responses utilized in barrier-specific counseling for use in physicians' practices. These responses may be used by physicians and/or their staff members to motivate women to have regular screening mammograms.

Fourteen possible barriers to mammography use are identified in the following pages. For each barrier the recommended messages which will help the patient overcome that barrier are identified. For most of these messages, examples of the script which successful counselors have used in response to that specific barrier are illustrated. Physicians may decide to use these guidelines to aid their non-compliant patients in overcoming their concerns about mammography, thereby facilitating their compliance with screening recommendations.

* * * * * * * * * * * *

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BARRIER-SPECIFIC COUNSELING FOR MAMMOGRAPHY

TABLE OF CONTENTS

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

1. LACK OF KNOWLEDGE ABOUT MAMMOGRAPHY

A) Define Mammography.

Example:

A mammogram is an X-ray of the breast. The X-ray itself is taken be a technologist who has special training in doing mammograms. Usually, two pictures are taken of each breast - one from the top and one from the side. After the X-rays are developed, they are read by a doctor/radiologist whose specialty is reading X-rays.

B) State the Purpose of Mammography.

Example:

The purpose of a mammogram is to find breast cancer early before it spreads outside the breast and before there are any symptoms. When breast cancer is found early, women have more choices about the kind of treatment they receive and they have an excellent chance of being cured. Nine out of ten women with early breast cancer will be cured.

C) State Who Needs Mammography.

Example:

All women 50 and older need to have a mammogram every 1 to 2 years. That is because as women get older, their chances of getting breast cancer are greater. Mammograms are very important for women 50 and older because they can find breast cancers early - often 1 1/2 to 2 years before there are any symptoms.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

2. NEVER THOUGHT ABOUT IT (HAVING A MAMMOGRAM)

A) Determine What the Woman Knows About Mammography.

Example: *Have you heard or read anything about mammograms?*

If no knowledge of mammography, define it and explain its purpose.

Example: *A mammogram is an X-ray of the breast. Its purpose is to find breast cancer early before there are any symptoms. That's when the chances for cure are greatest and women have more choices about their treatment.*

B) Determine If There Are Specific Reasons for Not Having Mammograms.

Example: *Are there any reasons that come to mind about why you might not want to have a mammogram?*

If specific barriers are identified, refer to the counseling guidelines for those particular barriers.

C) If No Reasons Cited. State Advantages of Mammography.

Example:

As women get older they are more likely to get cancer. In fact, about 1 out of 9 women will get breast cancer. And, the majority of breast cancer cases are in women over the age of 50. Mammograms can find breast cancer very early - often 1 1/2 to 2 years before it can be felt or before there are any symptoms. That's the. reason that women aged 50 and older should have a mammogram every 1 to 2 years.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

3. NOT INTERESTED IN HAVING A MAMMOGRAM

A) Find Out Why She Is Not Interested.

Examples:

1. Have you ever thought about having a mammogram?

2. Are there any reasons that come to mind about why you might not want to have a mammogram?

3. Has anyone you know ever had a mammogram? What did she have to say about it?

B) Give Examples of Other Women's Reasons for Not Having Mammograms.

Example:

Some women have said that they were not interested in having a mammogram because they were concerned about the cost or being exposed to radiation or finding something abnormal. Do any of these things sound like you?

C) If No Barriers Cited, Explain Importance of Mammography.

Example:

As women get older, their chances of getting breast cancer increase. In fact, about 1 out of 9 women will be diagnosed with breast cancer. And, most of the breast cancer cases are in women over the age of 50. Mammograms can find breast cancer very early - often 1.5 to 2 years before it can be felt or before there are any symptoms. That's why the National Cancer Institute and several other medical organizations say that women aged 50 and older should have a mammogram every 1 to 2 years. When breast cancer is found early, it has an excellent chance of being cured and a woman often has more choices about the way it is treated.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

4. IT'S NOT NECESSARY TO HAVE A MAMMOGRAM

A) Attempt to Determine Why She Believes This.

Example: *Can you tell me more about that? Are there some particular reasons that come to mind about why you think you do not need to have mammograms?*

B) If No Barriers Cited, Probe for Reasons.

Examples:

1. Some women think that they don't need to have a mammogram because they're not having any symptoms or breast problems... or because they don't have a family history of breast cancer.

2. Sometimes women who examine their breasts regularly themselves or have their breasts examined by their doctors feel that they don't need to have mammograms.

3. Still others think they don't need mammograms because they're too old or because they just don't think they'll get breast cancer.

Do you think any of these reasons sound like you?

C) If No Barriers Cited Still. State Importance of Mammography.

