

AD_____

Award Number: DAMD17-98-1-8350

TITLE: How to Increase Appropriate Use of Breast-Conserving
Therapy - Greater Access to Radiation Oncology Services or
Physician Education?

PRINCIPAL INVESTIGATOR: Laura Mae Baldwin, M.D.

CONTRACTING ORGANIZATION: University of Washington
Seattle, Washington 98105-6613

REPORT DATE: October 1999

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are
those of the author(s) and should not be construed as an official
Department of the Army position, policy or decision unless so
designated by other documentation.

20000829 001

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

* Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE October 1999	3. REPORT TYPE AND DATES COVERED Annual (30 Sep 98 - 29 Sep 99)					
4. TITLE AND SUBTITLE How to Increase Appropriate Use of Breast-Conserving Therapy -- Greater Access to Radiation Oncology Services or Physician Education?		5. FUNDING NUMBERS DAMD17-98-1-8350					
6. AUTHOR(S) Laura Mae Baldwin, M.D.		8. PERFORMING ORGANIZATION REPORT NUMBER Not Applicable					
7. PERFORMING ORGANIZATION NAMES(S) AND ADDRESSES(ES) University of Washington Seattle, Washington 98105-6613 E-MAIL: lmb@u.washington.edu							
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		10. SPONSORING / MONITORING AGENCY REPORT NUMBER					
11. SUPPLEMENTARY NOTES							
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. DISTRIBUTION CODE				
13. ABSTRACT (Maximum 200 Words) Breast conserving therapy with radiation (BCT) is underutilized in the treatment of stage I and II breast cancer. This project examines the degree to which distance to radiation therapy and the training and practice style of surgeons contribute to this underuse of BCT in elderly women, especially those living in rural areas. A comprehensive database linking information from the Seattle-Puget Sound Surveillance, Epidemiology, and End Results Program, Medicare part B claims, the American Medical Association Masterfile, and the American Board of Medical Specialties has been created for the study analyses. We will define cohorts of women based on 1) their distance from radiation therapy services, 2) their surgeons' characteristics, such as board certification status, gender, and time in practice, and 3) their consultation with medical and radiation oncologists prior to surgery. We will examine rates of use of BCT in these cohorts while controlling for patient characteristics such as age, co-morbidity, race, and marital status. The results of this study will be used to identify potentially modifiable causes for underuse of BCT and to determine whether interventions to increase availability of BCT should focus on physician education, public education, or improving access to radiation therapy services.							
14. SUBJECT TERMS Breast Cancer		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">15. NUMBER OF PAGES</td> <td style="width: 50%; text-align: center;">14</td> </tr> <tr> <td colspan="2">16. PRICE CODE</td> </tr> </table>		15. NUMBER OF PAGES	14	16. PRICE CODE	
15. NUMBER OF PAGES	14						
16. PRICE CODE							
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited				

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

_____ Where copyrighted material is quoted, permission has been obtained to use such material.

_____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

_____ Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

_____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

LMB For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

_____ In conducting research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

_____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Table of Contents

Front Cover.....

SF 298.....

Foreword.....

Table of Contents **4**

Introduction **5**

Body **6**

 Methods Overview 6

 Database Linkage 6

 Developing Analytic Files..... 7

 Work in the Coming Year..... 8

Conclusions..... **12**

References..... **13**

Introduction

Breast conserving surgery with radiation (BCT) is clearly underutilized in the treatment of stage I and II breast cancer (1,2). A number of studies have demonstrated that BCT offers equivalent survival rates to mastectomy for women with stage I and II breast cancer regardless of age (3-10). In 1990, the National Institutes of Health published a consensus statement recommending BCT for the majority of women with stage I and II breast cancer (11). Yet studies show that there is great variation in the use of BCT, with general underuse of this treatment option (1,2,12). Rural women in particular have very low rates of BCT compared to mastectomy (13). Elderly women with local and regional breast cancer who receive care in rural areas are half as likely to receive BCT as elderly women with the same stage breast cancer who receive care in large metropolitan areas.

