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AWARD NUMBER DAMD17-94-J-4438

TITLE: Population-Based Mammography Registry

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13. ABSTRACT (Maximum 200) The objective of his infrastructure project was to expand a population-based mammography registry to 24 counties of eastern North Carolina (NC), an area with a large rural and black population. Mammography and pathology databases have been developed which allow linking of screening mammography assessments with cancer outcomes. Data is being collected directly from mammography facilities including demographic data, breast history data, reason for and findings on the screening mammogram, data on other radiologic studies necessary to resolve the screening assessment, and recommendations for follow-up. The pathology data from the NC Central Cancer Registry is received on a fast report system (weekly) for pathology diagnosed within the 24 counties, and on an annual basis for the remaining counties of the state. At the end of three years, there are 72 facilities actively participating and another 18 in the process of having data converted for transmission. There are 242,994 records representing 143,328 women from facilities in 37 counties. The age distribution of these women is 8% under 40, 31% 40-49, 27% 50-59, 19% 60-69, 15% ≥70. The racial distribution is 19% black, 79% white and 2% other. Five-hundred-one cancers have been identified following within 12 months of a screening mammogram. Cancer incidence by age and race, and performance indices are presented in this report.				
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FOREWORD

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Bonnie C. Harkness 20 February 1998
PI - Signature Date

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INTRODUCTION

The main objective of this infrastructure project was to expand a population-based mammography registry to include every mammogram performed in practices in a 24 county area of North Carolina, which has a large rural, and black rural population. The goal is to link pathology data, mammography diagnostic data, outcome data and quality data to study the patterns or use of mammography, and the patterns of practice of mammography in this distinct geographic region.

Previous to this application, a mammographic data retrieval system had been developed by the investigators, and feasibility work performed to get it into practices outside of the academic medical center. The project was proposed for an area that was already organized for pathology retrieval for the Breast Cancer SPORE. Having the infrastructure in place would allow research on mammography outcomes, with the ability to compare women served by the CDC BCCCP program and to study differences between rural and urban, and black and white women. At the end of the 3rd year, we have over 200,000 records in the registry, and are beginning analysis of the data. The Registry has expanded beyond the 24 counties, and continues to grow, remaining representative of the population of women in NC.

WORK IN PROGRESS

Task 1: Organizational Development (0-6 months.)

- a. Create oversight committee: to set policy, definitions and time tables, and promotional guidance for registry.*
- b. Create executive committee for practice recruitment: to design outreach program, and publicity for recruitment.*
- c. Create executive committee for pathologist recruitment: to establish approach for pathologist recruitment.*

At the end of year 3, task 1 is completed. We have a comprehensive advisory committee comprised of radiologists, pathologists, consumers, technologists, and representatives from the state, the BCCCP (CDC project), and the Breast Cancer SPORE who oversee the project. We meet in person in June, and by phone or fax as needed. We also have an advisory radiologist group. We converse with the five radiologists on this group on an on-going basis. Recruitment is no longer active, as we have completed the recruitment phase. We continue to grow, as practices voluntarily request to participate in this project. We have expanded beyond the 24 counties originally targeted. We presently have 90 facilities in 37 counties sending data or in the process of having their data translated to our data structure for transmittal.

Task 2: Customize and install computer network and programs (0-12 months).

- a. Design and install computer interface and linking programs to enable linkage to Lineberger CCC and NCCCR.*
- b. Establish confidentiality and quality control protocols*

In the first year, we developed systems for quality control checks of the data. At the end of year two these programs have been built into a computerized data management system, that automates much of this work. It logs in records, pulls in the data quality programs, it lists edit reports to

send to the practice, and keeps track of edit returns. This has streamlined our process as we grow in number of practices reporting data to us.

Confidentiality of data has been a concern that we pay attention to at all times. We have made an effort to keep the issues of confidentiality forever on the front burner, and in everyone's mind on a continuing basis. We have a Public Health Certificate of Confidentiality which is being reissued this month (February) to explicitly state that it covers data on the patients as well as the providers as research subjects.