Example:

About 1 out of 9 women will get breast cancer sometime during her lifetime. Most breast cancers occur in women aged 50 and older. And, as women get older, they are more likely to get breast cancer. Breast cancer that is found early has an excellent chance of being cured. In fact, about 9 out of 10 women whose breast cancer is found early will be cured. A mammogram is the best way to find breast cancer in the early stages. A mammogram can find breast cancer at least 1 1/2 to 2 years before it can be felt. Finding breast cancer this early may mean a choice about the kind of treatment she has.

D) Discuss The Woman's Individualized Risk.

Her particular risk, based upon her personal as well as her family history may be appropriate to motivate her to have a mammogram. However, it is best not to over-state her risk so that she is then terrified into inaction.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

5. NOT NECESSARY - SPECIFIC REASONS CITED

A) Because of Age: Emphasize that risk increases with age.

Example:

As women get older, their chances of getting breast cancer are greater. The majority of breast cancers occur in women over the age of 50 and about half the women with breast cancer are 65 years of age and older. Older women are living much longer these days. (On average, a 65 year old woman will live another 18 years and a 75 year old woman another 12 years.) Therefore, it is important for all women 50 and older to have regular mammograms every 1 to 2 years. That is the best way to find breast cancer early, when the chances of its being cured are excellent and when women have more choices about treatment.

B) Because of Regular Breast Self-Examination: Emphasize that mammograms find breast cancer earlier.

Example:

Examining your breasts yourself is very important but mammograms can find most breast cancers at least 1 1/2 to 2 years before they can be felt. A mammogram can see a breast cancer as small as the size of the head on a straight pin; a breast exam cannot usually feel the cancer until it has grown to the size of a pea. The smaller the breast cancer is when found, the greater the chances that it can be cured.

C) Because of Regular Clinical Breast Examination: Emphasize that mammography complements regular clinical exams.

Example:

Mammograms can find most breast cancers at least 1 1/2 to 2 years before they can be felt as lumps. And, although mammograms find most breast cancers, there are some that a mammogram cannot find. That is why it is important for you to examine your breasts every month and to have a doctor examine them every year in addition to your having regular mammograms.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

5. NOT NECESSARY - SPECIFIC REASONS CITED (continued)

D) Due to Absence of Family History: Give Facts About the Importance of Family History of Breast Cancer.

Example:

Many women believe that they don't need mammograms because no one in their family has had breast cancer. But the fact is that 3 out of 4 women who get breast cancer do not have a strong family history of breast cancer. As women get older, their chances of getting breast cancer increase regardless of whether or not anyone in their family has had breast cancer.

E) Due To Absence of Symptoms: State the Purpose of Mammography (To find cancer before symptoms appear).

Example:

Some women don't think they need to have a mammogram unless they are having some problems. However, the purpose of a mammogram is to find breast cancer early - before a woman has symptoms. That is when there is the best chance for a cure. A mammogram can find breast cancer very early - at least 1 1/2 to 2 years before it can be felt. The sooner you do something about breast cancer, the more likely the treatment can be simpler, easier and less hassle than if you wait.

F) I Don't Want To Know If I Have Cancer: Emphasize the Advantages of Mammography.

Example:

Some women feel that as long as they feel fine they don't want to look for trouble. However, other women say something else which is very true: If you have cancer, you will eventually find out; so why not know now, when you can do more about it. Unless you have regular mammograms, you don't know your breasts are "in trouble" until you start having symptoms such as a lump, discharge, or dimpling of the breast - which might be signs of breast cancer. It is better to find breast cancer before there are any symptoms. When breast cancer is present and is found by a mammogram, you can have a head start on treating it. Breast cancer that is found early has an excellent chance of being cured.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

5. NOT NECESSARY - SPECIFIC REASONS CITED (continued)

G) Having One Mammogram Is Enough: Emphasize the Importance of Regular Mammography.

Example:

I'm glad to hear that you have had a mammogram. But, in order to find breast cancer early, women need to have mammograms regularly - every 1 to 2 years. Breast cancer can develop at any time. You need to have mammograms regularly, so that you can find it as early as possible, if it does develop.

H) I Don't Think I'm Going to Get Breast Cancer: Give Factual Information About Risk and Emphasize the Advantages of Mammography.

