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FOREWORD

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5.0 INTRODUCTION

5.1 Specific Aims

The primary question of focus for this study is:

1. How does physician gender influence the diagnosis and treatment of breast cancer in women?

Secondary questions to be explored in the analysis are:

2. What are the independent and joint influences of physicians' race, geographic location, practice specialty and age on (a) diagnosis, (b) treatment recommendations, and (c) referral patterns?
3. What are the independent and joint influences of patient age, race, socioeconomic status, comorbidity, and frailty on (a) diagnosis, (b) treatment recommendations, and (c) referral patterns for suspected and diagnosed breast cancer?
4. Can any variations in diagnosis and treatment patterns be explained by the interaction of patient and physician characteristics?

5.2 Fractional Factorial Experiment

We have developed a unique experimental design, where clinical "patients" are developed for videotape and enacted by actors to simulate patient-physician encounter. Versions of each videotape are produced that maintain the same clinical information while varying those patient features as part of the experimental design. In each of two medical scenarios, we shall investigate five patient factors: age, race, socioeconomic status, comorbidity and mobility. The patients enacted on videotape are either 65 or 80 years of age, and either black or white. Socioeconomic status is either upper-level or lower-level, as expressed by a complex of characteristics, including dress, idioms of speech, and coverage by Medex versus Medicaid health insurance. Comorbidity is dichotomized as a patient free of chronic illness, or one with stable hypertension and diabetes on oral medication. Mobility is defined as either no disabling condition, or frailty as a woman with osteoarthritis of the knees requiring the use of a walker.

Each of the 16 "characters" enacts two scenarios. In the first scenario, the patient presents with a question of a new breast mass, seeking diagnostic evaluation. In the second scenario, the patient presents with a confirmed .8 cm carcinoma by excisional biopsy and seeks recommendations for completion of diagnostic evaluation, primary and adjuvant therapies.

5.3 Physician Characteristics and Study Population Selection

We used matched pairs of male and female physicians to study our primary variable of interest, matching to control for geographic location, race, age and specialty.

In our previous reports we have detailed the methods of our recruitment strategy and exclusion criteria.

6.0 **BODY**

METHODS

6.1 Sampling and Recruitment Strategies

Geographic locations of where the physicians were recruited from was expanded in order to obtain additional eligible females to recruit into the study. States that were included in the sample are the Southern states: Atlanta, North Carolina, South Carolina, Tennessee, Alabama, Louisiana and Texas, Detroit and Chicago, and Northern California.

6.2 Interviews

We have a total of 64 interviews in Northern California, 64 interviews in Detroit/Chicago and 64 interviews in the Southern states, for a total of 192 physicians.

Characteristics of the subject are 50% female, 50% males, 69 (36%) of physicians recruited are in medical oncologists and 123 (64%) are surgeons. These numbers provide sufficient power to perform analyses by physicians specialty type, with the ability to detect at least an 18-24% difference between physician specialty with >80% power.

Unfortunately the total number of African American physicians recruited was 13 subjects, only 7% of the sample, and will result in low power for analyses by physician race. 10% of the sample would need to be African-American in order to detect a 22-36% difference by physicians' race with 80% power.

6.3 Data Management

6.3.1 Dataset Development

A completed SAS dataset has been created of the 100% of the sample. All of the variable frequencies and ranges were analyzed to look for coding errors. Outcome variables were created.

6.3.2 Quality Assurance

All instruments and data forms have continued to be checked on an ongoing basis for completion, accuracy and legibility of the interviews and instrument was performed. A quality

review of audiotapes on every interview has been completed. The Field Supervisor, Dennis Cohen, completed the logistical editing of all audiotapes and the Project Manager, Michelle Mancuso, reviewed all tapes for medical/scientific accuracy.

6.3.2 Programming

Programming of all three instruments has been completed. Variables have been developed based upon the major independent and dependent variables defined in our previous study.

6.4 Experimental Design

A fractional factorial, experimental design was employed, permitting simultaneous evaluation of five patient characteristics. Two medical scenarios were produced professionally for videotape, each of elderly women requiring breast cancer evaluation and care. For each scenario, 16 versions of each videotape was produced that maintained the same clinical information while experimentally varying patient age, race, socioeconomic status, comorbidity and mobility. Each subject viewed one version of each videotape, and provided their therapeutic recommendations based upon the case they viewed.

6.41 Medical Scenarios

Two videotape scenarios each depicted a doctor/patient encounter. The first scenario depicted the patient presenting for the evaluation of a possible breast mass, with an equivocal clinical examination, and a negative mammogram. In the second scenario, the patient presents for a second opinion for a Stage IIA, 0.8 cm infiltrating ductal carcinoma with equivocal hormone receptors. These two scenarios were developed as areas where there is the least clinical consensus on breast cancer management. The scripts were based on cases provided by two experienced clinicians and were reviewed for authenticity by a panel of practicing physicians. Videotape vignettes were 4 - 5 minutes in length.

For each of the two case scenarios, 16 versions were produced on videotape, varying the five patient characteristics: age, race, socioeconomic status, physical mobility, and comorbidity. Age of either 65 or 80 years and African-American or Caucasian race were portrayed by actresses of the corresponding age and race. Socioeconomic status was expressed visually in style of dress, verbally in minor grammatically alterations to the script, and by previous employment and current insurance coverage. Comorbidity was the presence of hypertension and diabetes or no other medical problems. Physical mobility was enacted with either no impairment or frailty defined as severe osteoarthritis of the knees in the patient synopsis, and portrayed by the actress using a walker. The same a middle- aged Caucasian male actor portrayed the physician in all scenarios. There are a total of $2^5 = 32$ possible combinations of these 5 dichotomous characteristics. We used a half factorial design, or 16 of the possible combinations. Sixteen versions of the videotape were produced for both Case 1 and Case 2. These were assembled into 16 pairs for use in the field, each pair consisting for one version of Case 1 which was viewed first, followed by a version of Case 2. The patients in each pair always differed with

respect to age, race and socioeconomic status. The pairing was maintained throughout the experiment. Strict quality control procedures were followed during videotaping to ensure identical scripts. The verbal and non verbal behaviors of the professional actors were standardized.

Each of the 192 subjects in the study viewed only one pairing of videotapes. Since there were 16 total pairings of videotapes, each of the pairings was viewed by $192/16 = 12$ of the study subjects.

6.5 Subjects

Study subjects were medical oncologists or surgeons, active in breast cancer care. Included were surgeons who had performed both a breast biopsy and mastectomy in the past five years, and medical oncologists who had cared for women with breast cancer in the past five years. Excluded were physicians who trained outside the United States. Physicians were randomly selected from listing of board certified physicians obtained through State medical registrations. In order to ensure a sufficient number of female physicians were included to answer the primary study question, we first recruited women to the study, and then matched male physicians to each female physician by geographic location. Three geographic regions were chosen for the study based on previous work that has shown a consistent geographic pattern of utilization of breast conserving surgery over time (Nattinger A,B): northern California, Michigan and Chicago, and six southern states (Alabama, Georgia, Kentucky, North Carolina, Texas, and Tennessee) representing areas of high, moderate, and low utilization of breast conserving surgery, respectively. To prevent confounding on other potential physician characteristics, we attempted to then match each male/female physician pair by specialty type, by Caucasian or African American race, and within a ten years of medical school graduation. If a perfect match was not found, we matched on as many characteristics as possible. In the final sample 99% of physician pairs were matched by specialty, 99% were matched by race, and 98% were matched within ten years of graduation from medical school. Each female/male physician pair viewed the same version of the videotapes.

Physicians were sent an introductory letter, followed by telephone recruitment calls by both study

6.6 Interviews

Semi-structured interviews were conducted by 7 trained interviewers. To enhance external validity, all interviews occurred in the physicians' offices during their regular office hours. For each scenario, physicians were invited to state what further diagnostic evaluation they would order. Upon requesting specific diagnostic tests, they were provided with the "results" in the form of a simulated laboratory reports. Physicians were allowed to order testing in sequential fashion, that is, obtaining further studies based on the results of the initial tests requested, to simulate ordering behavior in real practice. Each physician was asked what recommendation for evaluation and follow up he would make to the patient. Previous work revealed that reliability of physicians to correctly recall the patient characteristics on the videotapes was 82 – 97%.

6.7 Dependent Variables

The main dependent variables of interest for the first scenario were the physicians' estimates of the likelihood of breast cancer and whether either needle (defined as either core biopsy or fine needle aspiration biopsy) or open biopsy was planned. For the second scenario, variables included recommendation of an axillary node dissection and metastatic evaluation. Treatment variables included the use of breast conserving surgery, the use of primary therapy, defined as either mastectomy or lumpectomy with radiation, the use of adjuvant chemotherapy or tamoxifen, and the recommendation of reconstructive surgery.

6/8 Statistical Analysis

Univariate analyses were performed to determine proportions by physician gender. Multiple logistic regression models were used to assess gender, controlling for physician characteristics including gender, specialty, race, years since medical school graduation, geographic location, and the five study patient characteristics. Results are expressed as odd ratios (O.R.) with 95% confidence intervals (C.I.).

6.9 Results

By study design, 50% of physicians were female, and one third were from northern California, Michigan or Chicago, and the southern states. 50% of physicians were medical oncologists, 93% were Caucasian. The mean age of the female and male physicians was similar (44.8 vs. 45.7, $p = 0.19$) although the mean years since medical school graduation was less for women than men (16.7 vs. 20.9, $p < 0.001$).

Results are presented below separately for the presentations and manuscripts currently in preparation.

1. The Role of Physician Gender in Decision Making (see Appendix 1)

Case 1: A Possible Breast Mass

The mean cancer likelihood estimate for the first scenario was 37% and did not differ between women and men (39% vs. 35%, $p = .53$). Seventy one percent of physicians recommended some type of tissue analysis, 48% recommended a fine needle aspiration biopsy or core biopsy, and 32.5 % recommended open biopsy, with 8.5% proceeding to open biopsy after a negative needle biopsy result. There were no physician gender differences in biopsy recommendations.

Case 2: Stage IIA Breast Cancer

Axillary node dissection was recommended by 66.5% of physicians. Metastatic evaluation was recommended by 61% of physicians. Eighty eight percent recommended breast conserving surgery, and 83.5% recommended full primary therapy, that is, either breast conserving surgery and radiation, or mastectomy. Fifty two percent recommended tamoxifen, and 29.5% recommended chemotherapy. Seventy six percent of physicians would recommend reconstruction if the patient had a mastectomy.

Overall we found few differences by physician gender in management recommendations. Male and female physicians were similar in their rates of recommending axillary node dissection, metastatic evaluation, full primary therapy, breast conserving surgery and chemotherapy. The only difference noted was in tamoxifen use. In this clinical scenario of equivocal estrogen receptor where treatment with tamoxifen remains controversial, 60% of male physicians compared with 44% of female physicians recommended its use, ($p < 0.02$).

Multivariate models controlling for patient characteristics, and for physician geographic location, specialty, race, and years since medical school graduation did not change the findings. The only variable significant on multivariate modeling was tamoxifen use. Compared to male physicians, the odds ratio for female physicians recommending tamoxifen was 0.52 ($p = 0.04$).

2. The Role of Patient Characteristics in Physician Decision Making (See Appendix 2)

Bivariate and multivariate analyses were completed. Since significant findings did not differ between the two analyses, we report the bivariate proportions and significance values. We found that patient age did influence decision making in breast cancer care, but that patient race, economic status, mobility and comorbidities did not. In bivariate analyses, older women were less likely to be offered an axillary node dissection (47% versus 86%, $p < .001$), full primary therapy (74% versus 94%, $p < .001$), radiation (72% versus 93%, $p < .001$), chemotherapy (9% versus 51%, $p < .001$) and reconstruction (61% versus 91%, $p < .001$) than younger women. Frail women were less likely to have been offered reconstruction (68% versus 84%, $p < .01$) than agile women. Black women were more likely to be offered an axillary node dissection (74% versus 58%, $p = .02$) than were white women. No other findings were significant on bivariate analyses. Findings were unchanged in multivariate models which controlled for all patient characteristics, physician gender, experience, race, specialty and location.

3. The Role of Physician Specialty in Physician Decision Making (See Appendix 3)

Diagnostic Scenario: A Possible Breast Mass

We compared the mean estimates of the likelihood of breast cancer by physician specialty. Overall, oncologists gave a higher estimate of the likelihood of cancer for the scenario. Oncologists gave a mean probability for breast cancer of 43% compared to 33% by surgeons ($p = .002$). Seventy-eight percent of surgeons ordered some form of biopsy for the patient (including open, core or fine needle aspiration biopsy (FNAB)) versus 58% of oncologists

($p=.003$). Surgeons (56%) were specifically more likely to order a needle biopsy compared to 33% of oncologists ($p=.002$).

We found significant interactions between probability assessment, physician specialty and patient comorbidities, and mobility. Oncologists gave a higher mean cancer probability in healthy women (47%) than those with comorbidities (39%). Oncologists also gave a higher cancer probability in agile patients (53%) than frail patients (36%) ($p=.01$). Surgeons gave a higher mean cancer probability in comorbid patients (38%) than healthy patients (23%, $p < 0.01$), and at similar rates for both agile and frail patients (31% vs. 36%). Physicians did not differ in their probability assessments based upon the patients age, race, or economic status.

An interaction was noted with surgeons recommending FNAB to the 65 year old patient more often than to the 80 year old. Sixty percent of surgeons were offered FNAB for the 65 year-old patient whereas only 16% of oncologists offered needle biopsy to the same patient, while surgeons (52%) and oncologists (49%) made similar recommendation for FNAB for the 80 year old patient ($p<.01$). We also found a significant interaction between offering open biopsy and patient race, with 42% of oncologists ordered open biopsy for white patients, as compared to only 32% of surgeons. On the other hand, for the black patient, 36% of surgeons recommended an open biopsy compared to 16% of oncologists ($p=.04$). Oncologists are more likely to order an open biopsy for white patients compared with black patients, while surgeons made similar recommendations for both black and white patients. There were no significant interactions found with patient socio-economic status or health status.

Treatment Scenario: Stage IIA Breast Cancer

We found no significant differences between surgeons' and oncologists' recommendation of axillary node dissection, metastatic evaluation, full primary therapy, tamoxifen, radiation, or breast reconstruction. Fifty-one percent of oncologists offered the patient chemotherapy as compared to only 18% of surgeons ($p<.001$). Oncologists were also more likely to offer breast conserving surgery with 93% offering BCS to patients, as compared to only 85% of surgeons ($p=.02$).

We found significant interactions between physician specialty and patient age and race in adjuvant therapy recommendations. Overall when considering adjuvant therapy, 97% of oncologists offered chemotherapy or tamoxifen to the 65 year-old patient, as compared to 59% of the 80 year old patients. Surgeons offered adjuvant therapy to 72% of the 80 year old patients and only 55% of the 65 year old patients ($p<0.001$). These differences are better understood when examining separately tamoxifen and chemotherapy recommendations. Oncologists offer chemotherapy more frequently than surgeons to both 65 year old women and 80 year old women. Surgeons offer more tamoxifen to the 80 year old, with no differences between oncologists and surgeons in recommending chemotherapy to the 80 year old.

Oncologists offered full primary therapy to 93% of white patients and 79% of black patients, where surgeons offered full primary therapy 90% of black patients and only 76% of white patients ($p=.03$). Oncologists offered radiation to 90% of white patients and 77% of

black patients, while surgeons offered radiation to 92% of black patients and only 72% of white patients ($p=.02$).

There were no significant interactions found with patient socio-economic status, health status or comorbidities on any management variables for breast cancer management.

4. The Role of Geographic Variation in Physician Decision Making (See Appendix 4)

The goal of this analysis was to explore whether the findings of Nattinger et al showing geographic variation in breast conserving surgery extended to other areas of breast care management. The three geographic areas chosen for the study represented high (northern California) moderate (Michigan /Chicago) and low (southern states) utilization of breast conserving surgery in previous studies (Nattinger AB).

Our analyses confirmed the findings of Nattinger on breast conserving surgery. Breast conserving surgery recommendation rates were the lowest in the southern states (83%), higher in Michigan/Chicago (90%), and the highest in California (96%). In seven of the eight other interventions (axillary node dissection, metastatic evaluation, tamoxifen, radiation, reconstruction, open biopsy and needle biopsy) there was a pattern of highest rates in California, intermediate rates in the southern states and lowest in Michigan/Chicago. The overall effect of geographic location on the eight interventions combined was highly significant (Wilkes Lambda $p < 0.001$ from a multivariate ANOVA). Significant differences among geographic locations were found when comparing recommendations with individual modalities for metastatic evaluation ($p < 0.001$), tamoxifen use ($p < 0.03$), and breast reconstruction ($p < 0.06$). With regard to the eighth modality, chemotherapy, there were no regional differences ($p = .58$). Breast biopsy rates were 80% in California, 69% in the southern states and 53% in Michigan/Chicago ($p = 0.01$), despite the fact that the respondents in each region, on average, reported similar estimates of the probability of breast cancer.