This study's goal is to determine the degree to which poor access to radiation therapy services and the training and practice style of their surgeons contribute to this underuse of BCT in treating early stage breast cancer in elderly women, especially those living in rural areas. The results of this study can be used to identify potentially modifiable causes for underuse of BCT and to determine whether interventions to increase availability of BCT should focus on physician education, public education, or improving access to radiation therapy services.

Body

Methods Overview

This study uses a retrospective cohort study design to examine the effect of 1) access to radiation oncology services, 2) surgeon's characteristics, and 3) consultation with oncologists and radiation oncologists prior to surgery on the use of BCT in elderly breast cancer patients in western Washington State. The study population includes women reported to the Seattle-Puget Sound Surveillance, Epidemiology, and End Results (SEER) Program database with an initial diagnosis of stage I or II breast cancer in 1994 and 1995. A comprehensive database linking information from several sources provides information on patient, physician, and hospital characteristics for use in the analyses.

Cohorts of women will be defined based on their distance from radiation therapy services, their surgeons' characteristics, and their consultation with oncologists and radiation oncologists prior to surgery. Rates of use of breast conserving surgery with and without radiation will be examined for these cohorts, controlling for patient characteristics, hospital characteristics, and cancer stage.

Database Linkage

The first priority in this study was to create a unique and comprehensive database linking the 1994 and 1995 Seattle-Puget Sound Surveillance, Epidemiology, and End Results (SEER) database for breast cancer cases with 1993, 1994, and 1995 Medicare part B and enrollment databases, American Board of Medical Specialties data, and the American Medical Association Masterfile database. Much of the first year of the grant was spent on this first task. We identified 416,325 women 65 and older in Washington's 1994 and 1995 Medicare part A, part B, and enrollment files, and sent their Medicare identification numbers (HICs) to the HCFA Region X office so that they could add identifying information. This office was able to link identifiers (name, address, date of birth, and social security number) to 416,313 of these women. These identifiers and HICs were sent to the Cancer Surveillance System office that maintains the Puget Sound SEER database, and similar identifiers in the SEER data were used to link SEER and Medicare data. There were 6,098 breast cancer cases reported to the Puget Sound SEER database in 1994 and 1995, 6,063 of which were in women. Of these 6,063, 2,761 were 65 and older at the time of their diagnosis. Of these, 2,668 (96.6%) were successfully linked with a Medicare HIC number.

Simultaneously, we linked data from the ABMS and AMA Masterfile to describe the physicians caring for these breast cancer patients. These data include year of birth, specialty, year of graduation from medical school, type of medical degree (MD or DO), type of medical practice (solo, group), sex, and board certification status.

Developing Analytic Files

The next steps in the study were to refine the study questions, and develop the variables and analytic databases to answer these questions. We have developed two analytic pathways for this study—one that involves the physician as the unit of analysis, the other that involves the patient as the unit of analysis. Figures 1 and 2 illustrate the analytic models developed for each of these pathways, and identify the variables that we are developing for these analyses.

In order to carry out these analyses, two analytic files are being developed—a physician-based file and a patient-based file. To develop the physician-based file, we used the 1994 and 1995 Medicare part B claims data to identify all surgeons who performed breast conserving surgeries or mastectomies in the study years. We found 363 surgeons in Washington State performing these procedures. We added a series of variables on these physicians from the AMA Masterfile and ABMS data sources—physician age, medical degree (MD/DO), sex, board certification, type of practice (solo/group), year of graduation from medical school. We then identified 2830 women who had had a surgical excision for breast cancer (e.g., breast mass excision, mastectomy) by one of these surgeons. Medicare claims data for these women and these physicians were used to define other variables for the analysis: 1) percent of surgeon's visits that were breast-related, 2) practice location, 3) percent of breast cancer patients with local, regional, or distant disease, 4) percent of breast cancer patients with oncology or radiation oncology consultation in the three months before surgery, 5) average patient travel distance to radiation therapy, 6) average patient travel distance to the surgeon, and 7) percent of patients with BCT with and without radiation (stratified by cancer stage). This file has been completed, with the exception of the average patient travel distance to the surgeon.