Examples:

The fact is that there is no way to determine who will get breast cancer. We know that 1 out of 9 women will get breast cancer sometime during her lifetime. And most breast cancer occurs in women 50 and older

About 9 out of 10 women who get breast cancer can be cured if their breast cancer is found early, before it has spread outside the breast to other parts of the body. Mammograms can find very early breast cancers - often 1 1/2 to 2 years before they can be felt. Breast cancer small enough to be seen only on a mammogram usually had not had a chance to spread. As a result, it has an excellent chance of being cured. That is why mammograms are so important - particularly for women 50 and older.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

6. ANXIETY/NERVOUSNESS ABOUT HAVING A MAMMOGRAM

A) Help The Woman Identify Why She Is Anxious.

Example: *What do you think it might be about having a mammogram that makes you nervous?*

If she identifies a specific barrier, refer to the counseling guidelines for those particular barriers.

B) Determine If The Woman Is Nervous About the Procedure Itself.

1. Example if she has never had a mammogram:

Do you have any questions about what it's like to have a mammogram? Let me briefly tell you what to expect.

Example of Explanation:

The mammography technologist will ask you to take everything off from the waist up and to put on a hospital gown. The technologist will then place your breast between two plastic plates, which will be pressed together to flatten your breast as much as possible. Although this may be a little uncomfortable, the squeeze (compression) usually lasts for only about half a minute. It is needed to get a picture of as much of the breast as possible with as little radiation as possible.
A total of 4 X-rays will be made, 2 of each breast - 1 from the top to the bottom of the breast and the other from the sides of the breast. After the technologist has finished taking your mammogram, she will ask you to wait while she develops and checks the films to make sure they came out well. Your mammogram will then be read by a radiologist (a doctor with specialized training in reading X-rays and mammograms). The results will then be sent to your doctor.

2. Example if she has had a mammogram:

What was that like for you?

If the woman then cites a specific barrier, such as having had a painful experience or an abnormal result, refer to that particular guideline.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

6. ANXIETY/NERVOUSNESS (continued)

C) If The Woman Cannot State Why She Is Nervous. Encourage Her Anyway.

1. It might lessen her anxiety if she does have a mammogram.

Example:

For some women, thinking about having a mammogram reminds them about the chance that they could get breast cancer some time and that is very upsetting. It can be so upsetting that it makes it difficult for them to do what they need to do to stop worrying - have the mammogram.

Some women say they felt calmer and more in control after having a mammogram. They say that they couldn't decide never to get breast cancer, but they could try to beat it if they did get it. A mammogram can find breast cancer 1 1/2 to 2 years before it can be felt, and that means a head start on treating it. Remember - breast cancer that is found early has the best chance of being cured.

2. Suggest having her take a close friend or family member with her to the appointment.

Example: *Some women find it makes them feel less nervous if they take a friend to their appointment.*

D) Review of Personal Risk Profile.

This may help someone who feels overwhelmed with anxiety about breast cancer. Her individualized risk may not be as great as she believed. As a result, she may overcome her inaction and be motivated to have a mammogram.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

7. DISCOMFORT/PAIN ASSOCIATED WITH MAMMOGRAMS

A) Determine Why The Woman Is Worried About This.

Examples:

1. What have you heard other women say about their mammograms?

2. Where did you hear that having a mammogram is uncomfortable?

3. What have your mammograms been like?

B) Explain Reasons for Discomfort.

Examples:

Many women do say that having a mammogram is uncomfortable - for just a few moments. That is because the breast must be squeezed (compressed) to an even thickness. This compression helps get a good picture of your breast and lowers the amount of radiation needed. Most women say the mammogram is not really painful.

There are some things you might do to make the mammogram less uncomfortable. If you are still having periods, it is best to have the mammogram right after your period. Women taking hormones may also notice certain times of the month when their breasts are less tender and should have their mammogram during those times.

If you have had a painful mammogram in the past, you might mention this to your technician so she can be more sensitive to you. [You might also suggest going to another mammography center if the woman is still concerned.]

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

8. HAVING A MAMMOGRAM IS JUST LOOKING FOR TROUBLE

A) Explain The Advantages of Finding Cancer Early.

Example:

Some women do feel that having a mammogram is just looking for trouble. But, unless you have regular mammograms, you won't know that your breasts are "in trouble" until the trouble begins to show up in the form of symptoms, such as a lump, discharge, or dimpling of the breast. At that point, if you have breast cancer, it may have already spread outside your breast. After breast cancer starts to spread, it is much harder to control and to cure. It is much better to find breast cancer before there are any symptoms. In fact, you might say, it is much better to go looking for breast cancer, before it comes looking for you.

B) Point Out The Value of Regular Mammography.