5. The Role of Physician and Patient Characteristics in Decision Making for Breast Cancer Prevention Trials (See Appendices 5 & 6)

Recruitment to cancer trials has been a long-standing problem, with only 1.5% of women over age 50 enrolled in treatment trials. The problems are more acute when recruiting minority women to trials. The problems of trial enrollment are potentially increased for cancer prevention trials, where the population eligible for enrollment is at high risk for cancer, but not under the care of oncologists conducting the trials. We utilized the opportunity of this unique factorial design to investigate the influences of patient and physician characteristics on recommendation to enroll in the NSABP Breast Cancer Prevention Trial I, which randomized at risk women without invasive breast cancer to tamoxifen or placebo. At the end of the first scenario of a 65 or 80 year old woman presenting with a potential mass, study subjects were provided with the information that an excision biopsy revealed benign tissue without atypia. Providers were then asked a series of questions about their knowledge and attitudes towards recommending the BCPT to the patient on the videotape. 188 of the 192 subjects completed these questions.

Results indicated that over half of the physicians in this study enrolled patients in clinical trials (100/192) and 84% either enrolled or referred patients to clinical trials (162/192). The number who would refer or recommend the BCPT to the patient in the videotape, however, was much lower, 19% (35/188).

Physician and patient characteristics were associated with referral to the BCPT. Referral rates varied significantly by geographic region, with the highest rate in Michigan/Chicago, an intermediate rate in southern states, and the lowest rate in California. Referral rates also varied by specialty, with higher rates for oncologists than surgeons; and by years since medical school graduation, with recent graduates more likely to recommend the BCPT. Recommendation of the BCPT did not vary significantly by physician gender or race or by the five patient characteristics embedded in the videotaped scenarios. A multivariate model was constructed to predict recommendation of the BCPT to patients. In this model, surgeons were 25% as likely as oncologists to recommend the BCPT (95% CI of 10%-59%). Physicians in Michigan/Chicago were 6 times as likely to recommend the BCPT as physicians in California (CI 1.7-19.6). Patient age had a borderline effect with older patients less likely to receive a recommendation of BCPT (OR of .46, CI .20-1.12). Patient race, SES, mobility, health status and physician gender or race had no effects on whether BCPT was recommended to a patient.

We asked physicians their primary reasons for not referring to the BCPT. Of 101 responses, 48 felt that the patient was not at high risk for breast cancer, 25 believed that the patient was too elderly, and 13 physicians reported that they lacked information about the trial.

Potential benefits of tamoxifen were also asked of subjects. The physicians rated the potential benefits of prevention of osteoporosis, breast cancer, and coronary artery disease as less important for patients who were 80 years old than for those who were 65. Knowledge about potential preventative effects of tamoxifen was generally high: 136 (84%) indicated that breast cancer, 111 (60%) osteoporosis, and 101 (58%) cardiovascular disease were potential areas of preventive benefit of tamoxifen. Surgeons rated each of these potential preventative effects as less likely for the patient in the videotape than did the oncologists and this difference was statistically significant.

6.10 Future Analyses

Three ongoing analyses are continuing of the database, to address the following issues:

1) Physicians' attitude and decision making:

We have collected data on the following attitudes and are currently evaluating their association with physician decision making;

- Fear of malpractice scale
- Discomfort with uncertainly scale
- Reluctance to disclose uncertainty scale
- Risk taking attitudes scale

- Cost-consciousness scale
 - Attitudes towards women scale
 - Attitudes towards the elderly scale
- 2) Physicians' recommendation of and attitudes towards adjuvant therapy: chemotherapy and tamoxifen Given the significant variability of physician decision making about adjuvant therapy including both tamoxifen and chemotherapy, and the association of these specific variables with physician gender, geographic location, and specialty, and patient age, we wished to explore the reasons for these differences further. We are currently analyzing the data collected on reasoning to better understand these differences.

7.0 KEY RESEARCH ACCOMPLISHMENTS

1. First random sample of oncologists and surgeons with sufficient female providers to conduct comparison of differences in breast cancer care by physician gender.
2. Sample of three geographically diverse areas of USA allows for geographic variability analysis, and also allows for increase generalizability of the findings.
3. First factorial design to assess independently the effect of physician characteristics, and patient characteristics from physician gender in decision making.
4. Physician gender is not an important determinant of physician decision making in breast cancer care
5. Patient age is an important factor in physician decision making, with older patients receiving less aggressive care.
6. Patient race and economic status are not predictors of less aggressive care, and if anything; physicians appear to report more aggressive care to African-American patients.
7. Patient mobility and comorbidity were not associated with major differences in management recommendations.
8. Physician specialty training has a profound effect on decision making, with provider more likely to recommend modalities within their own field of expertise.
9. A consistent geographic pattern of breast cancer care was noted that extended across most therapeutic modalities.

10. Specialist providers are unlikely to recommend a cancer prevention trial. Even in a group with extensive experience of recommending, recruiting, and enrolling patients to therapeutic trials, prevention trials were not recommended.

8.0 REPORTABLE OUTCOMES

- 8.1 We have one manuscript in press and 5 in preparation.

Freund KM, Mancuso M, Petros JA, Wasserheit C, Roberson, NJ, Bennett J, Urban SY, Garber S. Preliminary research for the healthcare system: health care providers. National Cancer Institute Monograph on Recruitment of Women and Minorities into Cancer Prevention Trials. Annals Epid. 1999, in press.

- 8.2 We have made --- presentations of our data at 5 professional meetings:

- 1) American Association for Cancer Education, October 1997, Atlanta, Georgia.
Oral presentation, entitled, Physician Attitudes towards Cancer Prevention Trials.
- 2) Department of Defense Breast Cancer Research meeting, November 1997.
Poster presentation, entitled: Breast Cancer Care: Does Physician Gender Matter?
- 3) Society of General Internal Medicine, April 1998.
Poster presentation entitled: Breast Cancer Care: Does Physician Gender Matter?
- 4) Society of General Internal Medicine, May 1999.
Poster presentation entitled: Patient Sociodemographic Characteristics Influence Breast Cancer Treatment by Physicians
- 5) Society of General Internal Medicine, May 1999.
Poster presentation entitled: Differences between Surgeons and Oncologists in Breast Cancer Management
- 6) Association of Health Services Research, June 1998. Oral presentation entitled: Geographic Variation in breast Cancer Management.

- 8.3.1 Additional Funding based upon this award

Dr. Freund received a two year R03 from the NCI (R03 73297) of \$173,685. entitled *Prevention trial recruitment: patient and doctor factors*. The goals of the research was to extend the work on physician attitudes towards prevention trials, and survey primary

care providers, using a written survey with the same clinical content as the videotape scenario.

Ms. Ali Ordonez, first year medical student at University of Pittsburgh, received an \$8,000 student research award from her home institution to complete an analysis of the patient attitudes scales (see 6.6.2 Future Analyses) to be conducted 6/15 99 through 8/30/99.

Based in part on the expertise developed during this award, Dr. Freund received a 5 year contract from the Massachusetts Department of Public Health for \$500,000. Entitled *Breast and Cervical Cancer Training Institute*. The goal of the contract is to develop a statewide training institute to train health care professionals on breast and cervical cancer screening and management issues.

9 CONCLUSIONS

The research findings shed new light on the role non-medical factors play in how physicians make decisions in breast cancer care. It should be noted before focusing on the highlights of our research and their clinical and policy implications, that our study did not seek to address appropriateness of care. We specifically developed clinical scenarios lacking in data to establish a specific course of therapy as the most appropriate. However, within this setting, we can discuss how non-medical factors influence the type of clinical decisions made, and how extensive or aggressive care recommendations are based upon physician and patient characteristics.

1. Physician Gender

Given the extensive literature on physician gender differences in breast cancer screening, with multiple studies showing that women provide physicians provide more screening than their male counterparts, we were interested in the role of physician gender in breast cancer management. We found very few differences in breast cancer management by physician gender. We conclude that in specialties such as oncology and surgery, where there are still relatively few women providers, few gender differences exist in clinical breast cancer care.

2. Patient Characteristics

Our data support previous work that documents that older women received less extensive and less aggressive care for breast cancer. Our study is unique in its ability to control for comorbidity and for disability, and yet found persistent differences in care to older women. Despite the fact that studies indicate that the care to the elderly and their ability to benefit from care depends upon functional status and comorbidity, we could not demonstrate that these criteria are routinely used in clinical practice. Interventions to change physician perceptions about

caring for elderly women with breast cancer could have a profound impact in this group of women with the highest breast cancer incidence and mortality.

Unlike a recently published article (Schulman KA, 1999) demonstrating a 5% differences in cardiac catheterization by patient race using a similar methodology, we found that neither race nor economic status were associated with physician decision making. If anything, the findings support that when controlling for other variables, physicians treat African American women more aggressively, perhaps in part due to the known differences in breast cancer mortality by race.

3. Physician Specialty

We found in our data profound differences in decision making based on physician specialty. Surgeons appear more likely to recommend needle biopsies, and mastectomies, and oncologists appear more likely to recommend breast conserving surgery, radiation and chemotherapy. This would suggest that the type of treatment recommended to women might be most strongly influenced by the provider that women see. Further clinical investigation of the benefit of multi-disciplinary teams or second opinions from another specialty on treatment recommendations would be of value in addressing the policy issues of which specialty groups are best trained to provide the most appropriate therapeutic recommendations.

Further work on the interaction findings would also be of benefit. The interaction effects suggest that surgeons offer less aggressive care to elderly women, and that oncologists offer less aggressive care options to black women. Further work to validate these exploratory findings and their significance will be of benefit.

4. Geographic Variability

Our work found a persistent geographic variability in breast cancer care across multiple modalities of care, including biopsy, axillary node dissection, metastatic evaluation, tamoxifen use, and breast reconstruction. Our findings were consistent with previous work done using secondary administrative datasets, lending further validity to our methodology.

5. Physician Decision Making regarding Breast Cancer Prevention Trials

We utilized this opportunity to investigate physician decision making around cancer prevention trials. Our study group of physicians had extensively involvement in enrolling into treatment trials, but less than 20% would recommend the patient in the videotape to the cancer prevention trial. Physician specialty and geographic location were association with trial recommendations, and suggest avenues to explore in improving trial recruitment issues.

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11. APPENDICES

13. FINAL REPORTS:

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1. Freund KM, Mancuso M, Ash A, Scaramucci A, Burns RB, Moskowitz MA. The Role of Physician Gender in Decision-Making for Breast Cancer Care
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Abstracts

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2. Freund KM, Mancuso M, Ash A, Scaramucci A, Burns RB, Moskowitz MA. Breast Cancer Care: Does Physician Gender Matter? J Gen Intern Med 1998;13(Suppl 1):118.
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Appendix 1

**BREAST CANCER CARE:
DOES PHYSICIAN GENDER MATTER?**

Poster presentations

Department of Defense Breast Cancer Research meeting
November 1997

Society of General Internal Medicine
April 1998

BREAST CANCER CARE: DOES PHYSICIAN GENDER MATTER?

Karen M Freund, Michelle Mancuso, Arlene A Ash,
Amy Scaramucci , Risa B Burns, Mark A Moskowitz

Section of General Internal Medicine
Boston University Medical Center, Boston, MA

Recent studies have suggested that female physicians provide more complete preventive care for breast cancer; it is unknown if physician gender plays a role in care after breast cancer is diagnosed. We examined this issue using a factorial experimental design. Oncologists and surgeons were asked to view a 5-minute videotape of a woman presenting with stage IIA breast cancer and equivocal estrogen receptors. Sixteen versions of the videotape were professionally produced using actresses and holding all the clinical features of the case constant. Each physician viewed one of 16 versions of the scenario, where we systematically varied the patient's age (65 vs. 80 years), race (black vs. white), socioeconomic status (high vs. low) comorbidities (none vs. diabetes and hypertension), and mobility (agile vs. frail). Male and female physicians were randomly selected from 3 geographic areas and asked their management recommendations for the case viewed. Chi square analyses of 2X2 tables and Breslow-Day tests of homogeneity were performed.

We report an interim analysis, based on 91 female and 78 male physicians, 88% of the planned sample. Physicians provided different recommendations for older and younger patients. The older women were less likely to have recommended an axillary node dissection (48% vs. 85%), chemotherapy (9% vs. 54%), full primary therapy (76% vs. 92%) and reconstruction following mastectomy (62% vs. 90%), (all p 's < 0.05). Male and female physicians differed in their recommendation for tamoxifen, where 44% of women vs. 65% of men recommended tamoxifen ($p < 0.01$). Interactions were noted when comparing male and female physicians' use of adjuvant therapy for older women. Whereas both male and female physicians offered chemotherapy less often to older women, women physicians provided this recommendation more often than the male physicians to the older patients (13% vs. 5%, one-tailed Fisher exact test, $p = .15$). While overall rates of breast reconstruction were similar for male and female physicians, female physicians were more likely to offer this option to healthy women (90%) compared to their male counterparts (70%, $p = .02$).

Our data support other studies that indicate older women receive less aggressive therapy, including axillary node dissection, primary therapy, reconstruction and chemotherapy. Male physicians recommend higher rates of tamoxifen in a situation of equivocal estrogen receptors. Female physicians appear to recommend more aggressive therapy to older women and women without comorbidities.

Breast Cancer Care: Does Physician Gender Matter?

KM Freund, M Mancuso, AS Ash,
A Scaramucci, EP McCarthy, MA Moskowitz

Section of General Internal Medicine, Boston Medical Center

Funded by the Department of Defense
Breast Cancer Research Program

Background

- Women receive less aggressive treatment for cardiac, renal, and cerebrovascular disease
- Female physicians offer screening procedures more frequently to women than male physicians
- Little data on whether female and male physicians differ on treatment decision-making for women patients

Aim

To determine if female and male physicians offer different treatment for breast cancer

Methods

Videotape Clinical Scenario

- Patient-Physician Interview
- Scripted, professionally acted
- Patient with stage IIA breast cancer (tumor size 0.8 cm, 2/29 lymph nodes positive, +/- estrogen receptors)
- Physicians asked to state treatment preferences

Experimental Design

- Fractional factorial design
- 16 versions of scenario
- Each physician viewed only 1 version
- Permits simultaneous evaluation of a number of variables

Experimental Design (cont.)