The patient-based file is currently under construction. The first step in creating the patient-based file was applying inclusion and exclusion criteria to the linked SEER-Medicare breast cancer cases. Figure 3 demonstrates the development of our study population. Cases that were excluded were males, patients with 2 or more simultaneous breast cancers, patients under the age of 66 (to assure a full year of available claims data for comorbidity definition), and patients with prior breast cancers at any time and other prior cancers within the past 5 years. These exclusions resulted in a sample size of 2008 potential cases. We then excluded patients who had had enrollment in an HMO or incomplete Medicare part B coverage in the year prior to their diagnosis as these patients would not have had complete Medicare claims submitted for the medical services they received. After invoking these criteria, 1541 breast cancer patients remained in our study population. The patient-based file contains information on these 1541 cases.

Many of the variables in the patient file come from the SEER database, whose data elements form the basis for this file. A file of all Medicare claims in 1993, 1994, and 1995 for the 1541 patients was created, and is being used to define many of the other variables. Many of the same routines used for the physician file are being used for the

patient-based file to create similar variables: consultation with an oncologist or radiation oncologist in the two months prior to diagnosis, and distance to the nearest radiation therapy center. The Medicare claims in the ten months prior to the two months prior to the breast cancer diagnosis have been used to define comorbidity using the Johns Hopkins ambulatory care group (ACG) case-mix classification system.

Work in the Coming Year

The database creation has been much more time consuming than originally anticipated. We hope to complete the patient-based file by the end of March 2000. Once the databases are complete, we will examine the unadjusted and adjusted BCT rates for surgeons with different characteristics, as well as for patients living at different distances from radiation therapy. We will also determine whether patients who consulted with radiation oncologists or oncologists prior to their surgery were more likely to receive BCT than those who did not.