Example:

Having regular mammograms is the best way to find breast cancer early. Breast cancer can be found at least 1 1/2 to 2 years before it can be felt. Finding breast cancer that early gives you a head start on treatment and an excellent chance of being cured. In some situations, it may also mean you have choices about the kind of treatment you receive.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

9. CONCERN ABOUT RADIATION RESULTING FROM MAMMOGRAPHY

A) Determine What The Woman Has Heard or Read About the Resulting Radiation.

B) Give Facts Concerning; the Radiation Exposure During Mammography.

Examples:

When mammography was first used, over 20 years ago, the amount of radiation used was much higher than it is today. Today the amount of radiation used in taking a mammogram is very small (0.1 to 0.8 rads). In fact, your risk of getting breast cancer because of having had mammograms is 1 in a million.

Mammography machines are set so that the smallest amount of radiation is used. Facilities that are accredited by the American College of Radiology are checked often to make sure that the lowest possible amount of radiation is used.

C) Emphasize That the Benefits of Mammography Far Outweigh the Risk.

Example:

Experts agree that in women over 50 the benefits of mammography far outweigh the risks due to radiation. A mammogram can find breast cancer at least 1 1/2 to 2 years before it can be felt. This is when it is in the early stages - when it has an excellent chance of being cured and when you may have more choices about the treatment.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

10. CONFUSION ABOUT MAMMOGRAPHY RECOMMENDATIONS

A) Determine What The Woman Understands About the Guidelines.

B) Briefly Explain the Controversy.

Examples:

The National Cancer Institute recently changed its guidelines. Experts DO agree that studies have made it clear that routine screening mammograms can save the lives of many women ages 50 and over. But most experts agree the studies have not proven the effectiveness of mammograms for women between the ages of 40-49.

Please keep in mind that all medical organizations agree that women over age 50 need regular mammograms.

11. TRANSPORTATION PROBLEMS (GETTING TO MAMMOGRAPHY FACILITY)

A) Ask If a Friend. Neighbor or Relative. Can Give Her a Ride to Her Appointment.

B) Give Information About Transportation Alternatives.

Example: Volunteer programs which offer rides to facilities.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

12. TOO MUCH TO DO/NOT ENOUGH TIME/DIDN'T GET AROUND TO IT

A) Determine Why The Woman Doesn't Have Time.

Examples of competing demands: job responsibilities, caretaking responsibilities, recent personal/family crises, transportation time to mammography facility.

B) Suggest She Make an Appointment During a Less Busy Time or Find Someone To Help Make the Time.

C) Give the Message That She Needs to Take Care of Herself.

Example:

Having a mammogram is something you need to do for yourself so that you can continue to take care of those who depend on you. A mammogram can find breast cancer 1 1/2 to 2 years before it can be felt. That is early - when it has an excellent chance of being cured and when you might have more choices about your treatment.

D) Emphasize the Advantages of Getting a Mammogram.

Examples:

The mammogram itself usually only takes about 30 minutes from the time you walk into the facility until the time you walk out. That really isn't very much time, especially when you consider that a mammogram could save your life.

Some mammography centers are open in the evenings and/or weekends. That might be more convenient for you.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

13. WORRY CONCERNING A POSSIBLE ABNORMAL RESULT

A) Determine If There Are Specific Reasons The Woman Is Worried About This.

Examples:

Are there any particular reasons you're worried about your mammogram showing something abnormal?

Has this ever happened to you or anyone you know?

B) Give Facts About Additional Tests.

Example:

If your mammogram does show a problem, this doesn't always mean you have breast cancer. In fact, 8 out of 10 abnormal mammograms do not turn out to be cancer, but something like noncancerous tumors, cysts, or changes in the breast. These abnormalities are usually harmless and may not even require treatment.

C) Emphasize the Advantages of Early Detection If Cancer Is Found.

Example:

If it turns out that your mammogram has found breast cancer, it is likely that it has been caught at an early stage, when it has an excellent chance of being cured and you have more choices about treatment. In fact, about 9 out of 10 women whose breast cancer is found early will be cured. The sooner you find breast cancer, the more likely the treatment can be simpler, easier and less hassle than if you wait. A mammogram can find breast cancer at least 1 1/2 to 2 years before it can be felt, giving that much head start on treating it.

BARRIER-SPECIFIC COUNSELING
FOR MAMMOGRAPHY

14. CONCERNS ABOUT THE EFFECTIVENESS OF MAMMOGRAPHY

A) Give Information About The Accuracy of Mammograms.

Example:

No medical test is perfect, but a mammogram can find about 80-85% of all breast cancers present at the time of the exam in women age 50 and over. A breast exam by a health professional can find another 5-10% of the cancers. Together, the mammogram and breast exam will find more than 90% of all cancers present, even the smallest ones. Having a breast exam, examining your breasts yourself and having regular mammograms will increase the chance that breast cancer will be found early, if it is present.

