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13. ABSTRACT (Maximum 200 words)  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 was to link pathology and mammography data to study the patterns or use of mammography, and the patterns of practice of mammography in this distinct geographic region. Having the infrastructure in place would allow research on mammography practice and outcomes, with the ability to study differences between rural and urban, and black and white women. At the end of the first four years, we have recruited a total of 97 mammography facilities, 64 in the 24 counties and 33 in other counties in the state. There are data ready for analysis from 69 facilities, with 279,575 records in the registry for 185,956 women residing in NC. We have lined 857 cancers following within a year of a screening mammography exam, for a cancer incidence in those screened of 5.9 per 1,000. We are currently working on several manuscripts. The Registry has expanded beyond the 24 counties, and continues to grow, remaining representative of the population of women in NC. We have support to pilot a special project for Native American women in NC, and have submitted a grant to DOD for creation of a Native American Registry for the state, building on the pilot project.				
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Bonnie E. Hankes 19 October 1998  
PI - Signature Date

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## FINAL REPORT: POPULATION-BASED MAMMOGRAPHY PROJECT IN NC

### INTRODUCTION

Registries have been part of the national public health scene providing important public health information in many arenas, particularly in cancer surveillance. Though there have been mammography registries created, it is only recently that there has been an appreciation of the value of a national mammography data.<sup>1</sup> In 1994 the Department of Defense, through their breast cancer research program, funded the creation of several mammography databases including the Carolina Mammography Registry (CMR), to create an infrastructure of data that would provide the opportunity to better understand how mammography ultimately impacts upon women's health. The CMR along with several other population-based mammography registries around the country are now in existence.<sup>2-5</sup> The CMR has been established to study a population of approximately 360,000 women in 24 counties in the eastern part of North Carolina. This surveillance data was possible for two major reasons: 1) this particular area of North Carolina had already been mobilized for breast cancer research, and 2) we have an excellent state cancer registry, the North Carolina Central Cancer Registry (NC-CCR), that is providing outcome data, with excellent cooperation from the pathologists serving this area. In addition to having breast cancer outcome, we have information of benign outcomes that may help shed light on the non-cancerous mammographic findings that result in unnecessary biopsies in many women.

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 was to link pathology and mammography 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. The original application was funded at 50% of the requested budget, and the adjusted work statement reduced the project from 4 to 3 years of funding, and excluded analysis beyond descriptive work. The plan was to get other funding to support the analytic portion of this work. We have been successful beyond the original scope in building the registry, and in acquiring other funds to support continuation of this work both in scope and analysis.

At the end of the first four years, we have a total of 293,155 records in the registry. There are 279,575 records for 185,956 women residing in NC. We are actively working on several manuscripts. The Registry has expanded beyond the 24 counties and continues to grow, remaining representative of the population of women in NC. We have support to pilot a special project for Native American women in NC, and have submitted a grant to DOD for creation of a Native American Registry for the state, building on the pilot project.

At this point in the project, we are proud of our accomplishments, and the potential for future work. As with most work, there have been accomplishments planned, and several benefits from this work that had not been anticipated or at least not set as an original objective of the work.

- ◆ Our funding by NCI to expand this project as a member of the National Breast Cancer Surveillance Consortium. I, (Bonnie Yankaskas the PI of this project) am presently the Chair of the Consortium.
- ◆ Our newly funded pilot project to create a Native American Registry for North Carolina. (We have submitted a grant application to the DOD for carrying out this work, beyond the pilot).
- ◆ The on-going education that takes place in the screening facilities on screening assessment and outcomes. We have been excited by the amount of commitment on the part of the participating radiologists. They are genuinely interested in assessing how they perform, and want to know how they compare to the state practice as a whole. This registry has enabled us to do this. This will benefit women directly.
- ◆ The knowledge we have gained about the intricacies of data capture, data definitions, and data analysis for screening mammography that is being discussed and studied as part of the National Consortium. Particularly, we have learned that the ACR BI-RADS coding system for assessment of screening mammography does not get followed in a standard fashion in its general use. We resorted to a combination of the assessment code and a record of what the radiologist actually recommended following the screening mammogram for our definition of a positive mammogram.
- ◆ We have created a computerized mammography data system that has proven extremely useful for our research data, but equally useful for practices to track their mammography outcomes. They can easily produce reports for their MQSA inspections and for monitoring their practice activity and outcomes. More women will be successfully followed to completion of their work-up because of this partnership.
- ◆ We have reviewed the false-negative mammography screening studies and are about to publish a first estimate of what the community miss rate is among community based screening programs. We have already had feedback from the NC Malpractice Association on the value of having these data.

The final report in relation to the proposed research objectives is presented below.

*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.*

Task one was completed in the first phase of the project. We combined these three groups into one advisory committee, and subset them as appropriate for guidance and planning. Our advisory committee is an active group that meets formally once a year, and informally via email and phone conversations on an as needed basis. We have a comprehensive advisory committee that is comprised of radiologists, pathologists, consumers, technologists, and representatives from the state, the BCCCP (CDC project), and the Breast Cancer SPORE. We created an advisory group of our participating radiologists who have been an invaluable asset to this project, reviewing any changes we make to our data system, data collection sheets and clarifying practice related issue and definitions that arise in the data collection process. The six radiologists are: David Desrochers of Washington NC, Richard Bird of Charlotte NC, Bryan Koon of Durham NC, Claire Poyet of Chapel Hill NC, Cheryl Viglione of Greensboro NC and Bruce Schroeder of Greenville NC.