- Five dichotomous patient characteristics

Race	Caucasian	Vs.	African-American
Age	65 years	Vs.	80 years
SES	Low	Vs.	High
Mobility	Agile	Vs.	Frail (uses walker)
Comorbidity	Healthy	Vs.	Diabetes/HTN

- $2^5=32$ combinations of 5 characteristics
- Balanced set of 16 “characters” selected for videotapes

Subjects

- Oncologists and Surgeons
- Matched design
 - Gender
 - Year of Graduation
 - Geographic location
 - Northern California
 - Southern States
 - Michigan/Chicago

Outcome Variables

- Physicians' reported treatment preferences
 - Axillary node dissection
 - Metastatic evaluation
 - Full primary therapy
 - Use of breast conserving surgery
 - Use of tamoxifen
 - Use of chemotherapy
 - Offer breast reconstruction

Data Analysis

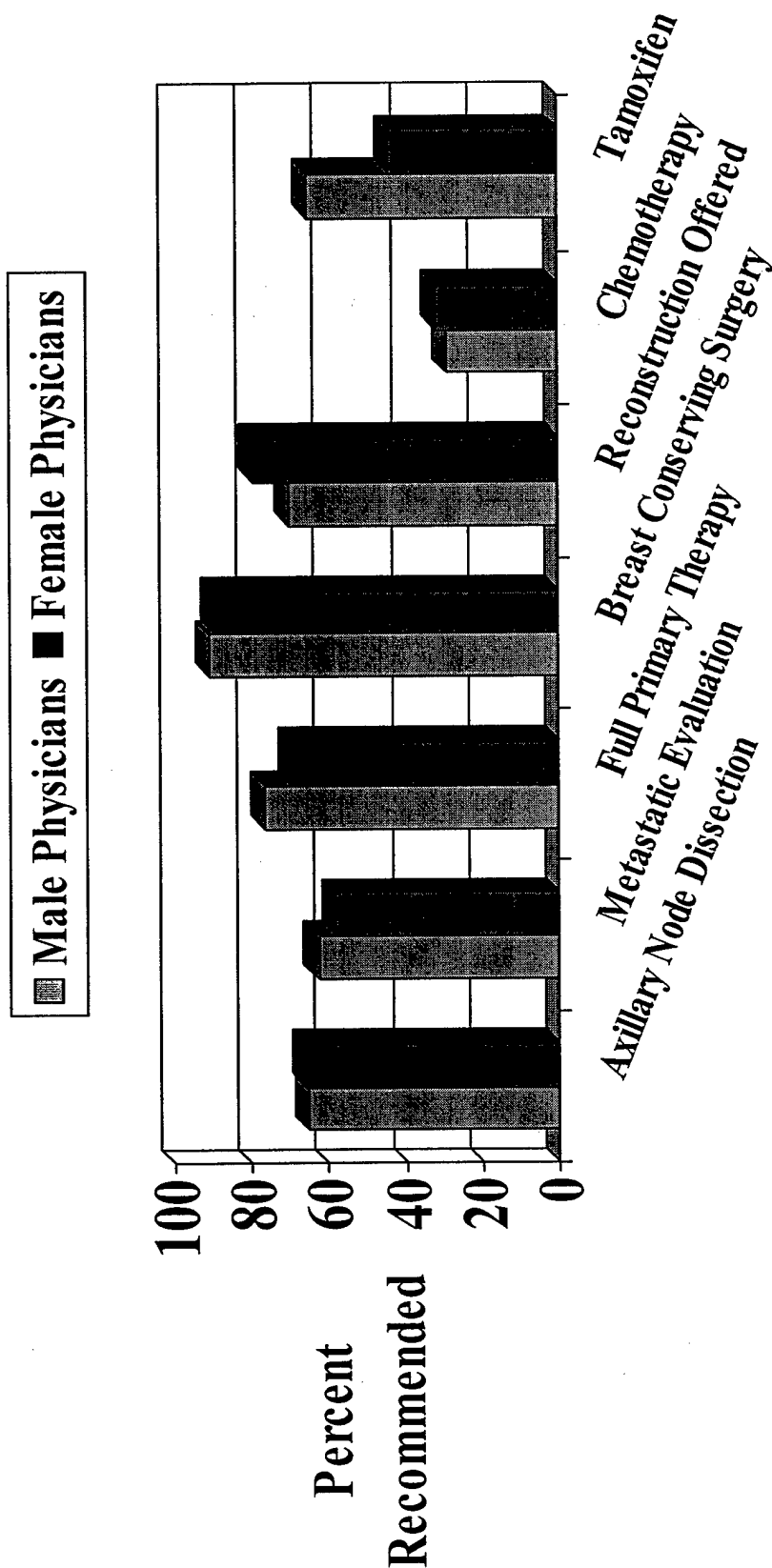
- Bivariate and stratified analyses to test whether male and female physicians differ on treatment decision making

Results

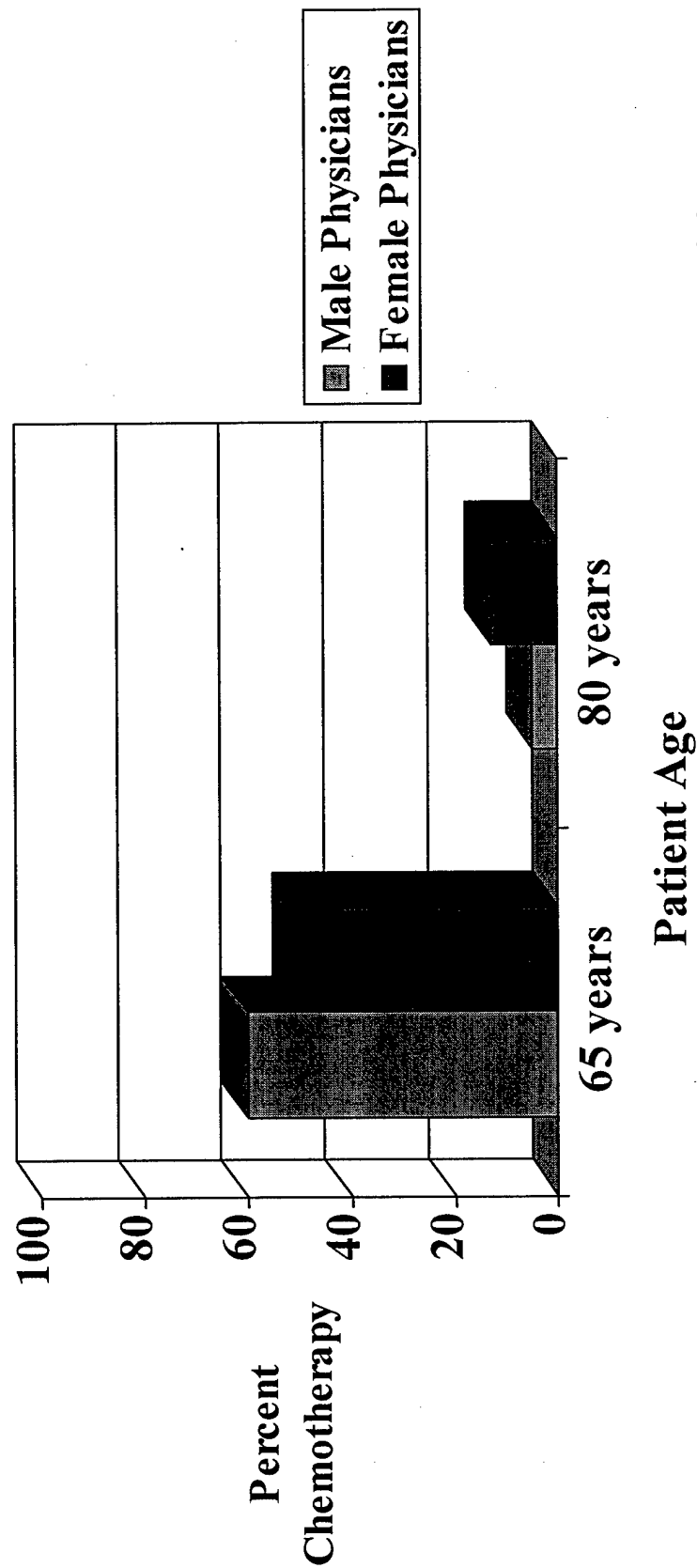
Physician Characteristics (N=169)

Gender	
Male	46%
Female	54%
Specialty	
Oncologist	37%
Surgeon	63%
Location	
Northern California	32%
Southern States	32%
Michigan/Chicago	36%
Mean Age	44 years

Gender Differences in Breast Cancer Treatment

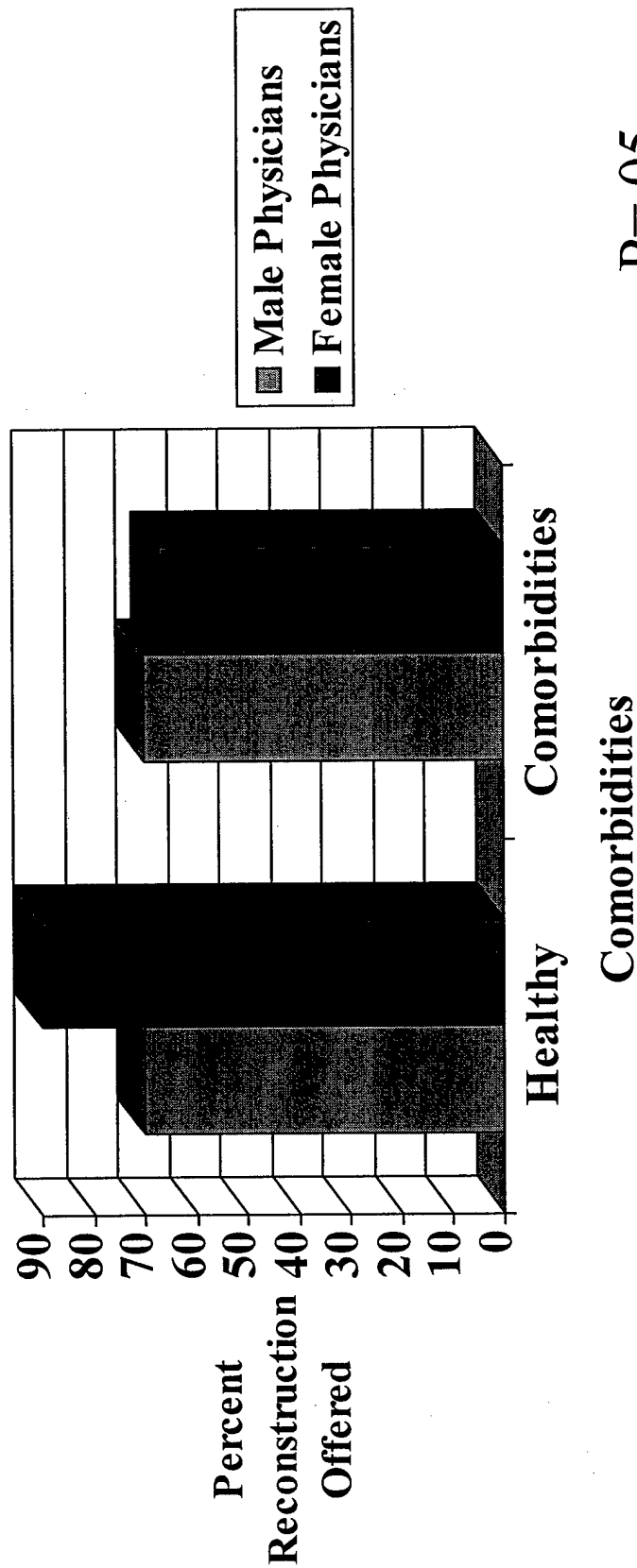


Interaction between Physician Gender and Patient Age in offering Chemotherapy



P=.09

Interaction between Physician Gender and Patient Comorbidity in offering Breast Reconstruction



Conclusions

- In contrast to breast cancer screening, female and male physicians exhibit few differences in treatment decision-making for breast cancer
- Male physicians report greater use of tamoxifen

Conclusions

- Female physicians are more likely to recommend chemotherapy to older women
- Female physicians offer more breast reconstruction, especially to women without comorbidities

Appendix 2

**PATIENT SOCIODEMOGRAPHIC CHARACTERISTICS
INFLUENCE BREAST CANCER TREATMENT BY PHYSICIANS**

Poster presentation

Society of General Internal Medicine
May 1999

PATIENT SOCIODEMOGRAPHIC CHARACTERISTICS INFLUENCE BREAST CANCER TREATMENT BY PHYSICIANS

Renee D Boss, Michelle Mancuso, Amy Scaramucci, Arlene Ash,
Mark A Moskowitz, Karen M Freund

Section of General Internal Medicine, Boston Medical Center, Boston, MA

Documented disparities in breast cancer outcomes by patient sociodemographic characteristics have been partially attributed to compromised access to care. It is yet uncharacterized how a patient's sociodemographic characteristics might influence physician decision making for patients within the healthcare system.

Oncologists and surgeons were asked to view two 5-minute videotapes, one of a patient presenting with a possible breast mass and one of a woman with stage IIA breast cancer. Sixteen versions of each videotape were professionally produced using actresses and holding all the clinical features of the case constant. Each physician viewed one of 16 versions of each scenario, as specified by a factorial design, where we systematically varied the patient's age (65 vs. 80 years), race (black vs. white), socioeconomic status (high vs. low), comorbidities (none vs. diabetes and hypertension), and mobility (agile vs. frail). Each of 192 physicians were randomly selected from 3 areas across the United States and asked their management recommendations for the cases viewed. Chi square analysis of 2X2 tables and Breslow-Day tests of homogeneity were performed.

Older women were less likely than younger women to be offered an axillary node dissection (47% versus 86%, $p < .01$), full primary therapy (74% versus 94%, $p < .01$), radiation (72% versus 93%, $p < .01$), chemotherapy (9% versus 51%, $p < .01$) and reconstruction (61% versus 91%, $p < .001$). Frail women were less likely than agile women to be offered a biopsy (64% versus 78%, $p = .03$) and reconstruction (68% versus 84%, $p = .02$). Women with comorbidities were less likely than healthy women to be offered reconstruction (71% versus 82%, $p = .08$). Black women were more likely than were white women to be offered an axillary node dissection (74% versus 58%, $p = .02$).

Despite identical clinical presentation physicians' management decisions varied significantly in association with patients' sociodemographic characteristics. Controlling for patient characteristics, factors which have confounded previous estimates of treatment variability, such as comorbidities and frailty, older women were less likely to be offered complete staging, primary therapy, chemotherapy and reconstruction.

BACKGROUND

- If a woman with breast cancer is elderly, African American or of lower Socio-economic status, she has less favorable outcomes than does a woman with breast cancer who is middle age, Caucasian or of higher Socio-economic status.

AIMS

- To evaluate the independent and joint influences of patient race, age, socioeconomic status, comorbidity and frailty on the diagnosis, treatment and recommendations for suspected and diagnosed breast cancer.

METHODS

Physicians were asked to view a videotaped clinical scenario

CLINICAL SCENARIO

- 5-minute videotape of office encounter
- Professionally acted, clinical information uniform
- 16 versions of each scenario allowed us to maintain identical clinical information while systematically varying the patients race, age, SES, comorbidity and frailty
- After viewing videotape, subjects were interviewed about their treatment preferences for the "patient"

CLINICAL INFORMATION

Patient presents with stage IIA breast cancer (T1 N1 M0)

- Tumor size 0.8 cm
- 2/29 lymph nodes positive
- +/- Estrogen receptors

METHODS (cont.)

EXPERIMENTAL DESIGN

- Fractional factorial experiment
- Permits simultaneous evaluation of patient characteristics
- Five dichotomous patient characteristics

Race	Caucasian	vs.	African-American
Age	65 years	vs.	80 years
SES	Low	vs.	High
Mobility	Agile	vs.	Frail (uses walker)
Comorbidity	Healthy	vs.	Diabetes/HTN

- $2^5 = 32$ combinations of 5 characteristics
- Balanced set of 16 "characters" selected for videotapes

SUBJECTS

- Oncologists and surgeons, active in clinical care
- Random sample obtained from Boards of Registration
- Matched design
 - Gender
 - Year of Graduation from Medical School (+/-10 years)
 - Geographic location
 - San Francisco area
 - Atlanta area
 - Detroit area

METHODS (cont.)

OUTCOMES

- Physicians reported treatment preferences
 1. Axillary node dissection
 2. Metastatic evaluation
 3. Full primary therapy (mastectomy or lumpectomy+XRT)
 4. Use of breast conserving surgery
 5. Use of tamoxifen
 6. Use of chemotherapy
 7. Offer breast reconstruction

DATA ANALYSIS

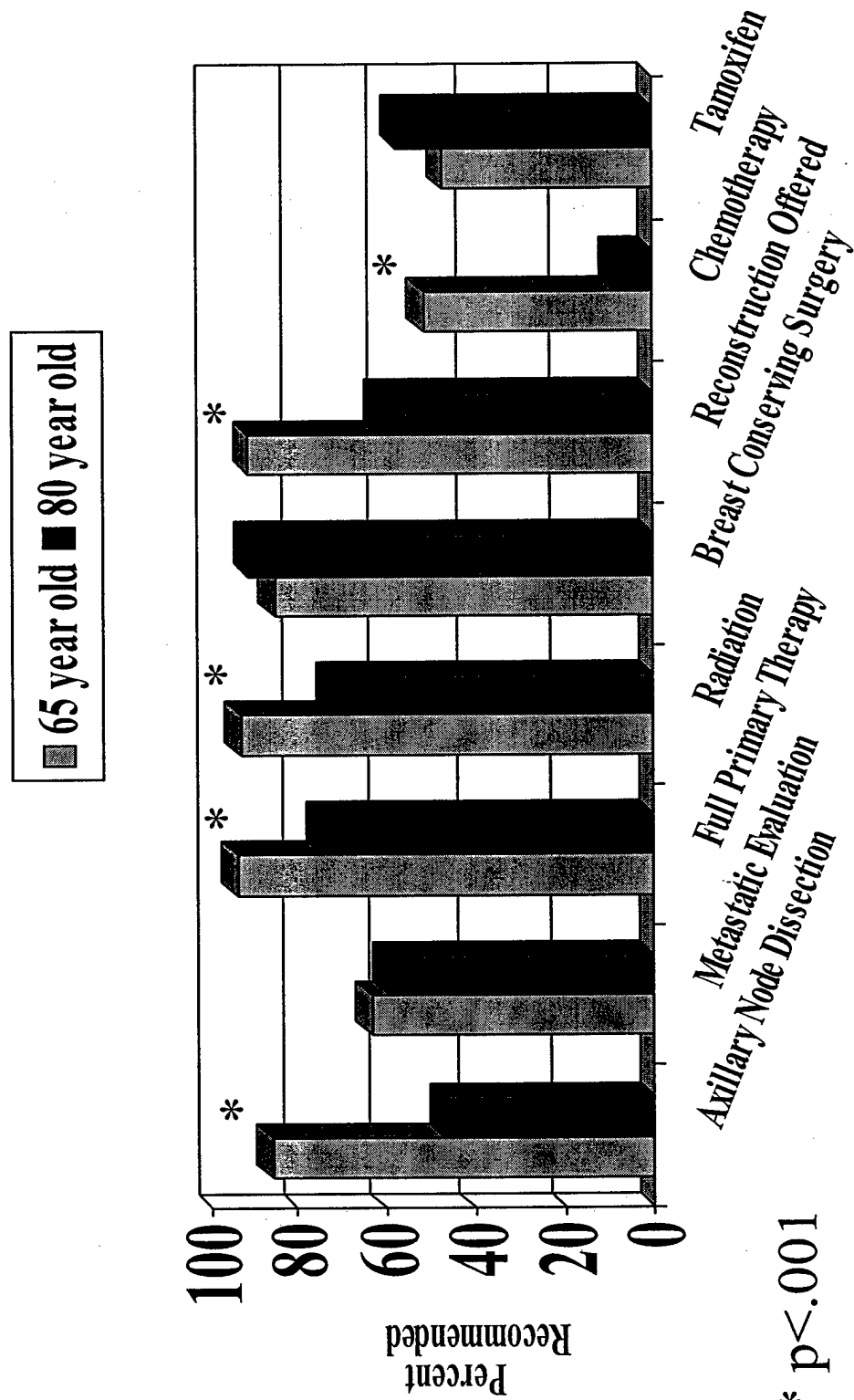
- Bivariate analyses to examine main outcomes by patient characteristics
- Significance defined as $p < .05$ for main outcomes
- Multivariable logistic regression models were used to assess the independent effect of patient characteristics, controlling for physician characteristics
- Bivariate and multivariate results were identical; bivariate percentages presented here.