We had completed Task 2 a year ago.

Task 3: Enroll Mammography practices and pathologists into registry (0-24 months)

- a. Contact every mammography practice in 24 counties to enroll in registry*
- b. Demonstrate and install mammography database in interested practices*
- c. Arrange for data transfer in practices already using a data system*
- d. Arrange for paper data collection and transfer in practices choosing this option*

We made tremendous progress in the past year. Table 1 which follows presents the practices now collecting data for the registry, the county, and the date they started collecting data. We now have data from all counties within the targeted with mammographic facilities. Three counties do not have any mammographic facilities. Though we do not have 100% of the facilities, the race and age distribution of the women in the registry is similar to the distribution for the 24 counties.

We only have one practice at this time sending data on paper. Most of our practices have gone to computerized data entry. Those using our data system now are on a routine schedule of data submission, many electronically and the edit process runs smoothly. With the changes in medical care, and the formation of managed care groups, some of our facilities were forced to move to a different data system for their facility. In these cases we are busy building interfaces to receive the data from their new formats. In most of these facilities when we finally begin getting data on a regular basis, we will get data back to the beginning of 1996 or 1997. Thus it is a loss of time, but eventually not of data.

We are going to begin installing an upgrade to our data system in March. We continue to improve the data system, using our experience to fine-tune the data collection process. This strengthens our quality control of the data, and improves our ability to have reports for the facilities.

- e. Establish process with each pathology site for acquisition of all breast pathology data: and expand process with those already cooperating with NCCCR, to acquire benign breast pathology.*

We now receive fast-report pathology data from 26 pathology sites in the 24 counties, and 15 of these also report benign data on a fast report schedule. We have been told the statewide Central Cancer data for 1996 will arrive by the end of February. This is most important for the sites outside the 24 counties, who do not enter their own pathology data into our system. We also get fast report benign data from 3 pathology facilities outside the 24 counties. We continue to receive pathology data for our pathology database from three sources: 1) the practices entering

pathology reports they receive directly into our mammography database system; 2) the fast report system from the CCR which gives us malignant and increasingly more benign data from the 24 counties, and selected other sites, and 3) the annual data which provides cancer data for the entire state. We are in the process of arranging for expanded receipt of fast report pathology data (malignant and benign) from the pathology services outside the 24 counties. This will give us outcome data faster for feedback to our participating facilities, and will enhance the outcome data collection for women receiving their mammogram within the 24 counties, and their pathology outside these counties. With the annual data we eventually get all cancer for the state, regardless of the fast-report status.

Task 4: Operate and Maintain Registry (0-36 months)

- a. On-going data cleaning and entry*
- b. On-going quality control*
- c. Linkage to NC-CCR and Lineberger CCC*
- d. Respond to requests for shared use of registry data (beginning at 36 months)*

The registry is operating well, receiving data, editing data, cycling back to the practices for edits, getting the edits returned, assigning unique ID's, removing identifying information, and linking with pathology all occur with systematic regularity. We have in place an automated error checking system, which allows us to check our data for inconsistencies more accurately; consequently increasing the integrity of our data. Unique ID's are now assigned using a probabilistic record-linkage methodology. In addition we now have an automated outcome system that lists for our practices the pathology outcomes for their patients, and the patients recommended for further work-up who have not returned. This is a service we offer in exchange for their participation in the project. It is a benefit to them and to us. We assist in follow-up when requested to do so. We are presently putting most of our effort into improving the rate of follow-up data. Our new outcome system should greatly enhance this effort. The first round of outcome reports were distributed in January, and the facilities are busy following up on the women we identified who were missing follow-up information. This is now an automated process. We will quarterly send these reports, then work with the practices to have complete follow-up on all women.

We have successfully linked mammographic data to pathology data, which is required for the outcome system to work. Some preliminary results dependent on this process are presented below.