B) Reinforce The Advantages of Mammography.

Office Systems for Promoting Screening Mammography

A Survey of Primary Care Practices

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Background. Office tracking, scheduling, and reminder systems have been shown to improve utilization of screening mammography, but little is known about the use of these systems by primary care physicians.

Methods. We surveyed 152 primary care and obstetrics and, gynecology practices affiliated with an independent practice association model heath maintenance organization in central Massachusetts to determine their use of reminder, scheduling, and follow-up systems, and education and counseling services aimed at increasing screening mammography rates.

Results. The use of chart flags to remind physicians of a patient's need for mammography screening was reported by 80% of practices. Thirty-one percent reported the use of flow sheets, and 27% reported the use of mail or telephonic patient reminders. At least one of these three: systems was used by 57% of the practices, whereas 43% reported having none of these three systems. Variations in the use of these office systems were related to specialty type, physician number, and clinical staffing. The majority of practices (77%) reported using written educational materials, and 42% offered prevention counseling with nonphysician staff. Very few offices (8%) reported using mail or telephone reminders for previously scheduled appointments.

Conclusions. Despite the proven effectiveness of reminder systems for screening mammography, many practices do not have a system in place. Promotion of reminder systems in primary care practices could have a substantial impact on mammography utilization.

Key words. Mammography; mass screening; preventive health services; physician's practice patterns; primary health care. *(J Fam Pract 1993; 37:569-574)*

Most authorities now agree that screening mammography is an effective and safe measure for reducing morbidity and mortality due to breast cancer among women aged 50 years and older.[1-3] In recent years numerous efforts have been undertaken to increase the use of screening mammography.[4-7] Although the proportion of women aged SO years and older in the United States receiving mammograms annually or biannually has been increasing, the percentage is still far from the target of 60%. set in the Healthy People 2000 objectives.[8] The recent Mammography Attitudes and Usage Study (MAUS) found that 31% of US women aged 40 years and older are in compliance with the National Cancer Institute's guidelines for mammography screening.[9] A study of women over 51 years of age enrolled in a health maintenance organization (HMO) showed that 15.7% had had the recommended number of mammograms.[10]

Investigators have identified several barriers to mammography use related to patient, physician, and organizational factors.[11-16] Barriers dated to cost are becomless important for persons medical insurance as more states mandate coverage for screening mammography by private insurers.[17] Failure of physicians to recommend a mammogram and lack of an identified personal physician have been found to be strong barriers.[7,11-13,18]

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The American Cancer Society (ACS) estimate that 2% of primary care physicians agree completely and 19% agree partially with ACS mammography screening guidelines.[19] Nevertheless, many physicians continue to have limited success in achieving high rates of breast cancer screening among their patients.[14,16,20-27] Several studies of administrative approaches to increasing mammography use have demonstrated the efficacy of physician reminders,[15,28-32] patient reminders,[15,31,33] and the combination of physician and patient reminders.[14,31,34] Computer-generated or nurse-indicated physician reminders have been shown in previous studies to increase physician screening for mammography by 0.7% to 29%.[15,28-31,34-35] The use of screening flow sheers has had mixed results in previous studies. However, at least three studies have shown an increase 7.8% to 32% in screening test utilization with the introduction of flow sheets.[36-38] We found a 7% increase in mammography utilization with the use of screening flow sheets.[32]

Although office systems have been demonstrated to improve compliance with mammography screening, little is known about primary care physicians' current use of office reminders, patient reminders, scheduling systems, and follow-up systems for mammography in their practices. To determine the prevalence of office reminder and scheduling systems and education and counseling services for screening mammography, we conducted a telephone survey of a group of primary care practices affiliated with an independent practice association (IPA) model HMO and of the mammography centers to which the practices refer their patients.

Methods

A 20- to 25-minute structured telephone survey was administered to an appropriate nonphysician staff person from a sample of medical practices in central Massachusetts between July and September 1991. Eligible practices had at least one physician member who was a primary care physician or obstetrician/gynecologist and who was affiliated with Central Massachusetts Health Care, Inc, an IPA-type HMO.

Of 157 eligible pratices representing 352 physicians, 132 practices (84.1%) representing 321 physicians participated in the survey. The practices surveyed represented 33.8% of the primary care physicians and obstetricians and gynecologists in all the towns in the HMO market area and 36.1% of physicians in such practices in Worcester, Massachusetts, the largest metropolitan area in the HMO market.[39]

The key respondent was the nonphysician staff person who had the most knowledge of the office systems and procedures for providing screening mammography. In approximately 75% of the offices, the key respondent was an office manager or nurse manager. Eighty-four percent of the respondents had been employed in the practice for more than 2 years. In some offices, multiple respondents were identified to ensure that the most accurate information was recorded on the survey. Two trained interviews conducted the interviews.