*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*

We had a rudimentary computerized data system that was being field tested and improved with the help of our first 5 participating practices prior to DOD funding. With funding under this project, we have built a computerized mammography tracking system (the Carolina mammography Data System, CMDS) that is used by most of our facilities. This system efficiently captures data on patient demographics, breast health history, other pertinent medical history, reason for mammographic visit, problems at presentation, what imaging is done, what is found, the findings and the appropriate code (using the American College of Radiology Lexicon coding system), the recommendations for follow-up and the recommended time for follow-up. There is also a screen for entering pathology data when it is received directly by the facility. The CMDS has built-in reports for practice activity, radiologist activity, listings of women with abnormal mammography for tracking purposes and much more. It has a fully functioning query system that allows the practice personnel to look at any of the data in the database created by the CMDS. The CMDS also has the ability to produce reminder letters for scheduling next visits, and for a follow-up reminder for women who do not respond to the reminder by coming in for a visit. The CMDS has worked so well that much of the growth of the Registry beyond the original 24 targeted counties is due to practices wanting to join the project to have the data tracking and reporting system.

In addition to the CMDS, we developed a computerized data management system that automatically logs in records, pulls in the data quality programs, puts out edit lists and reports that we send to the practices for data editing, and keeps track of edit returns. This system increases the integrity of the data and the completeness of the registry.

We have had two upgrades of our computerized system, making improvements to enhance speed of data entry, integrity of the data, and addition of new features to capture new data or improve capture of old data. The system now collects specific assessment of Ultrasound reports as well as mammography.

Rather than going out to link with pathology data at the NC Central Cancer Registry (NCCCR), we worked out an agreement with the NCCCR, and receive data directly to create a pathology database on site.

Confidentiality of data has been a concern that we pay attention to at all times. We have IRB approval from our institution as well as other major institutions whose data is shared with us. We have received IRB approval from hospitals who send pathology data directly to us. We have a Public Health Certificate of Confidentiality covers data on the patients as well as the providers as research subjects. We have established a very definite procedure to further protect all data, and remind staff continually of the importance of the responsibility to maintain confidentiality of the data at all times. Figure 1 is an outline of our confidentiality procedures. We share these with all our facilities in the original contract we make with them.

*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*
- 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 have contacted every practice in the 24 counties, many multiple times, and are no longer actively recruiting. All but 7 practices are collaborating with us. The 7 practices that refused to participate include one very large practice that refused to participate but agreed to give us limited data annually, which allows us to track women who attended this practice for follow-up imaging.

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 (present and retrospective) translated to our data structure for transmittal. At the end of the fourth year, we are well established in the 24 counties that were our original target, and have data from facilities in an additional 17 counties, including all facilities in the most western part of the state. As the western part of the state is culturally and ethnically very different from the eastern part of NC, having these two areas covered will enable the comparison of outcomes between these two parts of the state. 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 area that have 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 now receive fast-report pathology data from all hospitals connected with our reporting facilities, and fast reporting of all breast pathology (malignant and benign) from 20 of the 26 pathology hospital departments. We have received the 1996 annual Central Cancer Registry data, and hope to have the 1997 data by the end of this year. This is most important for the few



sites who use private pathology labs and do not enter their own pathology data into our system. We calculated that we receive approximately 90% of all cancers through the fast report system. We receive some that are missed by the Central Cancer Registry, thus between our fast report and the annual CCR data, we have good coverage for linkage with our mammography database. With the annual data we eventually get all breast cancer reported for the state, regardless of the fast-report status, which gives us more complete data for any one report as we have two opportunities to receive the same data. There is presently a bill before the state legislature in NC to make cancer reporting mandatory for all facilities, hospital and private labs with built in penalties for non-compliance. If this passes, it will make all our work easier.

*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. We receive data, edit data, cycle data back to the practices for edits, all with systematic regularity. The practices have become very compliant in returning edits in a timely manner, now that they understand the benefits to them in tracking their patients and monitoring how their practice performs. Assigning unique ID's, removing identifying information, and linking with the pathology database occurs on a regular basis. Unique ID's are now assigned using a commercial probabilistic record-linkage methodology Matchware<sup>®</sup>. With our support from NCI we have created 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 has greatly enhanced this effort. This is now an automated process. We send quarterly reports, then work with the practices to have complete follow-up on all women. Figures 2-4 display the flow for creating our mammography data system, our pathology data system and the outcome system. We also send an annual report with outcome data. (Example is in Appendix B).

*Task 5: Data Analysis and Report Writing (30-36 months)*

- a. Begin analysis on screening patterns and outcomes*
- b. Submit grants for support for the molecular biology and mammography project*
- c. Evaluate feasibility of making registry into a state registry.*

We were successful in getting NCI funding which is supporting continued development of this project, and data analysis. We have support for the biology project and have evaluated the pros and cons of making this a statewide Registry. With near complete coverage of facilities in the eastern part of NC, and complete coverage of the very western part of NC, and knowing that our population is representative of the age/racial distribution of the state, we have come to the conclusion that there is not much to be gained for the cost of going state-wide. Instead, we have targeted expansion to creating registration of all Native American women in the state. We have a pilot grant from NCI to test a new approach to accomplish this goal, and have submitted a full grant for this work to the DOD.