The following are the developments made to the mammography data system (CMDS) this year: The goal for changes is to have a system that is easy to use, operates in the various environments of our diverse facilities, meets reporting needs of the facilities, gives feedback on performance to the facilities, and improves confidential transmission and storing of data.

- ◆ Instituted a Mammography Tracking System to follow both normal and positive mammogram patients through the system. This provides all of the information necessary to contact any patient who has not yet returned for a scheduled visit.
- ◆ Constructed a detailed reporting system that would elaborate on mammogram volume by

radiologist and technologist for each site location and give distribution totals for mammogram interpretation results along with totals for recommended followup test(s).

Also included are volume totals for all screening and diagnostic tests entered into CMDS.

- ◆ Incorporated encryption routines to protect downloaded mammography and pathology data to ensure confidentiality of data while electronically enroute to CMR.
- ◆ Added pathology tracking system and reports to track patients recommended for biopsy whose pathology reports were absent from the system to allow more effective followup. Enhanced pathology reporting to include pathologic diagnoses along with summary statistics outlining case volume and breakdowns of benign and malignant findings along with unique breast cancer types for diagnosed at each site
- ◆ Standardized and improved data integrity through the incorporation of pick lists and data validity routines throughout the program.
- ◆ Incorporated a commercial grade linker for program to take advantage of both DUAL and PROTECTED Mode Memory Management.
- ◆ Instituted remote dial-in capability at various sites to allow electronic downloading of data directly into CMR.
- ◆ Made required changes to ensure complete Year 2000 compliance and modified the user interface to meet Common User Access (CUA) standards.
- ◆ Numerous changes were made to ensure this program will run on various Operating Systems and Network Operating Systems. Operating Systems include any DOS version from 3.3 or later, NT, O/S2, Windows 95, Windows 3.1, and Windows for Workgroups 3.1. (Program must be run in a DOS session when in these GUI environments.) Network Operating Systems that are compatible are those that are NETBios aware and compliant - including OS/2, NT, Windows peer-to-peer, Novel, Novel Lite, Lantastic, and others.
- ◆ Network performance and integrity was improved by ensuring that any/all temporary files have a unique name and is visible only to the creating workstation. Additionally, a new and more sophisticated Database Driver was incorporated for smaller, faster, more robust indexes.
- ◆ Enhancements were added to import data from a mainframe system for those sites that require it - currently 2 sites. These enhancements import, parse, convert and store the data into the data structures used by this program. Additionally, data validation and integrity are tested during these imports.

Other Activities.

As we reported last year, we were successful in being funded by NCI to become members of the National Breast Cancer Surveillance Consortium. The Principal Investigator, Bonnie Yankaskas, is a member of the Steering Committee of the Consortium, and will be the next Chair of this group beginning in April 1998. The consortium has now agreed on the core mammographic, pathologic and follow-up variables that we will collect for the national dataset. We were well poised to accomplish this with little extra work, as we had already designed a data collection system that is in line with the goals of the consortium. The consortium through its Statistical Coordinating Center will enhance our ability to strengthen any research we do by letting us compare results on a national scale. Several workgroups have been formed within the consortium for carrying out specific research projects. Again, this enhances any work we do with our data in NC. The NC data is the only population data with a large component of rural

south and rural African American data. With NCI funding, we have expanded to create a Native American Registry within our registry.

RESULTS: UNPUBLISHED, NOT FOR DISSEMINATION.

In the total registry, there are 158,845 women over the age of 21, residing in NC. Their urban/rural distribution is 59% in areas <50% rural, 22% in areas 50-74% rural, and 19% in areas that are 75-100% rural. The age and racial distributions are shown in figure 1. The other group consists of Asians, Native Americans, and Hispanics.

Based on the 41 facilities for whom we have been receiving data for at least 12 months, the average number of mammograms a month across these facilities ranges from 25 to 665, with a mean of 149/month. The distribution of screening and diagnostic mammograms over time based on all reporting facilities is displayed in figure 2. As can be seen, we have been growing steadily over time.