FIGURE 1 — Physician Model: Factors Associated with BCT Rates

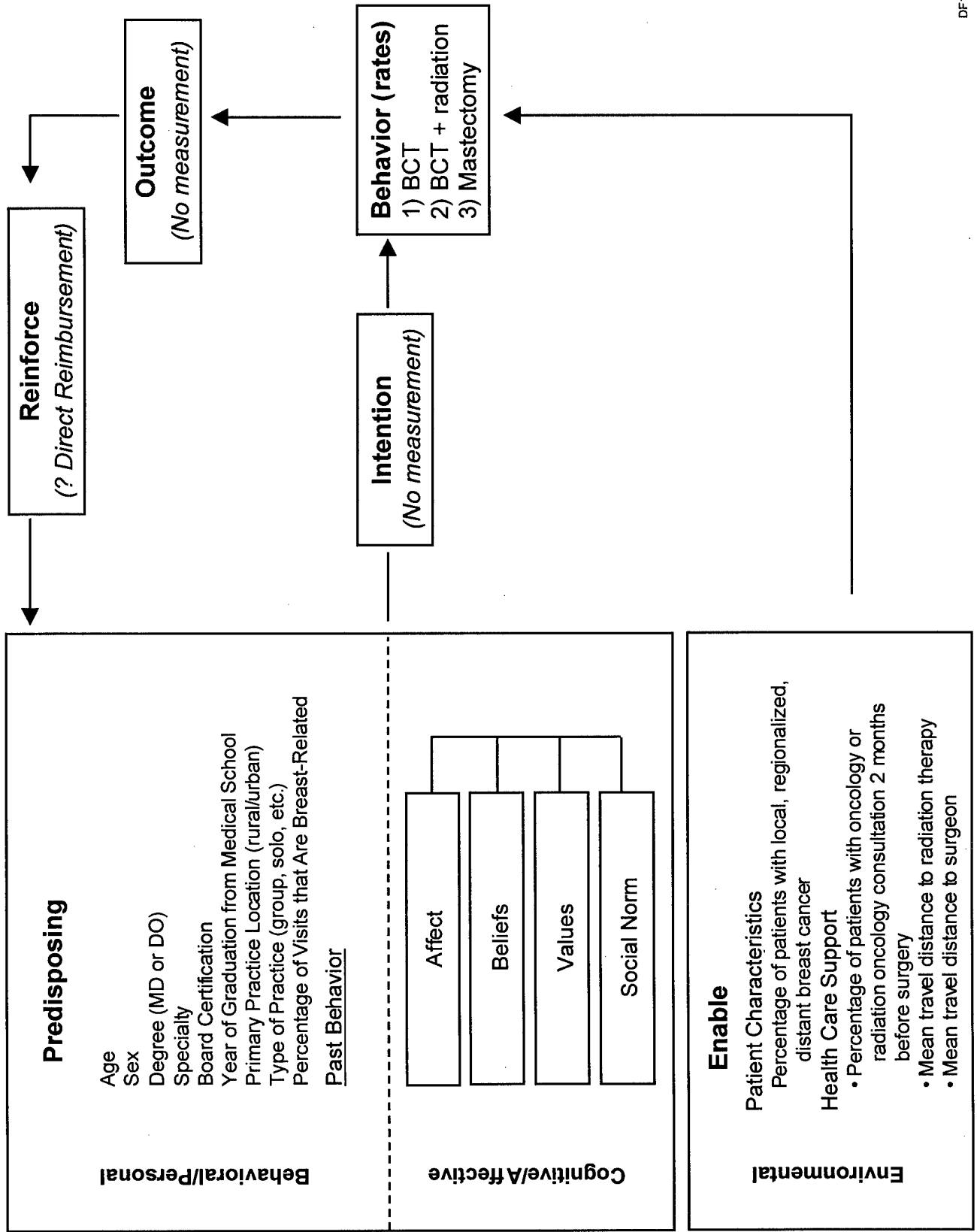


FIGURE 2 — Patient Model: Factors Associated with Choice of Treatment

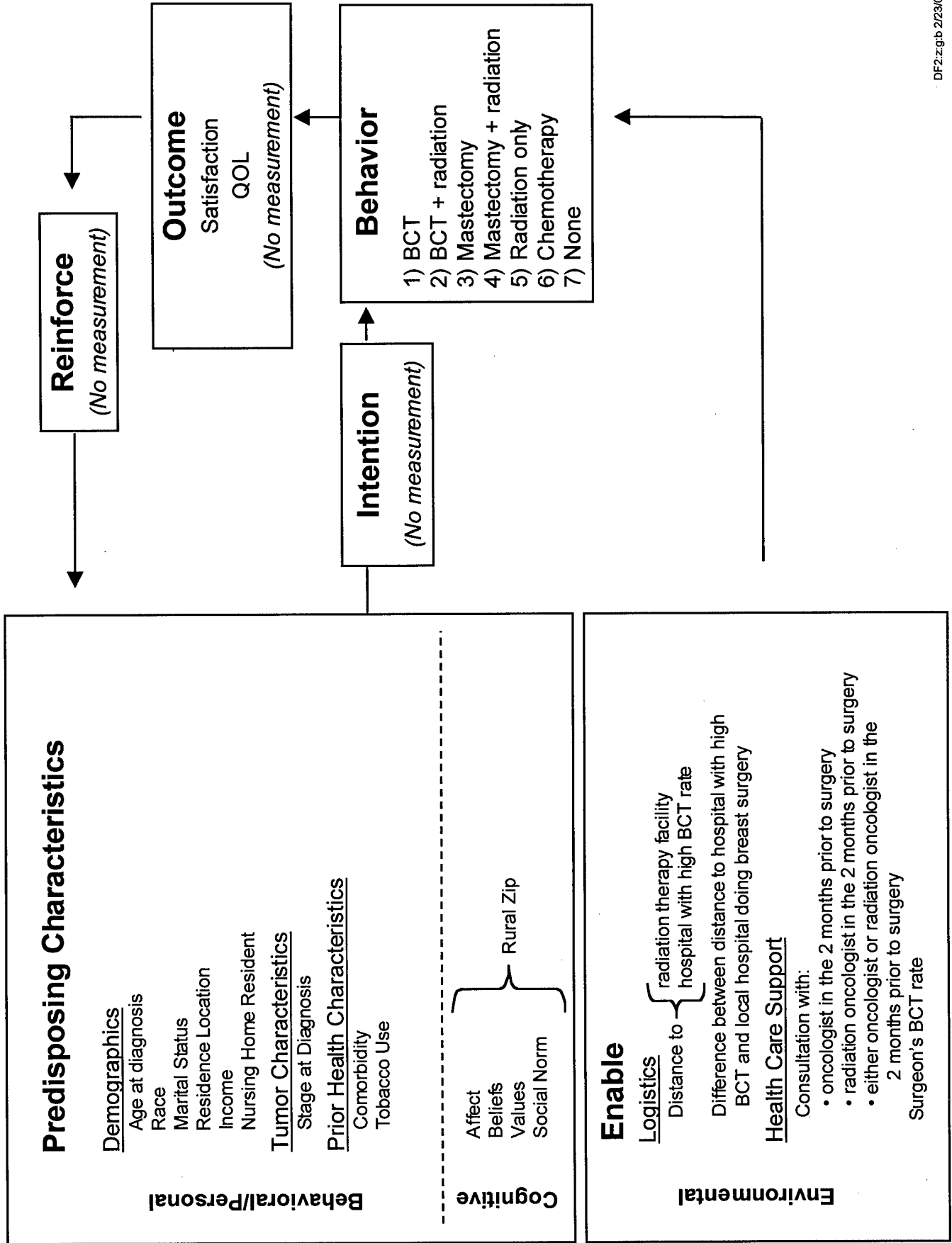
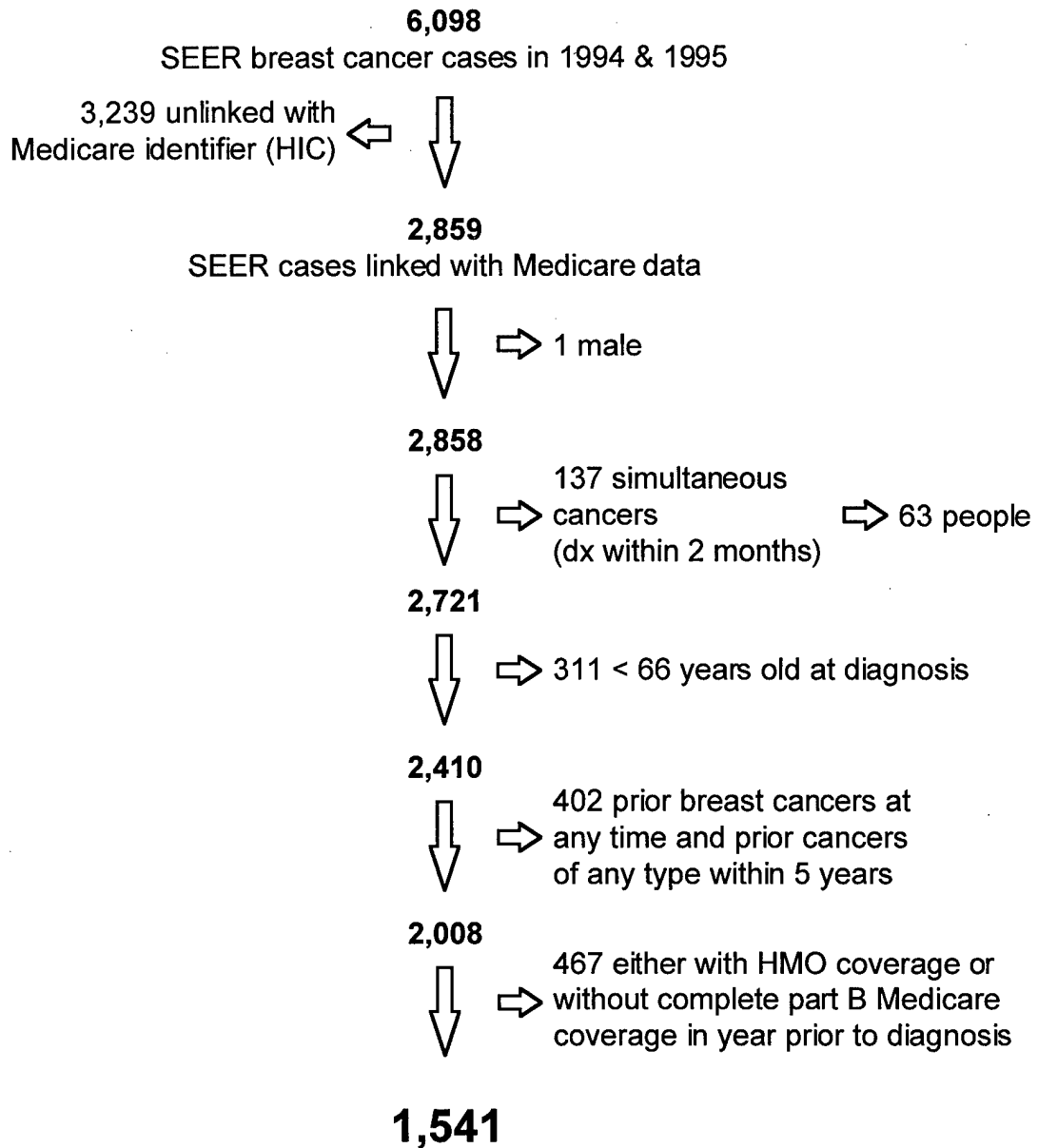