The survey instrument was a structured questionnaire. For most questions, the respondent was given a list of several possible categorical answers. The survey instrument consisted of questions in three areas: (1) demographic data on tie practice including staffing patterns, numbers of patients, and type of payment; (2) office systems for preventive services, counseling, and patient education, and (3) specific procedures for mammography scheduling and referral.

Data Analysis

Frequency distributions of survey responses and cross-tabulations of practice characteristics with office system variables were performed. Bivariate associations were assessed statistically with the chi-square test. To assess the independent association of practice characteristics with selected office system variables, logistic regression models were developed. Prevalence odds ratios and 95% confidence intervals were determined from the models.

To derived an index of each practices's "patient load," a patient-to-staff ratio was calculated by dividing the number of patients seen during an average week by the number of full-time equivalent (FTE) nonphysician staff members (one, FTE represents 40 person-hours of work). A measure of the amount of clinical staff support available to physicians and nurse practitioners was the ratio calculated by dividing the total number of clinical staff FTEs (registered nurses, licensed practical nurses, and medical assistants) by the number of primary care providers (physicians and nurse practitioners).

Results

The characteristics of the 132 practices surveyed are shown in Table 1. The majority of practices were solo practices (59.3%) and single-specialty practices (87.9%). The most common specialty was internal medicine (37.9%). The vast majority of practices were affiliated with two or more IPA-model HMOs (93.2%), and 75% had over 25% of their patient population enrolled in an HMO. About 73% of practices had a patient-to-staff ratio of 20 to 59 patients per staff FTE per week, and 62.9% had a ratio of nonphysician clinical staff FTEs to

Table 1. Characteristics of Primary Care Practices Affiliated with a Health Maintenance Organization in Central Massachusetts (n = 132)

Characteristic	%
Type of practice	
Solo	59.8
Group	40.2
Type of specialty	
Internists only	37.9
Family practitioners only	29.8
Obstetrician/gynecologist only	18.2
General practice only	3.0
Mixed specialty group	12.1
Patient-to-staff ratio*	
0-19	12.9
20-39	41.7
40-59	31.1
60-150	14.4
Ratio of clinical staff members to providers†	
0-0.49	22.7
0.50-0.99	29.6
1.00-1.49	33.3
1.50-2.00	14.4

**Number of weekly patient visits divided by total full time equivalent (FTE) staff members.*
†Number of FTE clinical staff members (registered nurses, licensed vocational nurses, medical assistants) divided by number of primary care providers (physicians and nurse practitioners).

Table 2. Methods Used by Primary Care Practices to Increase Screening Mammography Rates (n = 132)

Method	% of Practices
Office systems	
Chart flags, office cues for mammography	30.3
Flow sheets for mammography	31.1
Periodic chart review for preventive services	15.2
Patient reminders	
Mail or telephone patient reminders to schedule mammograms	27.3
Office reminder of mammogram appointment*	7.6
Scheduling and follow-up	
Mammograms scheduled by office staff	80.3
Office policy to usually contact patients with normal results	67.4
Office contacts patients if no show†	79.5
Education and counseling	
Pamphlets on mammography in examination or waiting rooms	76.5
Videotapes on mammography	12.6
Prevention counseling by nonphysicians	42.4

** n = 131.*
† n = 119.

primary care providers of 0.5 to 1.49. Forty-five percent of practices employed at least one registered nurse. As a measure of the socioeconomic status the practice: population, the percentage of patients enrolled in Medicaid was asked. Seventy-eight percent of practices reported that fewer than 25% of their patients were enrolled in Medicaid. The majority of practices were located in urban areas (56.8%).

The frequency of use of office reminder systems, scheduling and follow-up procedures, and education and counseling for screening mammography is shown in Table 2. The most commonly used office systems for reminders for mammography screening were chart flags, flow sheers, and mail or telephone reminders to patients to schedule an appointment which were used by 30.3%, 31.1%, and 27.3% of practices, respectively. A large percentage of practices (43.2%) did not report using chart flags, flow sheets, or reminders to patients, whereas 24.3% recorded using more than one of these three organizational systems. Few practices (7.6%) used all three.

A small number of the practices (15.2%) used a periodic chart review to identify patients in need of preventive services, and the majority of these 20 practices reviewed only a sample of charts. Utilization of a patien-held reminder or record for screening mammography was very low, with only two practices reporting use of this method.