Manuscripts are in preparation and are itemized below. We have used the Registry data to help the SPORE NC-Breast Cancer Screening Program evaluate their work, and worked closely with the CDC BCCCP for their work. We have streamline the data collection process such that the facilities that need to report to both our project and the CDC project can use our data form for both purposes. We are presently doing an analysis of the BCCCP women who are seen in facilities that participate in our Registry, comparing their outcomes and compliance with screening recommendations to the non-BCCCP women seen in the same facilities.

#### Other Activities.

Several workgroups have been formed within the National Breast Cancer Surveillance Consortium for carrying out specific research projects. 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 southern and rural African American women, and soon (we hope) will be the only population-based mammographic tracking system for Native American women east of the Mississippi River.

#### DATA ANALYSIS AND MANUSCRIPT DEVELOPMENT

*(Results unpublished, not for dissemination.)*

Following is a listing of our works in progress with preliminary results, and tables and graphs displaying some of our results for the years 1994-1997. These data are not to be disseminated or cited until published. We will forward copies of all manuscripts at time of submission and notify you of acceptance for publication. The data that are not shown here are related to the urban/rural breakdown. After many attempts to get a valid way to categorize data into urban/rural, what we have learned is there is not a standard way to accomplish this analysis. We are working on using census-tract information and MPA designations to assign each woman to an urban/rural status. North Carolina, which is a state that is rural in nature but has a high percent of population living in small cities (or large towns), does not fit neatly into most schemes for defining urban/rural. We are presently giving this much academic attention and when we have worked out a scheme that is rational and reproducible, we will analyze our data by this breakdown.

We have done extensive work looking at the question of assigning an SES classification to each woman. We have many facilities who refused to collect information on educational status, and a few who will not ask for racial information. We have studied the accuracy of using census data to estimate these characteristics using census block data. Unfortunately it works quite well for urban residents, but poorly for rural residents. This is on-going work.

We have published one manuscript:

Yankaskas BC, Jones MB, Aldrich TE. The Carolina Mammography Registry: A Population-Based Mammography and Cancer Surveillance Project. *J Registry Management* 1996; 23:175-178.

We have one presently being reviewed by JAMA.

Jennifer David Peck, M.S., Bonnie C. Yankaskas, Ph.D, Michael J. Schell, Ph.D, Janne Abullarade, M.S. Performance of Screening Mammography: Parenchymal Density and Age. Submitted, September 1998, and just returned for revisions. As soon as we have completed the revisions and resubmitted it to JAMA, we will forward a copy to you.

We have many other manuscripts in preparation at this time, 8 are listed below. I have only listed first author at this time. All are being prepared under my guidance or by me. We will gladly send copies to you when they are submitted for publication. It should be understood that all were possible owing to this infrastructure DOD grant and the further support for continuation of the Registry and data analysis from our NCI grant.

1. Yankaskas BC The Carolina Mammography Registry, Screening Practice and Outcomes in NC. This will be submitted by 1 December 1998. This is a descriptive paper of the early results for the years 1995-1997, and will have similar data to what is sent along with this report.

2. McFadden D. Screening mammography practice in NC among African American Women. This is in final stage of writing. The most interesting result of this work is how few differences exist between black and white women in screening behavior, screening work-up, screening outcomes or breast history. The two populations are striking similar. There seems to be no bias to the work-up and no difference in the distribution or incidence of cancer. The only difference we found is described in the next listing, and perhaps a slight difference in the age distribution in who is getting screened. We have slightly higher percent of younger women and slightly lower percent of older women in blacks compared to whites.

3. Kwok, R. The Use of Census Data to determine an Individual's Socio-Economic Status: A Validation Study. This is a study we did comparing known education and racial status to what would have been assigned using geocoded census block-group classification. The results showed that using the methodology of the majority racial and educational characteristics of a census block group proved reliable for only a small subset of white urban dwellers where the match rate was over 90%. All other match rates were between 26% and 89%.

4. Kemske. R. Estrogen and Progesterone Receptor status and Breast Cancer Detection by Screening Mammography. This will be submitted by 1 January 1998. We evaluated the ER and PR distribution and the combined ER-PR distribution for screen and interval detected cancers. Black women have a higher percent of ER and PR negative tumors, when compared to white women.

5. Kaminetzky CP. Timeliness of Follow-up After Abnormal Screening Mammography: The Role of the Referring Physician. This will be submitted this winter. The significant finding of this study is that patients are more likely to be compliant with follow-up recommendations when their referring physician is female and in certain practice specialties.

6. Yankaskas BC. Study of false negative screening mammography in the community. The draft of this is completed and is being reviewed by the co-authors and will be submitted shortly. We have done a film review to establish the percent of studies that were initially false-negative that would be false-negative when reread by a panel of 5 radiologists from the community who participate in the registry. It is close to 60%. This analysis has not been reported before.

7. Alexander J. Pattern and Timeliness of Follow-up After Abnormal Screening Mammography.

8. Callahan C. Timeliness of Follow-up After Abnormal Screening Mammography: The Role of Type of Mammography Facility. This work is in the final analysis stage, but preliminary results point to poorer compliance with quick follow-up behavior related to whether a woman had her screening mammography performed in a screening only facility or one that offered screening and diagnostic evaluation. This will be an important contribution and we hope will translate into a discussion of follow-up for women seen on mobile vans and receiving mammography screening in non-radiologic sites such as Family Practice and Obstetrics and Gynecology practices.