Table 2 presents the distribution of the radiologic assessment (ACR codes) for screening mammograms by age group. Sixty-percent of our mammograms are in women under 60 years of age, which sets us up well to examine screening outcomes in women in their 40's and 50'.

Tables 3, 4 and 5 present the cancer yield for all screening, cancer yield by race, and the cancer yield among the subgroup recommended for biopsy following a screening mammogram. The overall performance indices for the screening mammographic workup (includes radiologic studies performed as a result of the screening mammogram in the assessment) were: sensitivity .71 (95% confidence interval .66, .76), specificity .98 (.98, .98) and positive predictive value .13 (.09, .17).

Much more data will be forthcoming in our manuscripts which we will forward to you at time of submission for publication. The initial look at our data has given us confidence that we are getting a representative database, and that the distribution of screening to diagnostic mammograms is what we would have expected.

Five manuscripts are in preparation at this time.

1. The Carolina Mammography Registry, Screening Practice and Outcomes in NC.
2. Parenchymal Breast Density and Sensitivity of Screening Mammography.
3. The role of the referring physician in compliance with follow-up recommendations following a positive mammogram.
4. Screening mammography practice in NC among African American Women.
5. Estrogen and Progesterone Receptor status and Breast Cancer Detection by Screening Mammography

Table 1: Participating Facilities

	B	C	D	E	F	G	H
1	Facility Type	start up date	County		Facility Type	start up date	County
2	Original 24 Counties			NC Counties Outside Original 24			
3	PR	10/6/93	Alamance		HR	11/12/97	Cherokee
4	PR	5/31/95	Beaufort		PO	10/6/93	Gaston
5	HR	1/30/97	Beaufort		PO	10/1/97	Gaston
6	HR	8/30/95	Bertie		HC	9/13/95	Graham
7	HR	5/8/97	Chatham		PO	10/6/93	Guilford
8	PO	7/20/93	Durham		PR	10/6/93	Guilford
9	PR	7/20/93	Durham		HR	11/13/97	Jackson
10	PR	7/20/93	Durham		HR	10/1/96	Macon
11	PR	7/20/93	Durham		HR	8/18/97	McDowell
12	HR	2/26/97	Durham		PO	10/6/93	Mecklenburg
13	PO	2/26/97	Durham		PO	10/6/93	Mecklenburg
14	PO	2/26/97	Durham		HR	9/20/95	Mecklenburg
15	PO	2/26/97	Durham		MR	9/20/95	Mecklenburg
16	PO	6/6/97	Durham		PO	9/20/95	Mecklenburg
17	PO	2/26/97	Durham		PO	9/20/95	Mecklenburg
18	HD	12/3/96	Greene		PR	9/20/95	Mecklenburg
19	HR	7/11/96	Harnett		HR	4/11/96	Mitchell
20	PO	7/11/96	Harnett		HR	12/1/96	Surry
21	HR	10/7/96	Hertford		HR	11/13/97	Swain
22	PO	10/6/93	Johnston		22		11 counties
23	PO	5/21/97	Jones				
24	HR	7/26/97	Lee				
25	PR	4/8/97	Lenoir				
26	HR	3/5/96	Martin				
27	HR	6/1/95	Moore				
28	HR	6/1/95	Moore				
29	HR	7/7/95	Nash				
30	HR	10/1/95	Nash				
31	PO	11/6/97	Nash				
32	HR	1/1/94	Orange				
33	PO	1/1/94	Orange				
34	PR	1/1/94	Orange				
35	PO	8/1/95	Orange				
36	PR	3/26/96	Orange				
37	PO	11/5/93	Pitt				
38	PO	10/6/95	Pitt				
39	PR	7/29/96	Pitt				
40	PR	4/15/96	Wake				
41	HD	7/31/96	Wake				
42	PO	7/31/96	Wake				
43	PO	7/31/96	Wake				
44	PR	7/31/96	Wake				
45	HR	11/1/97	Wake				
46	PO	11/1/97	Wake				
47	PO	11/1/97	Wake				
48	HR	1/1/96	Washington				
49	MR	5/31/95	Wayne				
50	HR	10/23/95	Wilson				
51	PO	10/23/95	Wilson				
52	PO	8/14/97	Wilson				
53	50		21 Counties				