Printed material was the most common educational method for conveying information about screening mammography, with 76.5% of practices having materials available for patients. Of the 132 practices, 42.4% offered general prevention counseling by nonphysician staff, whereas 27.3% had registered nurses performing cancer prevention counseling.

In 80.3% of practices, mammograms were schedtied by the office staff, and in the remaining 19.7% of practices the patient was responsible for arranging a mammogram appointment. Of the 132 practices, 7.6% reminded their patients of a scheduled mammogram appointment by mail or telephone. The majority of practices surveyed contacted the patients who had normal mammogram results (67.4%) and an even larger number (79.8%) contacted those patients who failed to keep a scheduled mammogram appointment

Analysis of the association between selected practice characteristics and the use of office systems for screening mammography (Table 3) revealed differences among practices based on size (ie, solo or group) and specialty. The proportion of practices that used chart flags, flow sheets, or patient reminders, and the proportion that used any one or more of these three systems, were higher for group practices than for solo practices for all specialties, except for family and general practices; although the differences were not statistically significant. Fewer group family practices used chart flags (6.3%), flow sheets (12.5%), and any one or more of three systems (37.5%) than any solo or other group practice. An overall chi-

Table 3. Use of Chart Flags, Flow Sheets, and Reminders, by Practice Characteristics

Characteristic	Chart Flags,*† %	Flow Sheets, %	Patient Reminders, %	Any One or More of Three Systems, % ‡
Practice type and specialty				
Solo practice				
FP or GP only (n = 27)	14.8	25.9	33.3	51.9
Internal medicine only (n = 37)	32.4	24.3	13.5	45.9
Ob/Gyn only (n = 15)	26.7	40.0	40.0	66.7
Group practice				
FP only (n = 16)	6.3	12.5	18.8	37.5
Internal medicine only (n = 15)	33.3	33.3	46.7	73.3
Ob/Gyn only (n = 9)	55.6	44.4	33.3	77.8
Mixed specialty (n = 13)	46.2	61.5	23.1	76.9
Patio of clinical staff members to providers				
0-0.49	13.3	16.7	13.3	30.0
0.50-0.99	43.6	28.2	33.3	69.2
1.00-4.00	30.2	39.7	30.2	61.9

**Overall chi-square for test of association of practice type with chart flags, P < .05.*
† Significant difference between rations of clinical staff members (registered nurses, licensed vocational nurses, medical assistants) to primary care providers (physicians and nurse practitioners), P < .05.
‡ Significant difference between ratios of clinical staff members to providers, P < .001.
FP demotes family practice; GP, general practices; Ob/Gyn, obstetrics gynecology.

square test showed a statistically significant difference among the seven practice types only for the use of chart flags *(P = .016)*. Among practices with high ratios of clinical staff to providers (>0.5), the proportion using chart flags, Flow Sheets, patient reminders, and any one or more of these systems was higher than among practices with relatively fewer clinical staff (Table 3).

Differences among practice type were also found for nonphysician prevention counseling. Obstetrics and gynecology group practices had the highest proportion of practices using nonphysician counseling (71.4%), and solo family and general practices had the lowest (14.8%) *(P < .001)*.

Four practices, all solo practices, identified themselves as being general practices. Excluding the four general practices from the analysis increased the proportion of solo family practices using all types of the office systems studied, but did not change the relative ranking of practices as shown in Table 3. Information on board certification was available on 75.3% of the self-identified family physicians in the practices surveyed, and 91.4% were board certified in family practice.

The results from a logistic regression mode1 with the use of any one or more of three office systems (chart flags, flow sheets, or patient reminders) as the dependent variable arc shown in Table 4. Variables were rested in the model based on a priori judgments regarding the relation of various factors to the use of office systems for mammography and on detectable bivariate relationships, as well as on the magnitude and stability of the coefficients following the addition of each variable in the model. The most informative model used practice type and the ratio of nonphysician clinical staff members to primary care providers. Practice type was broken down by number of physicians and specialty because of interaction between these variables, particularly for internists and obstetrician-gynecologists. The referent categories were group family practices for pratice type and less than 0.5 for the ratio of clinical staff members to providers.