#### TABLES AND FIGURES

Figures 5 and 6 present graphically the growth of facilities and total records in the total Registry. These document our steady growth.

Figure 7 displays the cumulative growth of screening and diagnostic mammography records over time. The ratio of diagnostic to screen is what we expected and has been consistent as we have grown, adding to our confidence that we are getting complete reporting from our participating facilities.

Figure 8 and Table 2 present the age/racial distribution of all women residing in the Registry population as of November 1998. We presently have 279,575 records for women residing in NC in the Registry. This represents 185,956 women. The distribution is very similar to that of North Carolina.

Table 3 presents the distribution of women with at least one screening mammogram in the Registry by age group and the number of screening mammography studies they have in the Registry. Table 4 is the distribution for time between screening examinations for women with more than one record. As can be seen, for younger women, the distribution for number of studies and time to return are very similar. For older women, black women have a lower percent of multiple screening mammography examinations and a higher percent for longer time between repeat screens when they do return. The mean number of months between screens was 14.4 for white women, 15.1 for black women and 14.8 for our small group of other races. The mean times for the age groups were 15.6, 16.2, 14.3, 14.0 and 14.3 months for age groups respectively under 40, 40-49, 50-59, 60-69 and 70 and older.

Table 5 presents the distribution by race for the number of facilities women have visited. Ninety-five percent of the women have been seen in only one facility. Five percent have been seen in two and a very few in three.

This analytic database for evaluating screening mammography outcomes includes women with no history of breast cancer within 5 years. Family history for breast cancer in this group was reported positive in 9.4% of white women, 7.6% of black women and 5.8% of the other women. Beginning in the second year of the registry, we collected age of relatives with a history; these results show 1.3% of white, 0.9% of black women, and 0.5% of the other women, responding 'yes' to history of a first degree relative having had breast cancer diagnosed prior to age 50.

The distribution of the mammography interpretation for the initial screening examination is shown in Table 6, and for the end of the radiologic screening work-up in Table 7. At the Initial

Screen, younger women are more likely to be recommended for further work-up prior to making a screening interpretation, 4.2% of women under 50 fall into this classification compared to 2.6-3.5% for women 50 and above. The suspicion for malignancy increases with age, rising from 0.3% of women in their 30's to 0.7% for women 70 and above. When the radiologic work-up is completed, (Table 7) less than 1% of these women remain in the category for needs further evaluation, with the pattern the same. It is higher in younger women. These are women who for some reason were coded in this indeterminate category but for whom there are no further radiologic records. We are in the process of attempting to get follow-up information on these women. As would be expected the categories of suspicious lesions are higher at the end of the work-up than at the initial screen.

Table 8 displays the incidence of cancer in women in NC having a screening mammogram and a cancer diagnosed within a year of the mammogram, by age group. Cancer increases with age as expected. Overall, 18% of the cancers diagnosed within a year of a screening mammogram are ductal in-situ. The percent is highest in women under 50.

The linking of pathology and mammography data has also enabled us to estimate accuracy of mammography. As this was done exclusively under the NCI funding, we will wait to report these data in our publications. We will send you a copy when submitted.

## CONCLUSIONS

After 4 years of effort, we have built a registry to monitor screening mammography practice and outcomes in a defined population in the state of North Carolina. This involved developing computerized data capture systems for collecting mammography and pathology data in the community, a data editing and reporting system, and an analysis strategy. We have successfully recruited and enrolled 90 facilities, mostly in our original targeted 24 counties, but expanding to the western portion of NC as well. We have an active advisory board, a special radiology advisory group and a large staff, all necessary to maintain the momentum of this large project. We have developed procedures for building, maintaining and using the mammography and pathology databases, and an extensive process for maintaining confidentiality of all data in house and in transit to and from the practices.

We successfully applied for NCI funding to become part of the National Breast Cancer Surveillance Consortium. Our early work under DOD funding has given us a leadership role in this consortium. The NCI funding guaranteed the continuation of the effort funded by DOD, and gave us support for analysis and future growth. Early analyses have shown that the Registry is representative of the women in NC in terms of age and racial distribution. Distribution of the mammography assessments, cancer incidence and trends of age and outcomes all are in line with expectations from the literature. Our analyses in our on-going work should prove very valuable for evaluation of the practice of screening mammography in the community. We have one manuscript published, one in review and many more in preparation. The value of the DOD support to build this infrastructure cannot be underestimated, and is appreciated.