72 facilities reporting

Table 1: Participating Facilities

	B	C	D	E	F	G	H
1	Facility Type	start up date	County		Facility Type	start up date	County
54	Original 24 Counties				Counties Outside Original 24		
55	PO	interface	Craven		PO	contract	Forsyth
56	PO	interface	Nash		PO	contract	Guilford
57	HMO	interface	Orange		HMO	interface	Mecklenburg
58	HR	in process	Pitt		Van	interface	Robeson
59	HMO	interface	Wake		HR	contract	Swain
60	PO	interface	Wake		5		
61	PO	interface	Wake				
62	PO	interface	Wake				
63	PR	interface	Wake				
64	PO	interface	Wake				
65	HR	interface	Wake				
66	PO	interface	Wake				
67	PR	interface	Wake		18 will be sending data		
68	13						
69							
70	HR = hospital radiology practice						
71	PR=Private Radiology practice						
72	PO=Private non-radiology practice - screening only						
73	HD=health Department						
74							
75							
76							
77							
78							
79							
80							
81	Total committed to project as of end of 1997=90						
82							
83							
84							
85							
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**Figure 1: Women in the Registry 1994-1997
Age Distribution by Race**

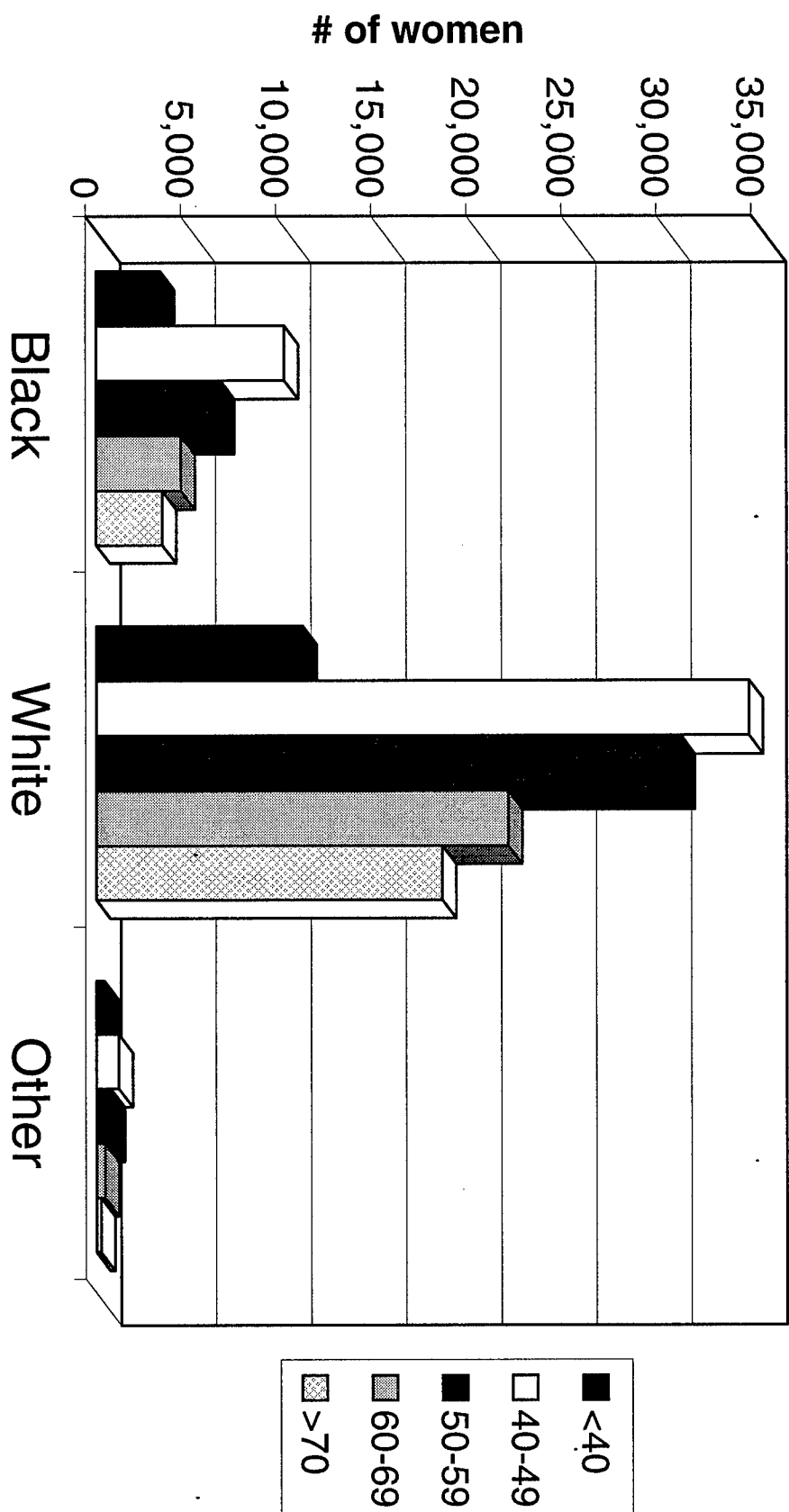


Figure 2: Cumulative Distribution of Screening and Diagnostic Mammograms

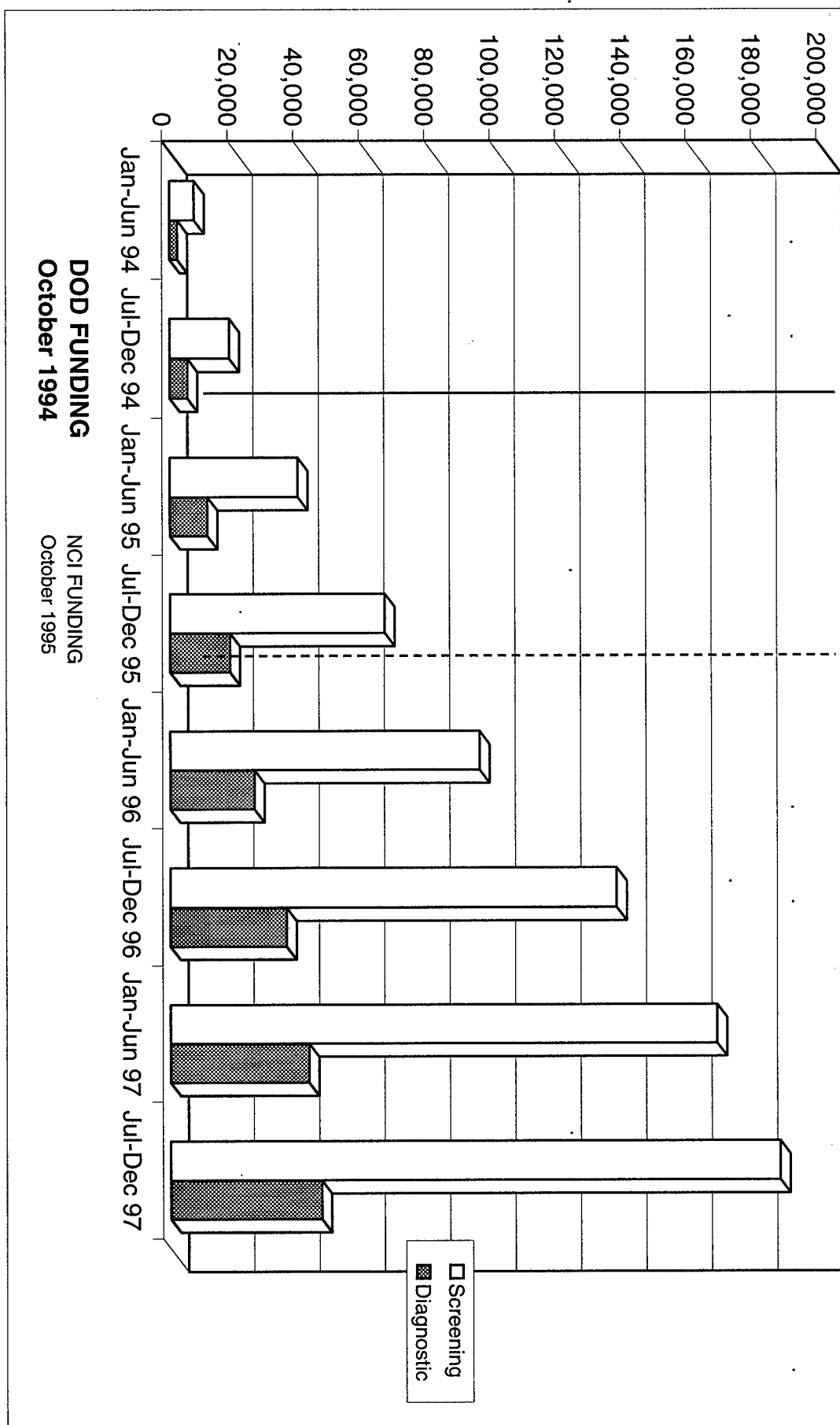


Table 2: Screening Mammogram Assessment by Age Group

Age Group	N=	ACR Assessment Category					
		<i>percent of age group</i>					
		0	1	2	3	4	5
21-39	13,557	11	64	16	8	1.4	0.2
40-49	40,934	6	65	20	8	1.2	0.2
50-59	34,108	4	67	22	7	1.1	0.2
60-69	23,970	4	67	21	7	1.2	0.3
≥ 70	20,041	3	66	23	6	1.6	0.6
Total	132,610	5	21	21	7	1.2	0.3

0 = needs further workup

1 = normal, no findings

2 = benign findings

3 = probably benign, recommend short term follow-up

4 = suspicious abnormality

5= suspicious for cancer

Table 3: Cancer Following Screening Mammogram
(within 12 months of screening)

Age Group	≤39	40-49	50-59	60-69	≥70	Total
n and % with cancer diagnosis	15 0.15	89 0.21	137 0.33	139 0.45	122 0.50	501 0.34
In situ ductal	5	22	20	26	17	90
Invasive ductal	9	56	97	99	93	354
Invasive lobular	1	11	20	13	11	56

Table 4: Cancer Following Screening Mammogram
(within 12 months of screening)

Racial Group	Black	White	Other	Total
n and % with cancer diagnosis	82 0.30	402 0.35	1 0.03	485 0.33
In situ ductal	16	71	1	88
Invasive ductal	58	286	0	344
Invasive lobular	8	45	0	53

Table 5: Cancer yield from recommendation for biopsy

Age Group	≤39	40-49	50-59	60-69	≥70	Total
n and % recommended for biopsy	87 0.9	423 1.0	417 1.0	367 1.2	337 1.4	1,631 1.1
n and % with cancer diagnosis	5 5.7	47 11.3	76 18.5	82 22.3	85 25.2	295 18.1
In situ ductal	2	16	11	13	13	54
Invasive ductal	2	25	57	62	65	211
Invasive lobular	1	6	8	7	7	29



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y)

14 Oct 99

MEMORANDUM FOR Administrator, Defense Technical Information
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SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for Grant DAMD17-94-J-4438. Request the limited distribution statement for Accession Document Number ADB236135 be changed to "Approved for public release; distribution unlimited." This report should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by email at Judy.Pawlus@amedd.army.mil.

FOR THE COMMANDER:

PHYLIS M. RINEHART
Deputy Chief of Staff for
Information Management

Completed
2-8-2000
B.W.