FIGURE 3 — Study Population



Conclusions

We have successfully created a very comprehensive database linking Medicare claims, SEER Program, ABMS, and AMA Masterfile data to identify factors associated with underuse of BCT in early stage breast cancer for elderly women. In the coming year, we look forward to testing our study hypotheses. Based on our study findings, we plan to propose interventions for assuring the availability of BCT to all women with early stage breast cancer.

References

1. Lazovich DA, White E, Thomas DB, Moe RE. Underutilization of breast-conserving surgery and radiation therapy among women with Stage I or II breast cancer. *JAMA* 1991; 266:3433-3438.
2. Lasovich DA, White E, Thomas DB, Moe RE, Taplin S. Change in the use of breast-conserving surgery in Western Washington after the 1990 NIH Consensus Development Conference. *Arch Surg* 1997; 132:418-423.
3. Lichter AS, Lippman ME, Danforth DN et al. Mastectomy versus breast-conserving therapy in the treatment of stage I and II carcinoma of the breast: A randomized trial at the National Cancer Institute. *J Clin Oncol* 1992; 10:976-983.
4. Morris AD, Morris RD, Wilson JF et al. Breast-conserving therapy vs mastectomy in early-stage breast cancer: A meta-analysis of 10-year survival. *Cancer J Sci Am* 1997; 3:6-12.
5. Sarrazin D, Le M, Rouesse J et al. Conservative treatment versus mastectomy in breast cancer tumors with macroscopic diameter of 20 millimeters or less: The experience of the Institut Gustave-Roussy. *Cancer* 1984; 53:1209-1213.
6. Veronesi U, Banfi A, Del Vecchio M et al. Comparison of Halsted mastectomy with quadrantectomy, axillary dissection, and radiotherapy in early breast cancer: Long-term results. *Eur J Cancer Clin Oncol* 1986; 22:1085-1089.
7. Veronesi U, Saccozzi R, Del Vecchio M et al. Comparing radical mastectomy with quadrantectomy, axillary dissection and radiotherapy in patients with small cancers of the breast. *N Engl J Med* 1981; 305:6-11.
8. Sarrazin D, Le MG, Arriagada R et al. Ten-year results of a randomized trial comparing a conservative treatment to mastectomy in early breast cancer. *Radiother Oncol* 1989; 14:177-184.
9. Fisher B, Redmond C, Poisson R et al. Eight-year results of a randomized clinical trial comparing total mastectomy and lumpectomy with or without irradiation in the treatment of breast cancer. *N Engl J Med* 1989; 320:822-828.
10. Fisher B, Bauer M, Margolese R et al. Five-year results of a randomized clinical trial comparing total mastectomy and segmental mastectomy with or without radiation in the treatment of breast cancer. *N Engl J Med* 1985; 312:665-673.
11. NIH Consensus Conference. Treatment of early-stage breast cancer. *JAMA* 1991; 265:391-395.

12. Farrow DC, Hunt WC, Samet JM. Geographic variation in the treatment of localized breast cancer. *N Engl J Med* 1992; 326:1097-1101.
13. Nattinger AB, Gottlieb MS, Veum J, Yahnke D, Goodwin JS. Geographic variation in the use of breast-conserving treatment for breast cancer. *N Engl J Med* 1992; 326:1102-1107.