## Figure 1: CMR CONFIDENTIALITY PROCESS

**The only good data is accurate data.** We work hard at quality control of the data. Here is a quick overview:

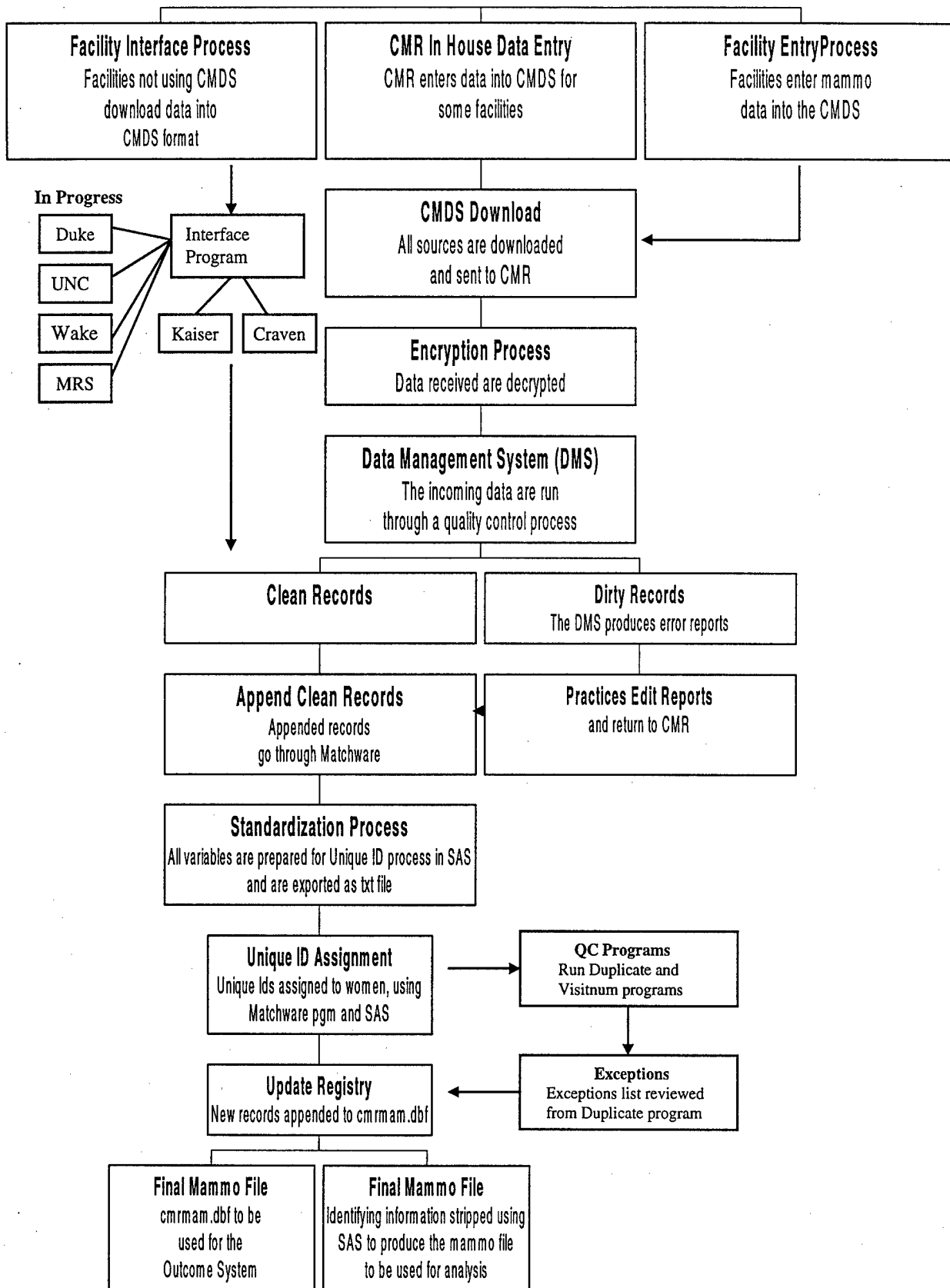
- At data entry there are built-in data entry controls and checks.
- Data are checked for errors when received at the CMR; including checking range of dates sent on disk; searching for exact duplicate records, listing missing essential data, inconsistent data, and implausible dates. We also do simple frequencies of the data to identify any obvious questionable data.
- Data are sent back to the practices for editing: data can be corrected or verified as correct.
- When annual reports are run, we check actual distributions of outcomes compared to those expected.