Table 4. Logistic Regression Model of the Association of Practice Type and Clinical Staff-to-Provider Ratio with the Use of Office Systems*

	Odds Ratio	95% Confidence Interval
Practice type and specialty		
Solo practice		
FP or GP only	2.42	(0.65-9.07)
Internal medicine only	1.78	(0.52-6.18)
Ob/Gyn only	4.64	(0.98-22.04)
Group practice		
FP or GP only †	1.00	
Internal medicine only	4.49	(0.94-21.36)
Ob/Gyn only	7.97	(1.11-57.11)‡
Mixed specialty	7.68	(1.36-43.34)‡
Ratio of clinical staff members to providers		
0-0.49†	1.00	
0.50-4.00	4.83	(1.88, 12.43)‡

**Outcome variable; any one or more of three office systems (chart flags, flow sheets, or patient reminders).*
†Reference value.
‡P < .05.
FP denotes family practice; GP, general practitioner; Ob/Gyn, obstetrics and gynecology.

Although the confidence intervals are wide as a result of small sample size, the results are consistent with the bivariate analysis. Group practices used more office systems for mammography than solo practices, except among family and general practices. Obstetric and gynecology practices had the strongest association with the use of any one or more of three office systems with an odds ratio of 7.97 for group practices and an odds ratio of 4.64 for solo practices when compared with group family practices. A ratio of nonphysician clinical staff member to providers greater: than 0.5 also had a strong independent association with increased use of office systems with an odds ratio of 4.83.

Several other models, which included the patient-to-staff ratio, urban vs rural practice, at least one female physician in the practice, and the percentage of patients with Medicaid, did not provide a substantially better fit or more informative models.

Discussion

Although office systems have been demonstrated to be an effective tool to increase mammography compliance, little information has previously been available to determine to what extent these systems are used. This study found that relatively few of the primary care practices affiliated with a large IPA-model HMO in central Massachusetts reported using office reminder systems for screening mammography. Many practices (43%) reported having none of the three office systems that we studied (chart flags, flow sheets, or patient reminders) in place. The utilization rates of office systems reported in this survey are probably overestimates of actual use, as practices may not consistently use their systems. Thus, despite a growing amount of evidence for the efficacy of physician and patient reminder systems, it appears that many primary care pratices have not yet adopted these systems.

The only area in which a clear majority of practices promoted screening mammography was through the use of printed educational materials. However, McPhee et al[16] have shown that providing printed educational materials about mammography alone does not increase mammography use. Approximately 40% of practices offered cancer prevention counseling by nonphysician staff members; a few of those practices had nurses providing this service. We cannot determine from this study how many physicians are counseling their patients about mammography, but without office systems in place to alert physicians and their staff, opportunities for counseling by physicians and staff may be lost.

Wolosin[33] reported that 16% to 24% of women scheduled for a mammogram fail to keep the appointment. Many of the practices in this study were following up on patients who did not show up for scheduled mammography appointments. We do not know of any studies of the effectiveness of contacting women who fail to keep appointments in improving overall mammography use. Since contacting women who fail to keep an appointment may be a widespread practice, it would be useful to determine how to make this contact most effective.

The results of most screening mammograms are normal, but only two thirds of the practices in this study contacted the patient when the result of her mammogram was normal. It is very likely that a substantial proportion of women received no written or verbal report about the result of their mammogram. Lack of communication about normal results could have detrimental effects on future compliance with screening mammography.

This study revealed that certain practice characteristics–the number of physicians, specialty, and me ratio of nonphysician staff members to providers–may be important determinants of the use of office systems for screening mammography. Group practices used more office, systems than did solo practices, except for family and general practitioners. This held true when the ratio of clinical staff members to primary care providers was controlled for in a logistic regression model. Group family practices generally used the fewest office systems, whereas obstetrics and gynecology groups used the most office systems. These findings could reflect differences in training or differences in basic administrative style. Sienker and Wright[40] found in a study of mammography utilization that obstetricians and gynecologists ordered screening mammograms most often, and family physicians least often. Internists ordered mammograms at an intermediate rate.

Practices with more than 0.5 FTE clinical staff per provider appear to use office systems more than other practices. This finding suggests that it may be difficult to implement systems to promote screening mammography without adequate support staff.

In conclusion, we found that in this sample of pracrices, office systems to identify women in need of a screening mammogram and to remind women of that need were not widely used. Variations in the implementation of office systems may be partially explained by factors related to specialty, number of physicians, and clinical staffing. These findings suggest that educational efforts to increase the use of office systems may need to focus on solo practices, family and general practitioners, and practices with low ratios of clinical staff members to providers. Further studies also need to be conducted to

determine the barriers to implementing office systems and the most efficient for increasing utilization of *mammography*. Given the large proportion *practices* and mammography centers that do not have office reminder systems for mammography screening and given evidence that such systems are effective in increasing mammography utilization, efforts to promote effective office systems could result in a substantial increase in compliance with screening mammography recommendations.

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