Results

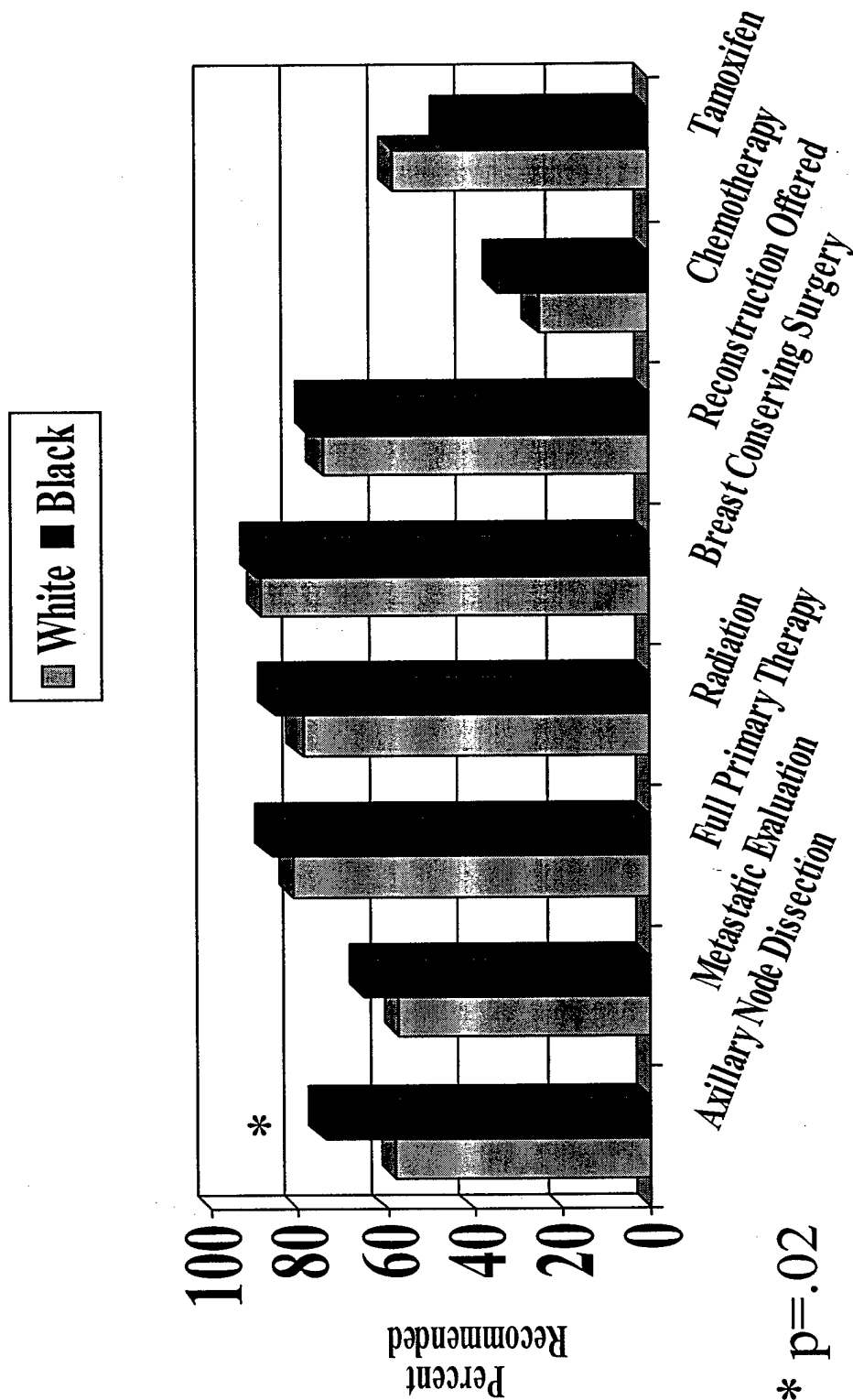
Physician Characteristics (N=192)

Gender	
Male	50%
Female	50%
Specialty	
Oncologist	36%
Surgeon	64%
Location	
San Francisco area	33.3%
Atlanta area	33.3%
Detroit area	33.3%
Mean Age	43 years

Breast Cancer Treatment Recommendations by Patient Age



Breast Cancer Treatment Recommendations by Patient Race



SUMMARY

- The older patients were less likely to have been recommended axillary node dissection, full primary therapy, radiation, chemotherapy and breast reconstruction.
- Adjusting for other patient factors we did not find that low income or African American women received less aggressive recommendations. In fact, physicians were more likely to perform an axillary node dissection on African American women, compared with Caucasians.
- Physicians' recommendations for treatment did not differ by patient socio-economic status, frailty or comorbidities.

CONCLUSIONS

- Despite the standardized clinical scenario holding comorbidity, mobility, and SES constant, older women were offered less aggressive management.
- There were no differences in breast cancer treatment recommendations based on patient race.
- Low survival among older women may be due in part to physician decision-making resulting in less aggressive care.

Appendix 3

**DIFFERENCES BETWEEN SURGEONS AND ONCOLOGISTS
IN BREAST CANCER MANAGEMENT**

Poster presentation

Society of General Internal Medicine
May 1999

DIFFERENCES BETWEEN SURGEONS AND ONCOLOGISTS IN BREAST CANCER MANAGEMENT.

Michelle Mancuso, Amy Scaramucci, Arlene Ash, Renee Boss,
Mark A Moskowitz, Karen M Freund,

Section of General Internal Medicine, Boston Medical Center, Boston, MA

Previous work has documented substantial variation in breast cancer management. We asked physicians how they would manage patients in videotaped clinical scenarios, in order to examine the influence of physician specialty (surgery and medical oncology) on the diagnosis and treatment of breast cancer.

Oncologists and surgeons were asked to view two 5-minute videotapes, the first of a woman presenting with a possible breast mass and the second of a woman presenting with stage IIA breast cancer and equivocal estrogen receptors. Both scenarios are without clear guidelines for management. Sixteen versions of each videotape were professionally produced using actresses and holding all the clinical features of the case constant. Each physician viewed one of 16 versions of each scenario as specified by a factorial design, where we systematically varied the patient's age (65 vs. 80 years), race (black vs. white), socioeconomic status (high vs. low), health status (no comorbidities vs. diabetes and hypertension), and mobility (agile vs. frail). A total of 192 physicians, 96 male and 96 female surgeons and medical oncologists, randomly selected from 3 areas across the United States, were asked their management recommendations for the case viewed. Chi square analyses of 2X2 tables and Breslow-Day tests of homogeneity were used to test for differences by physician specialty.

When evaluating a possible breast mass we found oncologists gave higher estimates of the probability of cancer than surgeons (43% v. 33%, $p=.009$). However, surgeons were more likely than oncologists to perform a biopsy (78% v. 58%, $p=.003$), and specifically more likely to perform needle biopsies (56% v. 33%, $p=.002$). When recommending a management plan for a stage IIA breast cancer, oncologists were more likely to perform axillary node dissection (75% v. 61%, $p=.04$), and to recommend adjuvant therapy (78% v. 66%, $p=.07$). Oncologists were more likely than surgeons to recommend chemotherapy (51% v. 18%, $p<.001$), while surgeons were marginally more likely to recommend tamoxifen (57% v. 43%, $p=.07$). We also found significant interactions between the physician's specialty and their recommendations depending on the patients' age, health status, and mobility.

Physician specialty influenced the evaluation and treatment of breast cancer. In evaluation, oncologists estimate a higher likelihood of breast for the patient, while surgeons are more likely to recommend and perform biopsies. In treatment, oncologists are more likely to recommend complete staging and chemotherapy than surgeons, while surgeons are more likely to recommend the use of tamoxifen.

BACKGROUND

- Previous research demonstrates wide physician variation in the management of breast cancer
- These observational studies are not adjusted for case mix and differences in case presentation

AIMS

Using a set of standardized clinical patient vignettes:

- To determine if surgeons and oncologists differ in treatment and evaluation of breast cancer
- To determine if patient characteristics modify management and treatment by physician specialty

METHODS

PHYSICIANS VIEWED TWO VIDEOTAPED CLINICAL SCENARIOS

Clinical Scenarios

- Professionally acted, clinical information uniform
- 5-minute videotape of office encounter
- Two separate scenarios: diagnostic and treatment
- Structured interview where physicians were asked to state treatment preferences after viewing videotapes

Diagnostic Scenario

- Patient presents with a possible breast mass
 - Non-discrete thickening on Clinical Breast Exam
 - Negative mammogram

Treatment Scenario

- Patient presents with stage IIA breast cancer (T1 N1 M0)
 - Tumor size 0.8 cm
 - 2/29 lymph nodes positive
 - +/- Estrogen receptors

METHODS (con't)

EXPERIMENTAL DESIGN

- Fractional factorial experiment
- Permits simultaneous evaluation of a number of patient characteristics
- Five dichotomous patient characteristics

Race	Caucasian	vs.	African-American
Age	65 years	vs.	80 years
SES	Low	vs.	High
Mobility	Agile	vs.	Frail (uses walker)
Comorbidity	Healthy	vs.	Diabetes/HTN
- $2^5 = 32$ combinations of 5 characteristics
- Balanced set of 16 "characters" selected for videotapes

SUBJECTS

- Random sample obtained from Boards of Registration
- Matched design
 - Gender
 - Year of Graduation from Medical School (+/-10 years)
 - Geographic location
 - San Francisco area
 - Atlanta area
 - Detroit area

METHODS (con't)

OUTCOMES - DIAGNOSTIC SCENARIO

- Physician reported estimate of cancer probability
- Physician reported treatment preferences
 1. Open Biopsy
 2. Needle Biopsy
 3. Any Biopsy (Open or Needle)

OUTCOMES - TREATMENT SCENARIO

- Physician reported treatment preferences
 1. Axillary node dissection
 2. Metastatic evaluation
 3. Full primary therapy (mastectomy or lumpectomy+XRT)
 4. Use of breast conserving surgery
 5. Use of tamoxifen
 6. Use of chemotherapy
 7. Offer breast reconstruction

DATA ANALYSIS

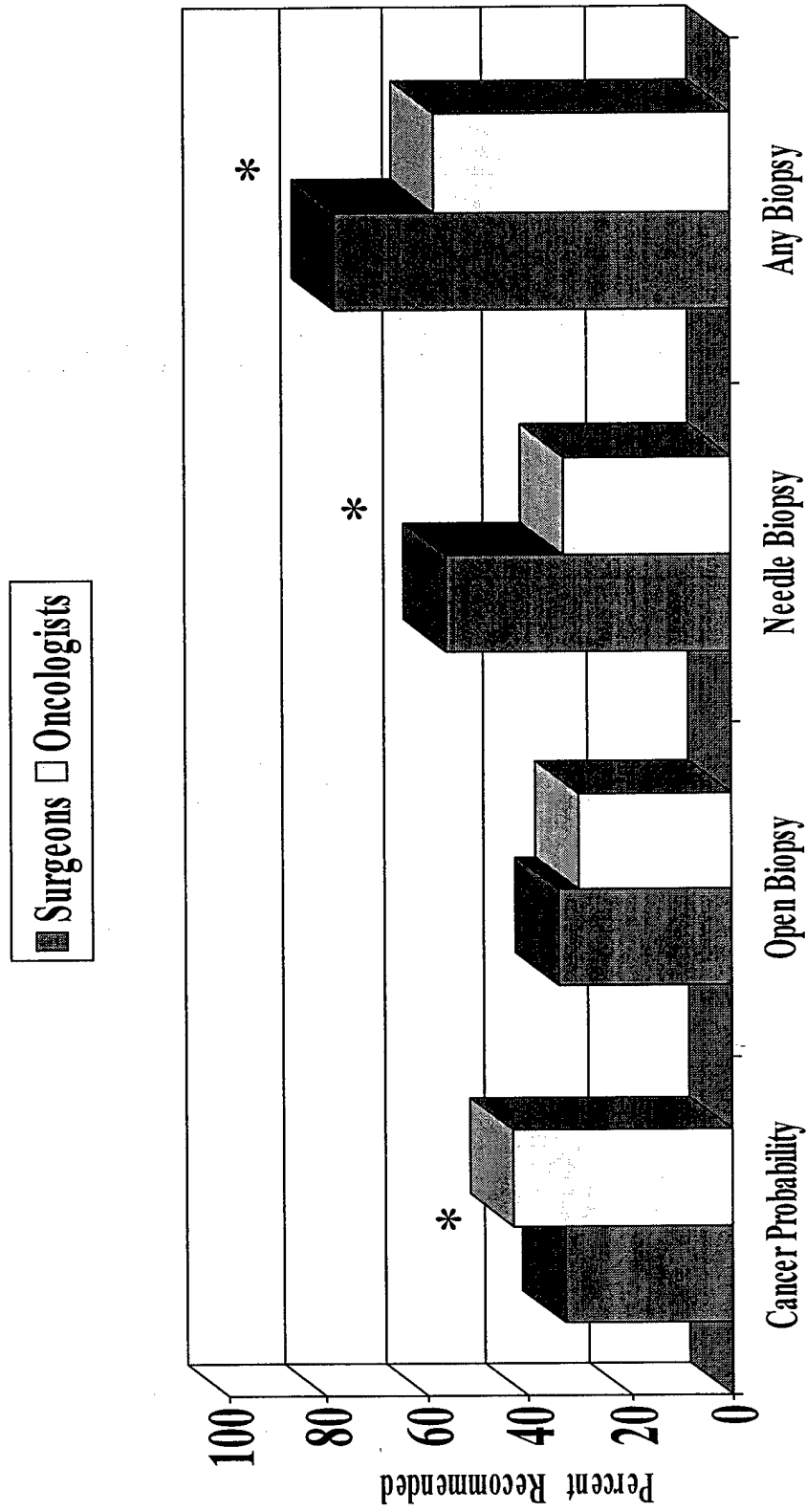
- Bivariate analyses to examine main outcomes by physician specialty
- Two-way interactions of physician specialty by patient characteristics
- Chi square analysis of 2X2 tables and Breslow-Day tests of homogeneity were performed
- Significance defined as: Bivariate analysis: $p < .01$ for main outcomes, $p < .05$ for interaction effects
- Multivariable logistic regression models were used to assess the independent effect of patient characteristics, controlling for physician characteristics

Results

Physician Characteristics (N=192)