**Confidentiality of the data** is a primary concern of ours at all times. We have the following protections in place:

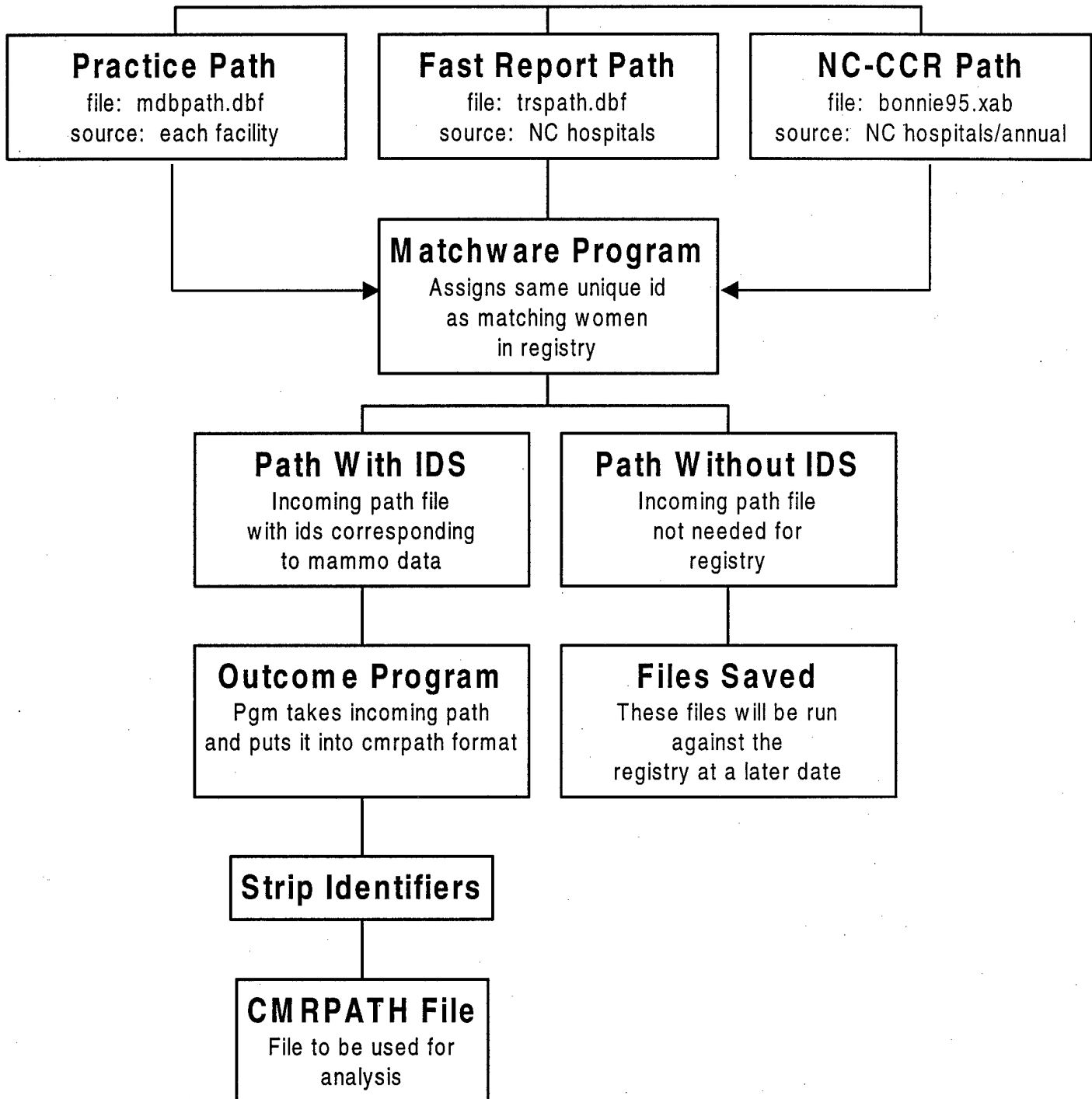
- Radiologist and Technologist codes are assigned by the practice. We receive the codes, not the names, thus the CMR does not have a link from these codes to actual names.
- Pathologist names or codes are not used anywhere in the system.
- Practices are assigned random alphanumeric codes which are used in place of practice names on all correspondence, reports, and in the registry data.
- All data are sent via Federal Express.
- Downloaded data on disks can only be read by our data system software.
- All disks received at the CMR are stored in a locked, fireproof, steel reinforced file cabinet.
- All data, including pathology data, are stripped of identifiers (name, street, address, SSN, and phone number) and assigned a unique identifying number for all future use. Mammogram data is linked to pathology data through this unique ID. This ID enables us to track a woman through the system, or from one practice to another.
- Only one copy of the linked unique ID file is kept. It is stored on a remote server, and is password protected.
- Data is linked by unique ID for data analysis, then unlinked for storage. Files that have mammogram data linked to pathology outcome data are never saved. The separate mammogram and pathology files are stored on a remote server and are password protected.
- No copies of reports sent to practices are kept at the CMR.
- We are protected by the NC state public record law, and have a United State Public Health Service Certificate of Confidentiality which protects the data here in NC and when it is shared with the National Breast Cancer Surveillance Consortium.
- All data shared with the consortium is with unique IDs only, with no access to the identifying data which has been stripped.

Our protection does not carry over to your offices. You have reports linking women to their data, and the outcomes of your performance. You can choose to save these data, or destroy them after editing for us and recording what you need for MQSA.

**Figure 2: CMR Data Flow Structure**

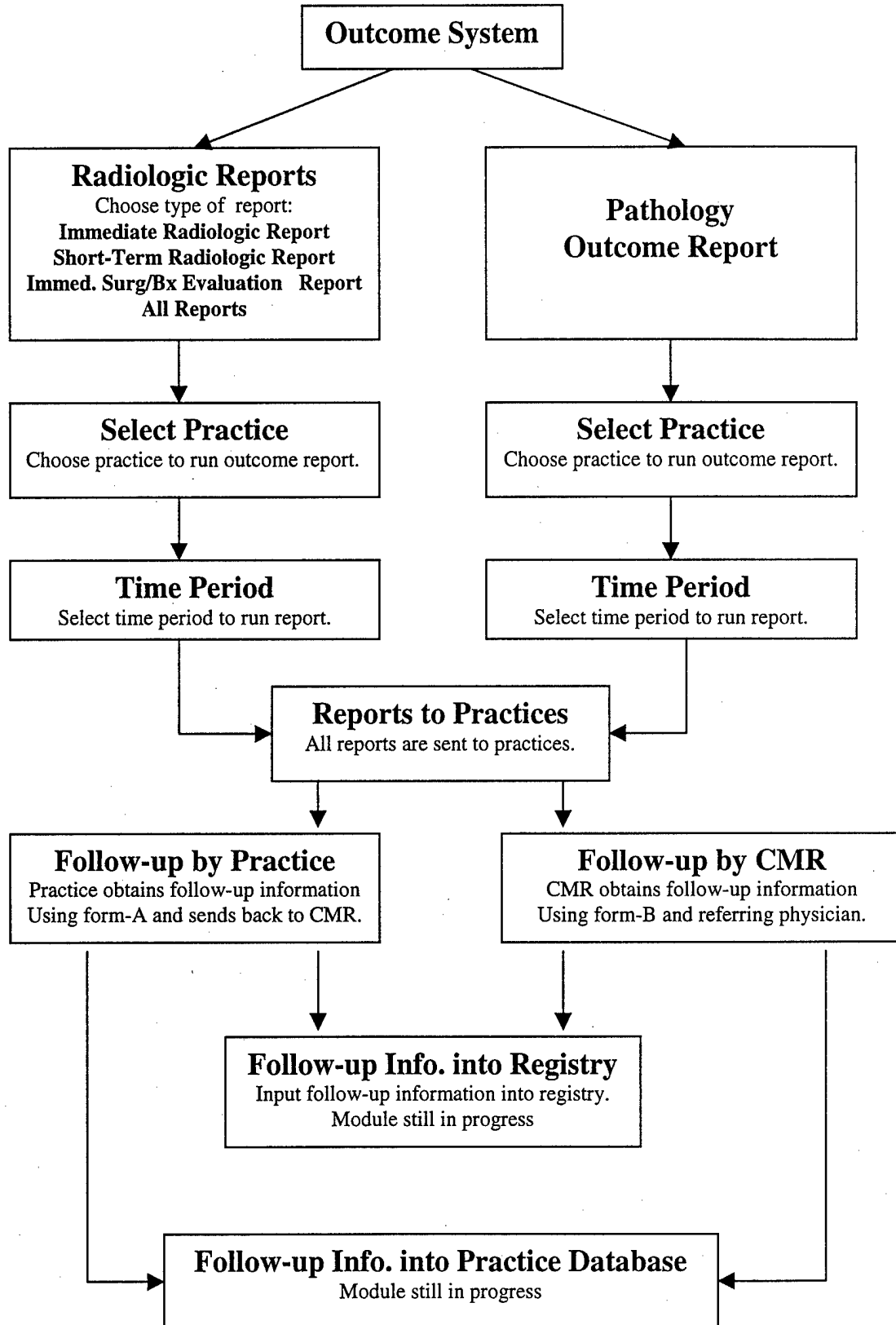


### Figure 3: CMR Pathology Procedure