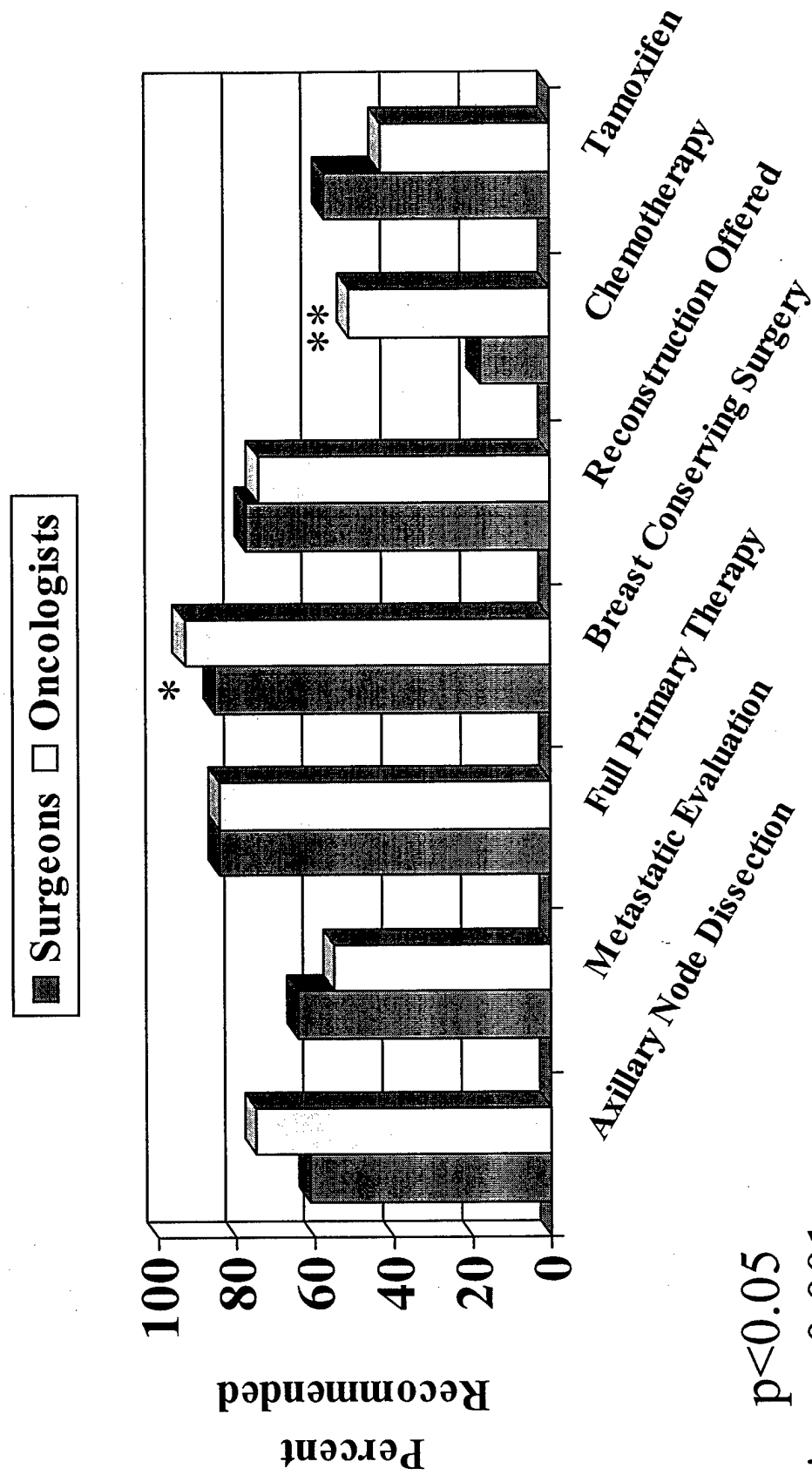
Gender	
Male	50%
Female	50%
Specialty	
Oncologist	36%
Surgeon	64%
Location	
San Francisco area	33.3%
Atlanta area	33.3%
Detroit area	33.3%
Mean Age	43 years

Differences in Evaluation of Breast Cancer by Physician Specialty *Diagnostic Scenario*



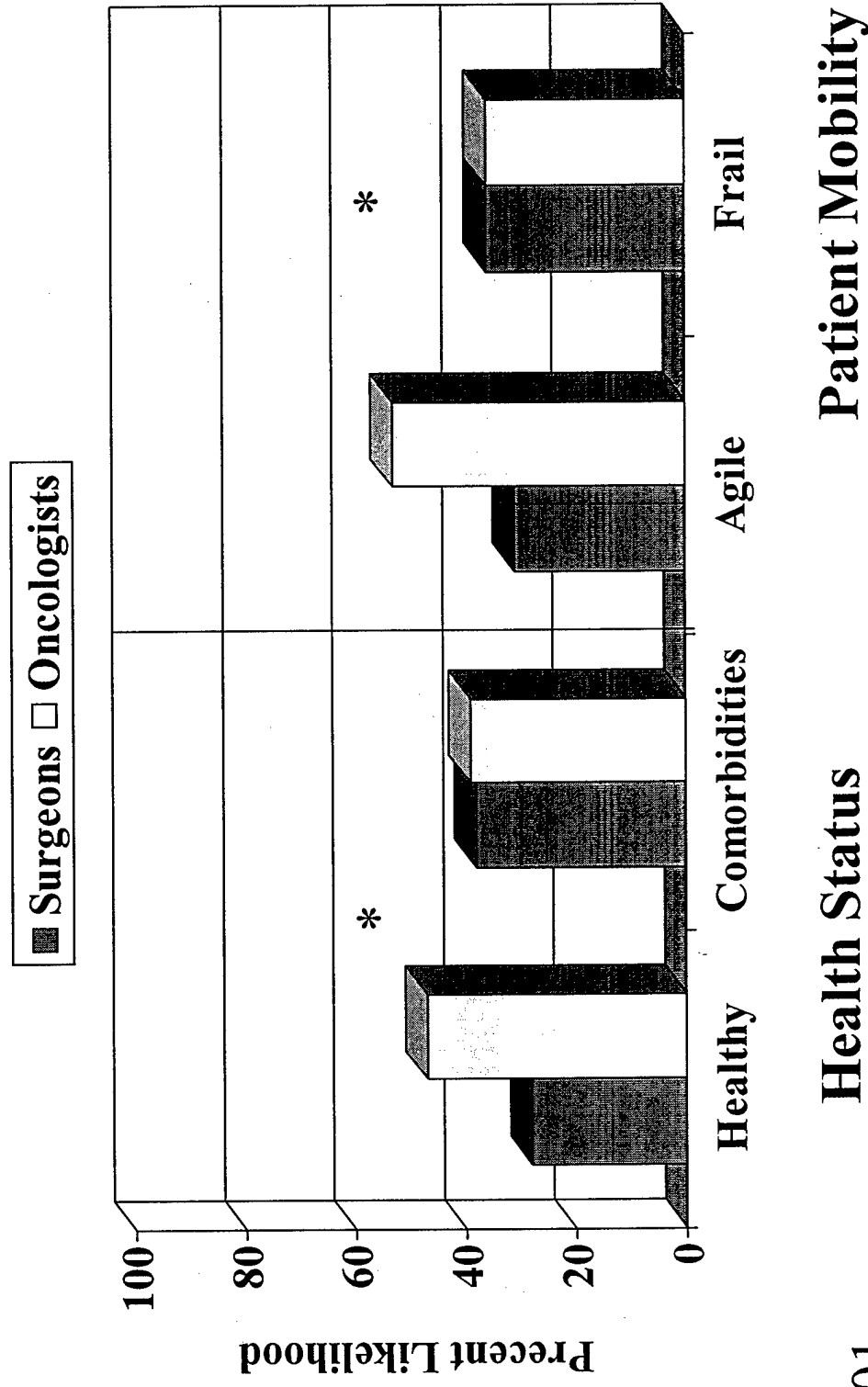
* $p < 0.01$

Differences in Treatment of Breast Cancer by Physician Specialty *Treatment Scenario*



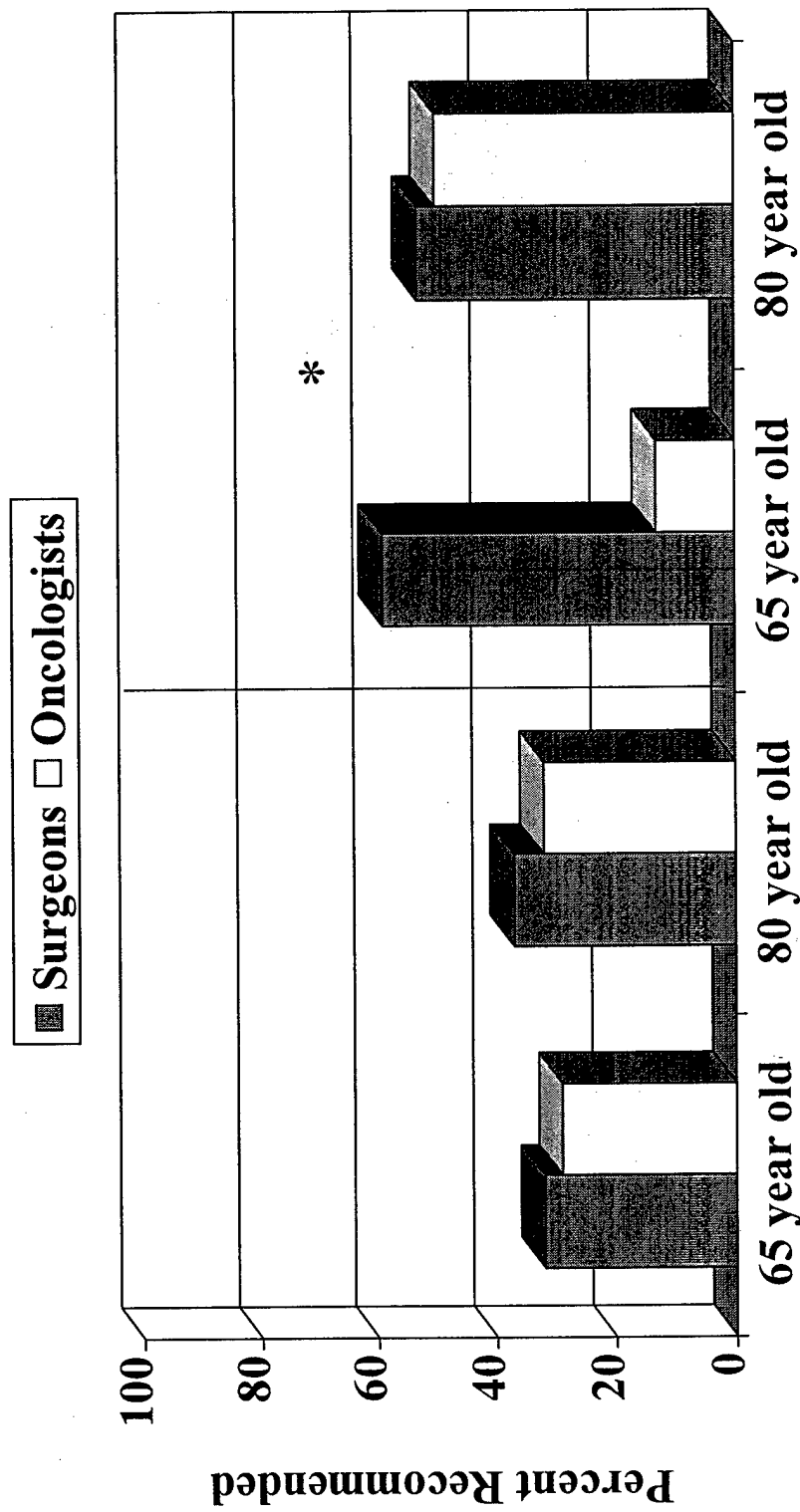
* $p < 0.05$
 ** $p < 0.001$

Interaction between Physician Specialty and Patient Health Status and Mobility in Assessing Cancer Probability



* p<0.01

Interaction between Physician Specialty and Patient Age in Recommending Biopsy

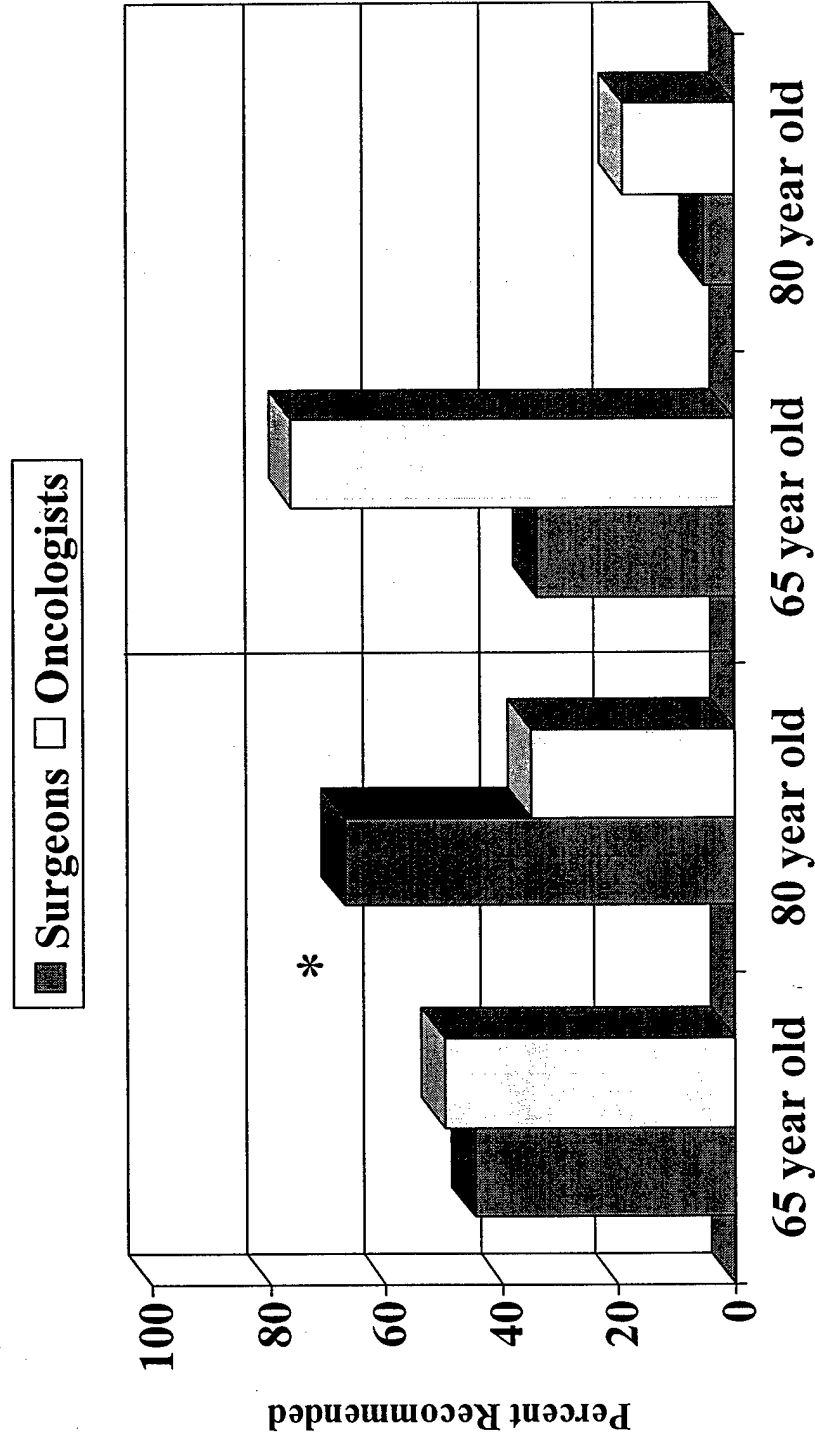


Needle Biopsy

Open Biopsy

* $p < 0.01$

Interaction between Physician Specialty and Patient Age in Use of Adjuvant Therapy

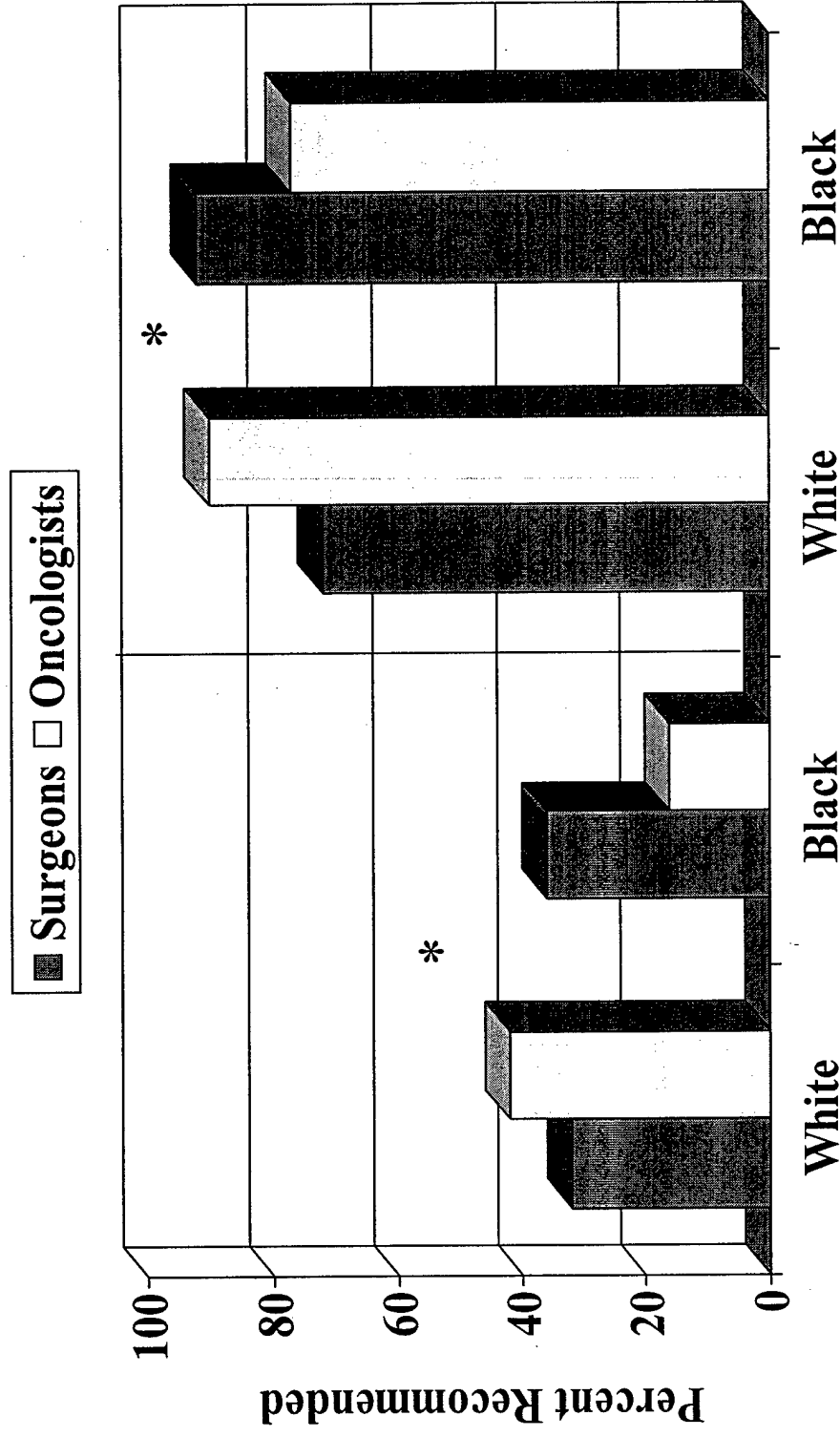


* $p < 0.05$

Tamoxifen

Chemotherapy

Interaction between Physician Specialty and Open Biopsy and Full Primary Therapy and Patient Race



Open Biopsy Full Primary Therapy

* $p < 0.05$

SUMMARY

FOR A CASE WITH EQUIVOCAL BREAST MASS

- Medical Oncologists gave a higher estimate of breast cancer for women overall, especially for healthy and agile women when compared with surgeons
- Despite the differences in cancer probability estimates, surgeons and medical oncologists recommended open biopsy in similar proportions, while surgeons recommended needle biopsy more frequently, especially for younger women and those with comorbidities

FOR A CASE of STAGE IIA (T1 N1 M0)

Medical Oncologists recommend more:

- 1) Axillary node dissections
- 2) Chemotherapy
 - Especially to patients with comorbidities

Surgeons recommend more:

- 1) Tamoxifen (in the case of equivocal estrogen receptors)
 - Especially to older patients
- 2) Full primary therapy to African-American women

Appendix 4

GEOGRAPHIC VARIATION IN BREAST CANCER MANAGEMENT

Poster Presentation

Health Services Research Administration
June 1998

GEOGRAPHIC VARIATION IN BREAST CANCER MANAGEMENT

Amy Scaramucci, MPH, Michelle Mancuso, BA, Arlene Ash, PhD, Renee Boss, BA, Mark A. Moskowitz, MD, Karen M. Freund, MD, MPH.

Section of General Internal Medicine, Boston Medical Center, Boston, MA

Research Objectives: Previous research using claims data has demonstrated geographic variation in breast conserving surgery. We wished to examine if there is geographic variation across a variety of breast cancer diagnostic and treatment modalities for older women.

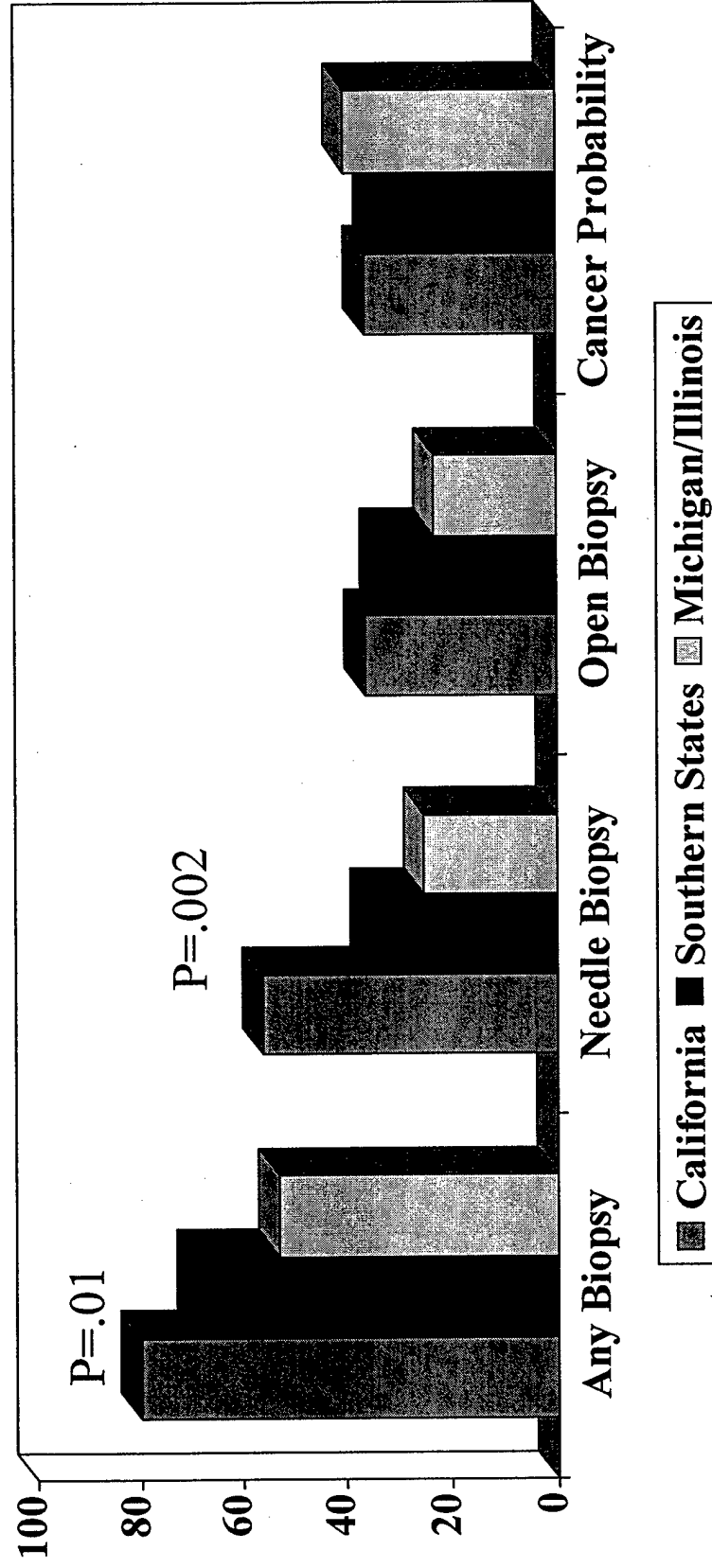
Study Design: Oncologists and surgeons were asked to view two 5-minute videotapes, one of a woman presenting with stage IIA breast cancer and one of a woman with a possible breast mass, both scenarios without clear guidelines for management. Sixteen versions of each videotape were professionally produced using actresses and holding all the clinical features of the case constant. We used a factorial experimental design to maintain geographic balance on several patient characteristics that might affect patient management. Each physician viewed one of 16 versions of each scenario, where we systematically varied the patient's age (65 vs. 80 years), race (black vs. white), socioeconomic status (high vs. low) comorbidities (none vs. diabetes and hypertension), and mobility (agile vs. frail). Male and female physicians were randomly selected from 3 geographic areas: 1) California, 2) Michigan and Illinois, and 3) 7 southern states. These were selected to represent areas that previous research has demonstrated as areas of high, moderate, and low use respectively of breast conserving surgery, and geographically large enough to recruit sufficient female physicians. Physicians were asked whether they would recommend surgical and needle biopsy, axillary node dissection, metastatic evaluation, chemotherapy, tamoxifen, radiation therapy and breast reconstruction. Differences between geographic regions were tested using Chi square analyses of 3X2 tables.

Principal Findings: The use of breast conserving surgery confirmed the previous findings, with the lowest rates in the South (83%), higher in Michigan/Illinois (90%) and highest in California (96%). In 7 of the 8 possible interventions there was a pattern of highest rates in California, intermediate rates in the South, and lowest in Michigan/Illinois. The overall effect of geographic location on the eight interventions combined was highly significant (Wilkes Lambda $p < 0.001$, from a multivariate ANOVA). With regard to the eighth modality, chemotherapy, there were no regional difference ($p = .58$). Breast biopsy rates were 80% in California, 69% in the South, and 53% in Michigan/Illinois ($p = 0.01$), despite the fact that the respondents in each region, on average, reported similar estimates of the probability of breast cancer. Significant differences among geographic locations were found when comparing recommendations for metastatic evaluation ($p < 0.001$), tamoxifen use ($p < 0.03$) and breast reconstruction ($p < 0.06$).

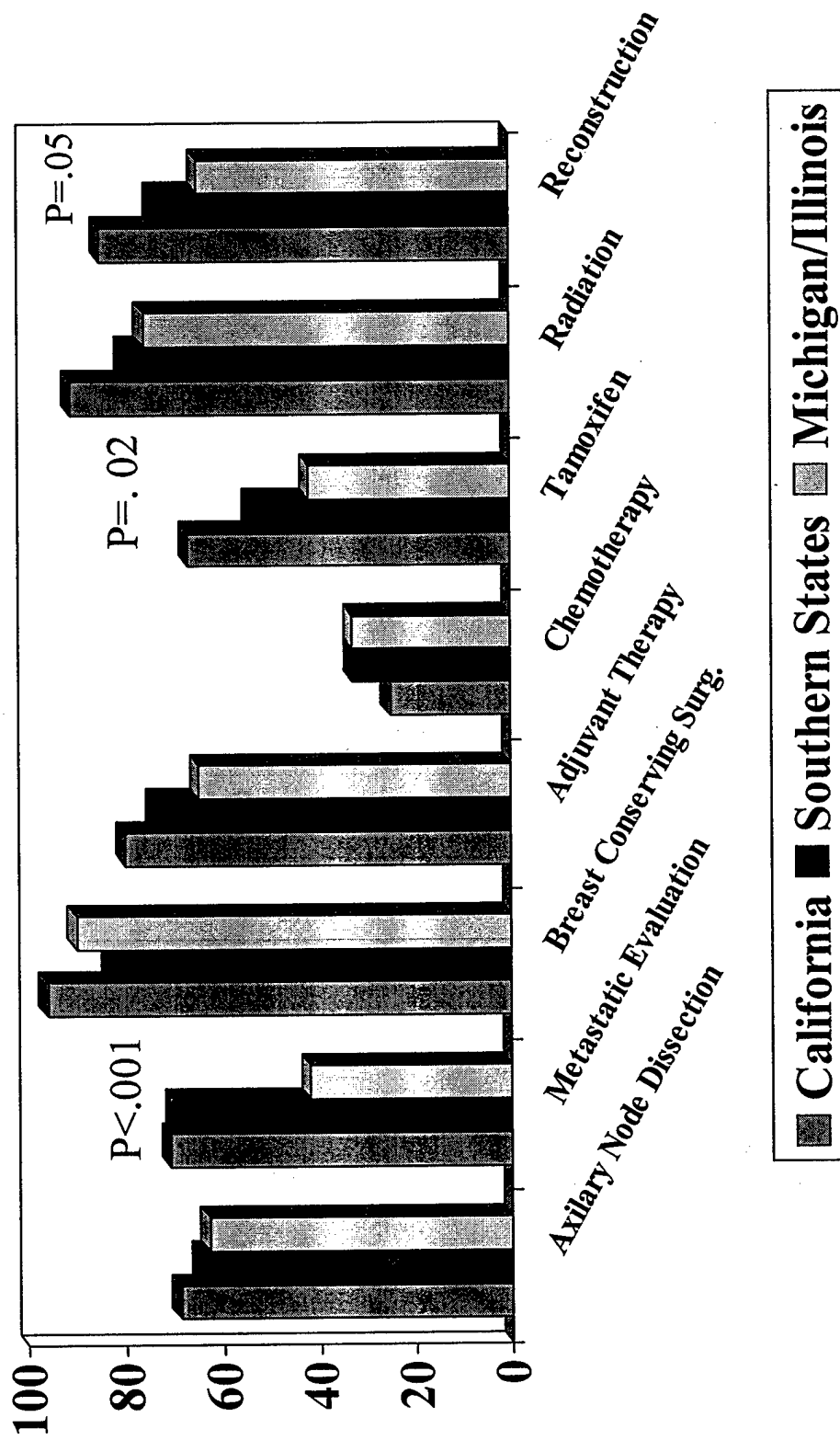
Conclusions: The study methodology was validated against secondary data analysis regarding recommendations for breast conserving surgery. A consistent geographic pattern was noted in the recommendation of seven other breast cancer management modalities.

Implications for Policy, Delivery or Practice: Controlling for patient clinical characteristics, geographic variation in breast cancer management follows consistent patterns of low and high utilization across a range of management modalities. Not only does breast cancer management for older women differ regionally, but regional differences appear to have "fingerprints" related to an entire complex of utilization. This suggests that adoption of more aggressive management of elderly women occurs at a regional level and is linked across different treatment modalities. The use of strategies that address the entire spectrum of care for breast cancer, not single specific modalities separately, may be more useful in changing management patterns.

Geographic Differences *Diagnostic Outcomes*



Geographic Differences *Treatment Outcomes*



Appendix 5

PREVENTION TRIAL RECRUITMENT: PATIENT AND DOCTOR FACTORS

Oral Presentation

National Cancer Institute

Participation of Women and Minorities in Clinical Cancer Research Workshop

July 13-14, 1998

Prevention Trial Recruitment: Patient and Doctor Factors

Marianne Prout, MD, MPH,

Karen Freund, MD, MPH,

Michelle Mancuso, MPH

Amy Scaramucci, MPH

Boston University Medical Center, Boston, MA

this research has been funded by :

NCI grant # R03 CA73297

Department of Defense Breast Cancer Research Program

DAMD17-94-J-4302

Background

- Cancer prevention trials
- Role of primary care physicians
- Joint effort of primary care physicians and specialists

Goals

- Physician's perceptions of barriers to cancer prevention trials
- Primary care providers
- Specialists
- Focus on low-income women and minorities

Ongoing studies

Specialty Providers

- Physician Decision Making
 - videotape of woman with benign breast disease
 - opinion regarding BCPT

Primary Care Providers

- Physician Decision Making
 - written scenario of woman with benign breast disease
 - opinion regarding BCPT
- Focus Group of Primary Care Providers

Specialty Methods

VIDEOTAPE CLINICAL SCENARIO

- Patient-Physician Interview
- Professionally acted
- Uniform clinical information
- Patient presents with lump and biopsy is an option

Specialty Subjects

- 192 oncologists and surgeons
- Subjects matched on:
 - Gender
 - Geographic region
 - Number of years since graduation from medical school

Specialty Methods

EXPERIMENTAL DESIGN

- Fractional factorial design
- Permits simultaneous evaluation of a number of variables
- Five dichotomous patient characteristics

RACE	Caucasian	vs.	African-American
AGE	65 years	vs.	80 years
SES	High	vs.	Low
MOBILITY	Agile	vs.	Frail (uses walker)
COMORBIDITY	Healthy	vs.	Diabetes/HTN

- $2^5 = 32$ combinations of 5 characteristics
- Balanced set of 16 "characters" selected for videotapes

BCPT QUESTIONS ADDED

(After completion of videotape and management options)

1. Suppose this patient had an excisional biopsy, which revealed fibrocystic changes with no atypical hyperplasia and with no evidence of malignancy. Would you refer or recommend to this patient the Breast Cancer Chemo-prevention trial, which would randomize her either to placebo or tamoxifen?
2. (If No)-What would be your main reason for not recommending this trial?
3. In your opinion, what disease is tamoxifen likely to prevent?
 - A. Osteoporosis
 - B. Breast Cancer
 - C. Coronary Artery Disease
4. Which of these potential benefits is important for this patient when entering her in a trial?
 - A. Prevention of osteoporosis
 - B. Prevention of breast cancer
 - C. Prevention of coronary artery disease

Specialty Group Results Life Expectancy Estimates

Health Status	Race	Age	Life Expectancy Median Range
Healthy	Black	65	16.5 (7-35)
	Black	80	8 (8-20)
	White	65	16.5(8-20)
	White	80	8 (8-15)
Diabetes/HTN	Black	65	13.5 (5-20)
	Black	80	8 (5-20)
	White	65	16.5(5-22)
	White	80	8 (3-20)

Specialty Group Results

Question	# answered yes/total	Percent
Do you enroll patients in clinical trials?	100/192	52%
(If No) Do you refer patients for clinical trials?	62/89	72%
Number who either enroll or refer to clinical trials.	162/192	84%
Would you refer or recommend the BCPT to this patient?	35/188	19%

Specialty Group Results

Patient Characteristics	Would Refer (n=35)	Would Not Refer (n=153)	p-value
White	21(23%)	70(77%)	
Black	14(14%)	83(86%)	.13
65 years	22(22%)	76(78%)	
80 years	13(14%)	77(86%)	.16
Upper SES	17(18%)	78(82%)	
Lower SES	18(19%)	75(81%)	.80
Agile	17(18%)	80(82%)	
Frail (uses walker)	18(20%)	73(80%)	.69
Healthy	21(22%)	74(78%)	
Comorbidities (Diabetes/HTN)	14(15%)	79(85%)	.21

Specialty Group Results

Reasons for not recommending the BCPT

(n=101)

Patient without high risk of breast cancer	48	(48%)
Patient too Elderly	25	(25%)
MD lack of information about trial	13	(13%)
Lack of trial experience	4	(4%)
Opposition to trial	4	(4%)
Risk of complication outweighs potential benefit	2	(2%)
Need to travel to outside institution	2	(2%)
Patient has diabetes and HTN	1	(1%)

Specialty Group Results

Knowledge of Tamoxifen effects

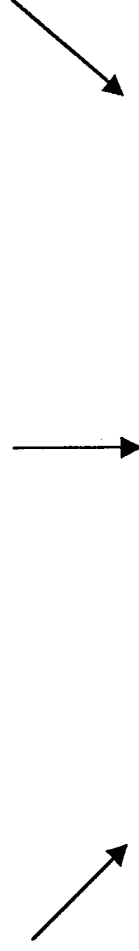
	In general	For this patient
Osteoporosis	111 (60%)	99 (52%)
Breast Cancer	136 (84%)	143 (78%)
Coronary Artery Disease	101 (58%)	98 (53%)

Focus Group Methods

- Focus group of 7 primary care providers
- Verbatim transcript
- 3 reviewers independently identified major ideas
- Grouped into themes

Focus Group Themes

Community Patient Physician



Benefits
Access
Knowledge/Recall
Media
Cultural Sensitivity
Trust/Commitment

Focus Group Themes

Specific to Primary Care Physicians

- Threats to Primary Care
- Philosophy of Prevention
- Dual Role

Written Survey of Primary Care Providers

- Written Survey Instrument
- Experimental design similar to subspecialty study
- 2 waves of mailings -- before and after the BCPT results were announced

Appendix 6

Paper

NATIONAL CANCER INSTITUTE MONOGRAPH
RECRUITMENT OF WOMEN AND MINORITIES INTO CANCER PREVENTION TRIALS

CHAPTER 18
PRELIMINARY RESEARCH FOR THE HEALTHCARE SYSTEM: HEALTHCARE
PROVIDERS

Annals of Epidemiology

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Chapter 18

Preliminary Research for the Healthcare System:

Health Care Providers

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ABSTRACT

Purpose: A patient's decision to participate in a prevention or clinical trial is influenced by the role of his or her physician. The purpose of our investigations are to identify the role of the physician in the recruitment of women and minorities into cancer prevention trials.

Methods: We report here on four investigations that sought to describe physicians' attitudes, knowledge, and behavior in recruiting patients into cancer prevention trials. These investigations utilized a number of methodologies, including qualitative analysis of physician focus groups and quantitative analyses conducted on surveys and interviews. The investigations looked at a range of cancer prevention trials, addressing prostate, colon and breast cancer. In addition, they include a large, national cross-section of providers, including primary care and specialty physicians who care for demographically diverse populations, with a particular emphasis on those who serve African American and Latino communities.

Results: The findings of these studies identified a number of unique barriers to the recruitment of minority populations into cancer prevention trials. These barriers include: lack of knowledge on the part of the physician; lack of compensation for physicians' time and effort in recruitment; loss of influence over patient care; perceptions of research team's lack of commitment to local communities; recruitment and inclusion criteria that discourage minority participation; and patient, community, and physician's lack of trust in the research.

Conclusions: Prevention trials that address the effect of protocol design and inclusion criteria on minority participation, and include primary care physicians as co-investigators, may address trust and knowledge barriers to minority population enrollment.

Key Words: Minority Groups, Clinical Trials, Research, Physicians

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ABBREVIATIONS

BCPT - Breast Cancer Prevention Trial

GSMA – Georgia State Medical Association

NCI – National Cancer Institute

NIH - National Institutes of Health

NMA – National Medical Association

NSABP - National Surgical Adjuvant Breast and Bowel Project

PCPT - Prostate Cancer Prevention Trial

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BACKGROUND

The role of the physician is a key factor in the decision-making process of patients who participate in prevention and clinical trials. Some of the barriers to enrolling women and minorities into clinical trials are unique; others are the same as those encountered in enrolling majority and male populations, just heightened. The knowledge and attitudes of health care providers concerning provision of clinical care to minority groups and women influence their perceptions of the utility and value of promoting clinical trials, and may amplify difficulties encountered in enrolling these groups. Physicians may perceive the typical barriers to recruitment—access to trials, complexity of trial procedures from informed consent to follow-up, and lack of compensation to providers—to be greater for women and minorities (Mansour, 1994, Swanson, 1995, Kaluzny, 1993). The advent of cancer prevention trials raises new challenges for enrollment because of the need to enroll healthy, at-risk individuals (Kaluzny, 1993). Investigators in traditional cancer treatment trials are often actively involved in the care of patients regardless of trial enrollment. In comparison, prevention trials require coordination with primary care providers (Swanson, 1995, Wadland, 1990). Lack of experience in trial enrollment, lack of compensation, and fear of losing patients add unique barriers to enrollment. Identification of the specific issues in enrollment of patients to cancer prevention trials has not been investigated. Such investigations require inclusion of providers in both specialty and generalist fields, especially those caring for diverse populations, and requires a broad range of methodologies to generate and test hypotheses about barriers to enrollment.

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AIMS

There are a number of aims that investigations of the role of health care providers in recruitment to prevention trials seek to address.

1. What are health care providers' knowledge of cancer prevention trials and the need for cancer prevention strategies for specific minority groups and women?
2. What are health care providers' attitudes towards cancer prevention trials in general?
3. What are providers' attitudes towards recruitment of women and minority patients to cancer prevention trials, including perceived barriers to enrollment?
4. Can we document physician behaviors in recruiting women and minority groups into prevention trials? Do reported attitudes towards prevention trial recruitment correlate with behavior?

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METHODS

We report on the preliminary results of a group of studies and a range of methodologies used to address the above questions regarding recruitment of minority groups and women into cancer prevention trials. The investigations utilized qualitative and quantitative methodologies and span a broad range of prevention studies, including prostate, breast, and colon cancer. The studies specifically addressed demographically diverse populations, with a focus on African American and Latino populations, and included trials of both men and women.

Listed are the four studies and their specific aims to determine the physicians' role in recruitment of patients to cancer prevention trials.

Breast Cancer Prevention -- Noting the low enrollment of minority women to clinical and prevention studies in general, and specifically low enrollment by African American women, a study by Freund, Mancuso and Prout sought to address the role of physicians in enrollment to the Breast Cancer Prevention Trial (BCPT) (Freund, 1997). The study focused specifically on the role of primary care providers. The study also sought to address whether physician gender, race, and years of experience influence their behavior in enrolling women in general and African American women specifically into the trial.

Latino Americans and Cancer Prevention - The Latino population in the New York City metropolitan area is predominantly of Puerto Rican and Dominican origin. A national cancer database reported that Puerto Ricans represent 29% of cancer cases in New York City (US Department of Commerce, 1990). Wasserheit, et al., developed a study in response to concerns that the Latino population has traditionally been underrepresented in cooperative group clinical trials. They conducted a focus group of Latino physicians to identify barriers to Latino patient participation in cancer prevention clinical trials and to propose potential solutions to overcoming these barriers. Ultimately, the long-term goal of this project is to implement suggested solutions, including the development of educational materials, and to increase accrual of Latino Americans into these trials.

African American Men and Prostate Cancer Prevention -- An investigation by Petros, et al., sought to address the low enrollment of African American men into clinical trials in

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general and into the Prostate Cancer Prevention Trial (PCPT) in particular (Reynolds, 1993). This study described the development and testing of a physician survey designed to understand the knowledge, attitudes, and behaviors of physicians regarding the referral of African American men into this trial.

African American Women and Cancer Prevention – A descriptive, cross-sectional survey design is being used by Roberson, et al., to describe physicians' knowledge and perceptions about cancer prevention trials and their efforts to refer eligible African American women to clinical trials. The study will be surveying physicians providing primary care to African American women.

Qualitative Methods Used in the Four Studies

Qualitative methods were used in studies conducted by Freund et al., Wasserheit et al., and Petros, et al., as a method of hypothesis generation and testing. The goal of the qualitative methods was to elicit directly from physicians new themes that relate to barriers to enrolling patients into cancer prevention trials. Each study took advantage of the focus group methodology in obtaining in-depth information from a small group of comparable physicians. In each case, information obtained from the focus groups was used in the next step of the investigation.

Breast Cancer Prevention (Freund, et al.)

In this study, investigators conducted a focus group on breast cancer prevention with seven primary care providers who serve predominantly inner-city, low-income, and minority populations (Freund, 1997). These physicians were recruited from varying institutions in the metropolitan Boston area and were invited to the focus group based on their work with minority and low-income populations. A set of questions was developed in order to facilitate discussion about the physicians' attitudes towards breast cancer prevention, clinical trials in general, and the BCPT in particular. The focus group was conducted at Boston Medical Center in December 1996, during the accrual period for the BCPT.

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The focus group was audiotaped with the consent of all participants and a verbatim transcript was produced. Three reviewers analyzed the transcripts, independently identified key phrases, jointly discussed the combined list of key phrases, and developed a set of common themes (Smith, 1989). The groupings of key phrases were independently and jointly reviewed. Key phrases that did not achieve consensus were dropped, and a final list of themes with corresponding key phrases was developed. Important and frequently expressed ideas were then reviewed for patterns of connection, which were then grouped into broad categories or themes. (Smith, 1989). These themes, as well as themes and barriers identified previously in the literature, were then used in the development of a comprehensive survey administered to primary care physicians to determine their perceptions of at barriers to enrollment into prevention trials.

Latino Americans and Cancer Prevention (Wasserheit, et al.)

A focus group was conducted to identify barriers to enrollment of Latinos in prevention trials and to develop possible solutions to overcoming these barriers. The focus group facilitated discussion between primary care physicians in the Latino community and oncologists affiliated with institutions conducting cancer prevention clinical trials.

Primary care physicians and oncologists were recruited from the New York City metropolitan area to attend a 2 1/2-hour focus group. Recruitment was conducted through several sources, including Cooperative Group Affiliates, InterAmerican College of Physicians Surgeons (ICPS), a national professional organization of Hispanic physicians with over 450 members in New York City, and Latino physicians who serve primarily Latino patients. Among these groups, several participants served as member of the planning committee, which addressed recruitment of participants, development of evaluation tools and questionnaires, and the focus group format.

An anonymous questionnaire was developed containing demographic information about physicians, their practices, and the patients they serve. The questionnaire included a set of open-ended questions about barriers they believed existed to the participation of Latinos in cancer prevention clinical trials, and potential solutions to these barriers.

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The 2 1/2-hour session was organized into multiple components. First, participants were presented with highlights of the first National Surgical Adjuvant Breast and Bowel Project's (NSABP) breast cancer prevention study (Fisher, 1998) and then discussed the guidelines for the upcoming NSABP breast cancer prevention study, emphasizing the importance of accruing Latino subjects. Participants then met in facilitated subgroups of 8-10 participants, with oncologists meeting separately from the primary care physicians. In the smaller groups, participants completed questions including a demographic information and open-ended questions concerning barriers to recruitment. The facilitator then led a 20-minute discussion of the barriers mentioned by each physician. Next, the participants completed a set of open-ended questions concerning potential solutions to overcoming barriers. This was then followed by a 20-minute facilitated discussion about these potential solutions.

Responses to the questionnaires were entered into a computerized database. For the open-ended section on barriers and solutions, a descriptive analysis of the responses was generated and responses were coded to generate standardized, quantitative data. For the barriers and potential solutions, each response was categorized and percentages by category reported. We report later in this paper on the responses of the primary care physicians.

African American Men and Prostate Cancer Prevention (Petros, et al.)

A study by Petros, et al., of prostate cancer and prevention trials addressed the low enrollment of African American men into such trials. A survey was created that incorporated general questions about clinical research and trial design, prostate cancer, and the Prostate Cancer Prevention Trial (PCPT). The survey was then revised by the research team, which included an urologist, clinical psychologists, and a clinical trials research nurse, and independently reviewed by three physicians not involved with the study. The instrument was tested in 1998 in a focus group of 21 physicians and in individual interviews at the Georgia State Medical Association (GSMA). The GSMA meeting was chosen because of its similarity to the National Medical Association, in terms of membership of African American physicians and organizational orientation focusing on African American healthcare issues. Physicians agreeing to participate in the

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focus group and personal interview provided informed consent to participate in the study and were paid \$100 for their efforts. The research team discussed all concerns and issues brought forth during the individual interviews. A prioritized list of questions was then generated that guided further modifications of the survey instrument and recruitment process.

Quantitative Methods Used in the Four Studies

Three of the investigations being considered here developed survey instruments that allow for sampling a broader subset of physicians. Combined, the studies draw from a broad geographic sample of the United States and target primary care and specialty providers, as well as subgroups of physicians caring for minority populations.

Breast Cancer Prevention (Freund, et al.)

Two separate surveys on breast cancer prevention were completed, one of 200 primary care providers, and one of 192 specialists in medical oncology and surgery. These studies addressed the knowledge, attitudes and behavior of providers regarding prevention health recommendations for women, experiences with clinical trials in general, and the Breast Cancer Prevention Trial (BCPT) in specific.

For the primary care study, self-administered surveys were developed based on the focus group results (described above). The surveys were then conducted to evaluate the independent influences of a number of patient characteristics and physician recommendations regarding cancer prevention trials. Surveys were mailed to a random sample of male and female internists and family physicians, obtained from listings of physicians from the State board of medical registrations for northern California, Georgia, and Michigan. Each survey contained a written clinical vignette of a patient considering enrollment in the BCPT, and asked physicians to indicate whether they would encourage the patient to enroll in the trial.

For the specialist study, investigators developed a set of videotaped clinical vignettes for surgeons and oncologists to view, for which semi-structured interview questions were developed. The clinical vignette depicted a patient presenting for the

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evaluation of a breast mass, with a subsequent benign biopsy. As part of the semi-structured interview, physicians were asked to indicate whether they would recommend that the patient enroll in the BCPT. Study subjects were surgeons who had performed both a breast biopsy and mastectomy in the past five years, and medical oncologists who had cared for women with breast cancer in the past five years. Physicians were randomly selected from listing of physicians obtained through State medical registrations, the American Medical Association, and the American Board of Medical Specialties.

For both studies, three geographic regions—northern California, eight southern states, and Michigan—were selected to sample physicians, as these areas correlate with high, moderate, and low utilization rates of breast-conserving surgery (Nattinger, 1992, 1996) and may serve as a proxy for geographic variability in other areas of breast cancer care. Sixteen versions of both the written clinical vignettes and videotaped clinical vignettes were written. Each version kept all clinical information constant, but systematically varied the patient's age (65 or 80 years), race (African American or Caucasian), socioeconomic status (high or low), comorbidities (diabetes and hypertension or none) and mobility (osteoarthritis with use of a walker or none). This balanced factorial design allows for the assessment of any one individual characteristic, independent of confounding from the other characteristics.

African American Men and Prostate Cancer Prevention (Petros, et al.)

In this study, a survey, modified based on focus group results (described above), was administered to 260 physicians during the 1998 National Medical Association meeting. Participants were recruited at booths in the registration area, near a prostate cancer-screening event, and through announcements during the meeting. Any physician attending the meeting was eligible to participate in the study. As an incentive to participate, each physician completing a survey was entered into a raffle for a 13" color television.

African American Women and Cancer Prevention (Roberson, et al.)

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Roberson, et al., conducted a survey to investigate physicians' perceptions and practice behavior about cancer prevention trials and to describe physicians' efforts to refer African American women to cancer prevention trials. A draft of the questionnaire was initially developed and reviewed (with a questionnaire assessment form) by experts in research design and clinical care, and by a community advisory board. Pilot testing was conducted on 34 practicing physicians.

Primary care physicians of 250 African American women in western New York State were identified by women participating in another arm of the study. The physicians were mailed the self-administered questionnaire, which consisted of 45 items covering 7 topics: 1) practice profile, 2) knowledge about clinical studies, particularly prevention trials, 3) perceptions about participation, 4) prevention trial participation, 5) referral to prevention trials, 6) recommendations for recruitment strategies, and 7) demographic profile.

PRELIMINARY FINDINGS

We report on the preliminary findings of three of the investigations. First we present data from Freund et al on the BCPT, including the focus group analysis, and analyses of surveys of primary care providers and specialists. Second, we present Wasserheit and colleague's data on Latino Americans, analyzing the barriers to enrollment and solutions to barriers derived from their focus group analysis. Third, we present the results of the survey of Petros et al on the PCPT and African American men.

Breast Cancer Prevention (Freund, et al.)

Focus Groups

Nine themes were identified in the focus group conducted with primary care providers regarding cancer prevention and the BCPT. The first six themes were expressed as they related to three groups—the community, the patient, and the primary care physician. These themes included: 1) benefits of the research to the patient, the community as a whole and the primary care physician; 2) access to information and

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participation in the research to patients, communities and primary care physicians; 3) knowledge and recall as it pertains to the research study and its goals, for the patient, community and primary care physician; 4) influences of media coverage on the patient, community and physician; 5) cultural sensitivity of the research group to the community and the subjects recruited from that community; 6) trust by and perceived commitment of the researchers to the patient, community and primary care physician. The three additional themes were directed specifically toward the primary care provider and include: 7) threats to the primary care relationship; 8) general philosophy towards prevention and 9) the dual role of the physician as patient advocate and promoter of research within their institutions.

The issue of trust in the research enterprise was raised in a number of contexts, including levels of trust in the research project on the part of individuals considering enrollment within a community, and by the individual physicians enrolling their patients into trials. Community perceptions can also be important. For example, the following quote represents a view that researchers have no stake in the community they are trying to enroll, their presence is temporary, and their requests take resources in terms of participation rather than contributing: "*. . . it's where the guys come in from the research institutes and it's like a safari ... they are in the ... outback for 2 weeks and they are going to take a lot of pictures and then go back and show their slides. And they are not committed at all. They come and they take.*" Physicians also expressed their personal distrust of the researchers' motives in enrolling patients, even when the primary care providers disagree, as in "*What am I going to do? They made a choice that she fit the trial, they don't need our permission*".

The possibility that enrollment in a trial could interfere with the primary care relationship was also expressed as a theme, especially for physicians caring for poor and underserved populations. Difficulties in coordinating primary care with clinical research were expressed in the following quote "*She's missed her last 2 appointments with me, but she's getting 500 bucks from you and she is making all your appointments and missing mine.*"

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Many of the primary care providers expressed a philosophy of prevention involving lifestyle modification, and not active therapeutic agents. An example: "*A primary prevention trial, which is geared towards reinforcing a positive lifestyle is one thing, but when you are using an active agent, such as a medication, that has a potential downside.*"

Primary Care Provider Survey

A preliminary analysis of the first half of data collected between September 1997 and March 1998 (n=89) found that of the primary care providers surveyed, 44 (49%) would encourage their patient to consider enrolling in the BCPT. Significant differences were found in physician recommendations according to the age of the patient. Providers were more likely to encourage enrollment into the BCPT for women age 65 than for women age 80 (64% vs. 34%, $p < .05$). No significant differences were found to be associated with other patient characteristics including race, SES, comorbidities, or frailty. Significant geographic variation was found in physician recommendations to enroll women in the BCPT. Providers in Michigan were less likely to recommend enrollment than were providers in Georgia or California (28% in MI, 57% in GA and 65% in CA, $p < .05$).

Specialist Survey

The specialists in this study included 192 medical oncologists and surgeons, of whom 84% referred or enrolled women into therapeutic trials. After viewing a videotaped simulation of a physician interviewing a patient who was potentially eligible for the first BCPT, only 19% of these physicians stated that they would have referred the patient on the videotape for enrollment in the BCPT.

The design of this study, fractional factorial design, allowed for the independent assessment of whether individual patient characteristics influenced decision-making. We found that there were no significant differences in physician recommendation to enroll the patient in the BCPT that were associated with any of the five patient characteristics portrayed on the videotape; age, race, SES, comorbidities or frailty. However, significant differences in geographic variation were found. Physicians in California were

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less likely to recommend enrollment to the BCPT, than were providers in the southern states or Michigan (6% in CA, 16% in GA and 33% in MI, $p < .001$).

Latino Americans and Cancer Prevention (Wasserheit, et al.)

In this study, a total of 38 participants attended the focus group, 31 of whom were physicians. Of all the physicians, 21 (68%) were Latino. There were 21 (68%) primary care physicians, 8 oncologists, and 2 other sub-specialists. The mean age was 43 (range 30 to 70). Approximately half (54%) of the physicians were in private practice, with the remainder working in academic teaching hospitals or clinics.

The physicians reported that their patients were predominantly Latino (71%) and these Latino patients were predominantly Puerto Rican or Dominican (88%). The majority of patients in the physicians' care was over age 50 (59%) and covered either by Medicaid (33%) or Medicare (27%).

Physicians who participated in the focus group expressed interest in increasing the accrual of their Latino patients to cancer prevention clinical trials, but most had little experience in referring patients to such trials. While 68 % of participants had referred a patient to a clinical trial, either for treatment or prevention, 41% had not referred a patient in the last year, and only 15% had referred more than 10 patients in the last year.

Barriers to Enrollment

The 21 primary care physician participants identified 32 different barriers to trial enrollment, categorized into one of seven areas as follows:

- a) Socio-economic patient factors: The most frequent barrier cited pertained to socio-economic issues, listed 27 times (24%). More than half of the responses responded that the time commitment required of patients to participate in clinical trials was problematic due to work and/or family responsibilities. Other barriers in this category included difficulties with transportation and lack of medical insurance for patients.
- b) Knowledge: The second most frequent barrier cited related to knowledge and understanding, listed 26 times (23%). Almost two-thirds of responses referred specifically to patient lack of knowledge and/or understanding of clinical trials.

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Other responses included a generalized lack of understanding of cancer prevention by Latino patients and a generalized lack of education.

- c) **Language:** The third most often cited barrier was language, reported 22 times (19%). This included patient's inability to speak English, lack of bilingual physicians and/or staff, and lack of information in Spanish for patients about clinical trials.
- d) **Fear:** Issues regarding fear and mistrust were cited 12 times (11%). The responses included what physicians perceived to be patient-related mistrust of clinical trials, patient mistrust of the medical system, mistrust of medical science, and fear of cancer in general.
- e) **Cultural:** Cultural barriers were noted 11 (10%) times. These included cultural disparity between investigator and patients, a perceived fatalistic view by the Latino culture relative to other cultures, reliance on folk medicine, lack of involvement of patients' families, and the lack of Latino community support for patients participating in clinical trials.
- f) **Access:** This barrier was noted 6 times (5%) and referred to both lack of access to health care and lack of access to clinical trials.
- g) **Physician- Related Barriers:** Barriers involving physicians were cited 10 times (9%). These included lack of awareness of available clinical trials, lack of involvement of community physicians in clinical trials, physician time and financial constraints, and fear of losing patients to investigators. Other physician barriers included are physician lack of knowledge of the Latino culture and language barriers.

Potential Solutions

Participants in this study were asked to list potential solutions for overcoming barriers. These solutions were categorized as follows:

- a) **Socio-economic:** Potential socioeconomic solutions were cited 33 times (32%). These include having flexible hours for enrollment and trial participation; bringing the participation site closer to where the patients live; and providing incentives such as transportation, child care, payment, and food.

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- b) Education: Education was cited 26 times (26%). Patient education efforts needed included information about cancer prevention, the nature of benefit of trials, and education about specific trials. Educational strategies included use of Spanish-speaking television, radio, and newspaper; the use of community and religious leaders and institutions; and the use of primary physicians or clinical trial staff. Physician-focused education efforts included providing more and better information about clinical trials as well as education of non-Latino physicians about the Latino culture and Spanish language.
- c) Language: Solutions involving overcoming language barriers were cited 24 times (24%), and included use of more Spanish-speaking physicians and clinical trials staff, emphasis on learning or improving Spanish-speaking skills for non Latino physicians who care for Latino patients, use of translators when needed, and culture-specific educational written material in Spanish.
- d) Involving community physicians: This potential solution was cited 10 times (10%) and included working with community physicians, for example, by providing staff and financial aid, and encouraging community physicians to participate in research.
- e) Involving community and religious leaders and institutions: This potential solution was cited 6 times (6%). Again, participants suggested using resources from the Latino community to help improve communication.
- f) Other solutions: Participants discussed the importance of involving the patients' families in medical decision-making and care.

Prostate Cancer Prevention Trial (Petros, et al.)

Final Survey

The survey used in the study by Petros, et al., was completed by 260 physicians. The average age of the respondents was 46 years; 98% of respondents identified themselves as African American or Black. Forty-two percent of respondents were in private practice and 29% were located at a university; 19% were salaried physicians and were 10% government physicians. Specialties represented included Internal Medicine

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(22%), Family Practice (13%), Urology (9%), Pediatrics (9%), OB/GYN (8%), Surgery (5%), Emergency Medicine (4%), Psychiatry (4%) and General Practice (3%).

Analysis of the data from this survey found that 90% of the respondents believe that African Americans are under-represented in clinical cancer prevention trials, while 79% said that women were similarly under-represented. Eighty-three percent (83%) of the respondents stated that clinical trials have actively discriminated against African Americans in the past, while 70% believed that current clinical trials continue to discriminate against African-Americans. Seventy-four percent (74%) of respondents stated that the fact the National Institutes of Health (NIH) is a sponsor of a clinical trial does not decrease their concerns about study design. Fourteen percent (14%) of respondents felt that NIH does not actively promote the inclusion of women and minorities into medical research.

Ninety-seven percent (97%) of the physicians surveyed felt that prostate cancer was a common cause of death in African Americans, while only 71% felt that prostate cancer was a common cause of death in white Americans. Eighty-seven percent believe that screening for prostate cancer with subsequent treatment changes the survival rate and 95% believe that screening should include examination in addition to serum PSA testing.

Respondents were 3 times more likely to prefer the use of limited financial resources for prevention trials to treatment trials. Only 9% believed that enrolling patients in clinical trials had an adverse effect on patients' personal finances.

Sixty-eight percent (68%) of respondents had been asked in the past to enroll a patient into a clinical trial, 53% had referred a patient for enrollment in a clinical trial, and 37% had either been an investigator or part of a research effort that enrolled patients into clinical trials. Only 21% of respondents felt that clinical trials take into account important race-related issues, such as disease incidence. Eighty-nine percent (89%) of respondents said that they would be more likely to enroll patients if they knew that prominent African American leaders were involved in the design of clinical trials.

Of the 260 physicians completing the survey in this study, 25% (n=65) reported that they had heard of the PCPT. Of these 65 physicians, 56 said that they would consider enrolling a patient in the PCPT, and 8 had actually enrolled a patient in the trial.

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Twenty-two physicians had been encouraged by another physicians to enroll a patient in the PCPT, and 4 had been told by other physicians not to enroll patients into the PCPT. Thirty-six of the 65 physicians familiar with the PCPT believe that the entry age of 55 years old discriminates against African Americans. Twenty felt that financial considerations were important in the design and implementation of the PCPT. When asked specifically about race and the PCPT, 61/65 physicians said that African Americans should be recruited to in the PCPT in specific. Sixty-three said that African Americans would benefit from the information obtained from the PCPT and 60 of the 65 physicians said that African-Americans would not be harmed by participation in the trial.

SUMMARY

The four investigations described in this paper are among the first to address the role of physicians in recruiting minority populations and women into cancer prevention trials. The broad range of methodologies, from in-depth focus group analyses to larger physician studies, across a broad range of primary and specialty physicians, provides a unique view of the role physicians' play in the recruitment process to these trials.

Overall the studies suggest that many physicians lack knowledge of cancer prevention trials, and expressed both favorable and unfavorable attitudes toward enrollment. Recruitment efforts were further hampered by lack of compensation for time and effort on the part of physicians.

Specific issues with regard to primary care physicians are apparent. Physicians expressed concern about losing patients and influence over patient care if their patients enroll in trials. They also expressed concern about the research team's lack of commitment to the communities where minority populations live and seek health care, which would in turn undermine their own credibility with their patients.

Physician characteristics did, however, modify these findings. Of note, specialist physicians were not better informed about prevention trials than primary care providers, which may be the result of one group having little contact with trials, while the other has little contact with prevention medicine. Minority physicians were better informed about disease specific issues for minority populations, but not about clinical trials. African American physicians were well informed about the increased incidence of prostate cancer

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and younger age of presentation in African American men, and were supportive of enrolling African American men into prevention trials for prostate cancer, although only 25% were aware of the PCPT. Latino physicians expressed positive attitudes about entering patients into trials, but were not informed about potentially relevant trials.

Physicians also expressed concerns about trial procedures as a barrier to minority recruitment. African American physicians felt that enrollment criteria should take into account differences in disease incidence and presentation by race, and felt that the age cut-off for enrollment in the PCPT was too high to ensure adequate enrollment of African Americans. Physicians caring for the Latino community expressed the need for improved competency in the Latino culture and Spanish language. All groups cited economic barriers as important in minority communities. One set of focus groups also expressed concerns about how they as physicians might lose patient trust by advocating for clinical trials, and could do so only with a well-established doctor-patient relationship. Other physicians felt that efforts by NIH to recruit minority patients were insufficient, and that trials needed to provide benefits to encourage enrollment.

Geographic variation in the physician attitudes and decision-making was studied for the BCPT and demonstrated wide local variation. Findings were not consistent across regions for primary care and specialty providers. Recommendations to the BCPT did not correlate consistently with higher regional use of breast conserving surgery (Nattinger, 1992, 1996). The low rates of referral to the BCPT by specialty providers in California probably reflects local resistance to the trial. Reference will be provided

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RECOMMENDATIONS

While none of the current investigations have reported results of interventions to improve minority and women enrollment into cancer prevention trials, their findings suggest approaches worth evaluating to improve enrollment through facilitating physician recruitment efforts.

First, involvement of minority physicians and consumers in planning all phases of trials would identify, at an early stage, methods to enhance enrollment by addressing gender- and race-specific differences in disease presentation and incidence and by accounting for language and cultural issues when considering enrollment and protocol design criteria.

Second, specific programs to enlist the assistance of minority physicians and physicians who serve predominantly minority communities, are likely to enhance minority recruitment. Seeking such physicians and groups within and outside of academic medical centers is critical. Data from these studies suggest that minority physicians may be the most effective advocates for prevention efforts within their own communities.

Third, while cancer prevention trials have grown out of the important work of NIH and oncologists, prevention trials require the collaboration of oncology and primary care. Primary care providers have a number of their own specific issues related to enrolling patients into trials that require incorporation into the trial design. Inclusion of primary care providers in the planning phases of prevention trials, and encouraging investigators to include primary care providers in the group of co-investigators may serve to address these issues and improve the recruitment efforts in primary care towards prevention trials.

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Table 1

Breast Cancer Prevention Focus Group Themes

- ◆ **Benefits** of the research
- ◆ **Access** of the research to these groups
- ◆ **Knowledge and Recall** as it pertains to the research study and its goals
- ◆ Influences of **Media** coverage
- ◆ **Cultural Sensitivity** of the research group to the community and the subjects recruited from that community
- ◆ **Trust** of the researchers by each of the three groups and **Commitment** perceived by each group of the researchers.

Primary Care Physician

- ◆ **Threats to primary care relationship**
- ◆ **General Philosophy towards Prevention**
- ◆ The conflict in their **Dual Role** as patient advocates and advocates for research within their institutions.

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Table 2

Barriers to the Participation of Latino Americans in Prevention Trials

BARRIERS

Patient-Related Factors

- ◆ Socio-economic
- ◆ Knowledge and understanding
- ◆ Fear and mistrust
- ◆ Cultural
- ◆ Access to health care/lack of access to clinical trials

Physician-Related Factors

- ◆ Lack of awareness of clinical trials
- ◆ Lack of involvement of community physicians in clinical trials
- ◆ Physician time constraints
- ◆ Enrollment into trials "not profitable"
- ◆ Fear of losing patients to investigators
- ◆ Physicians lack of knowledge of the Latino culture and Spanish language

POTENTIAL SOLUTIONS TO BARRIERS

- ◆ Socio-economic
- ◆ Education
- ◆ Language
- ◆ Involving community physicians
- ◆ Involving community and religious leaders and institutions