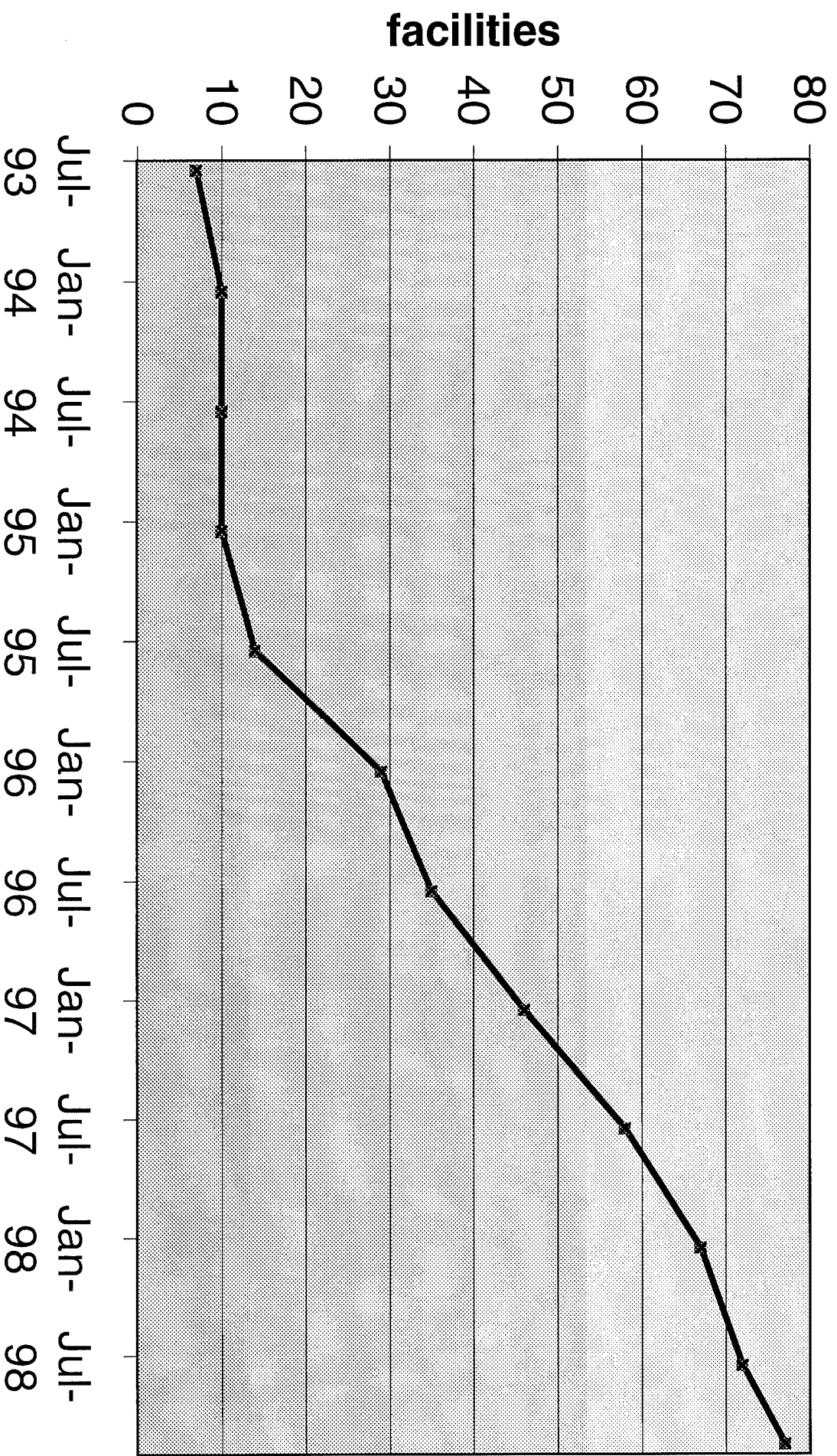




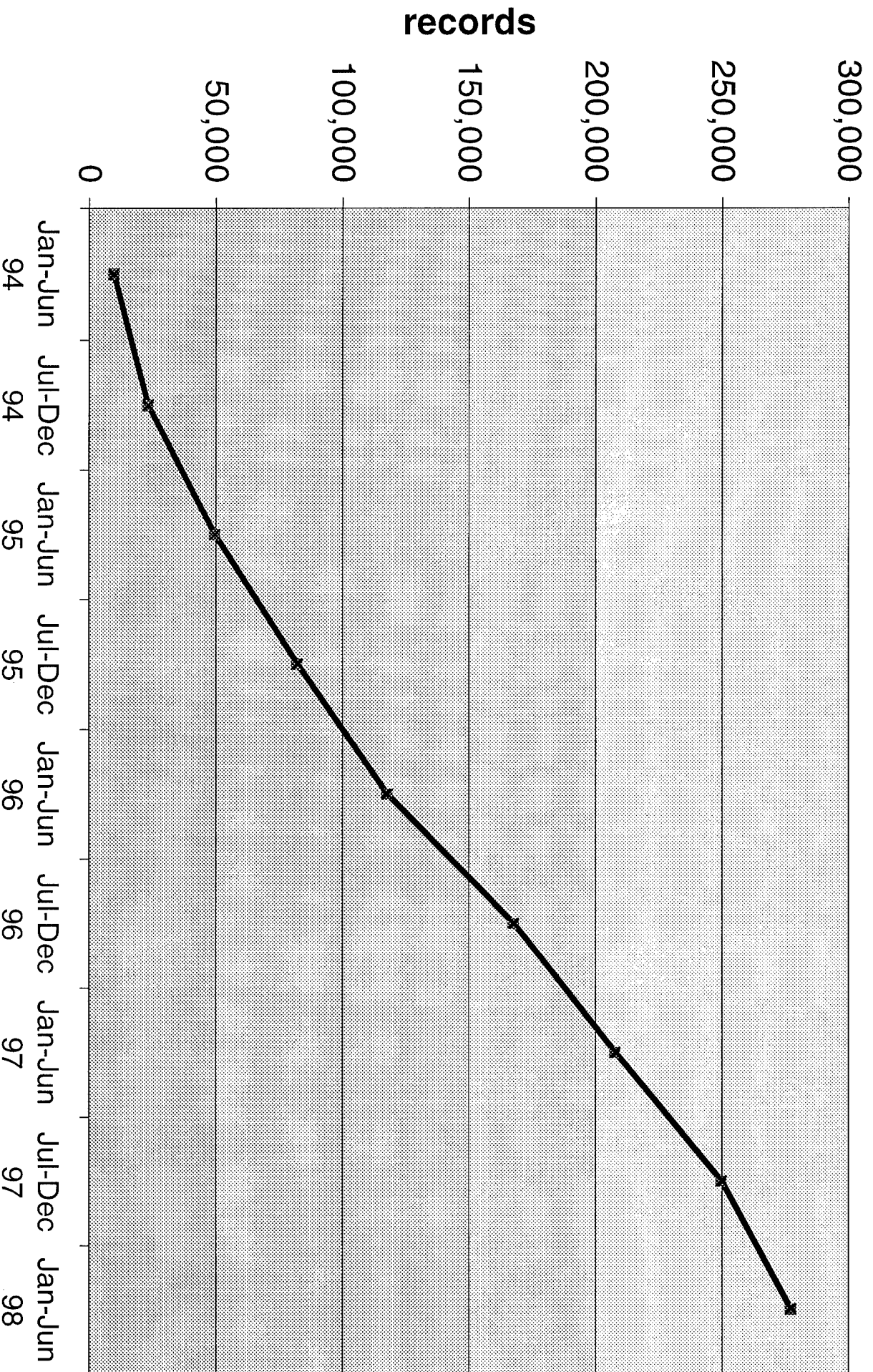
**Figure 4: CMR Outcome Procedure**



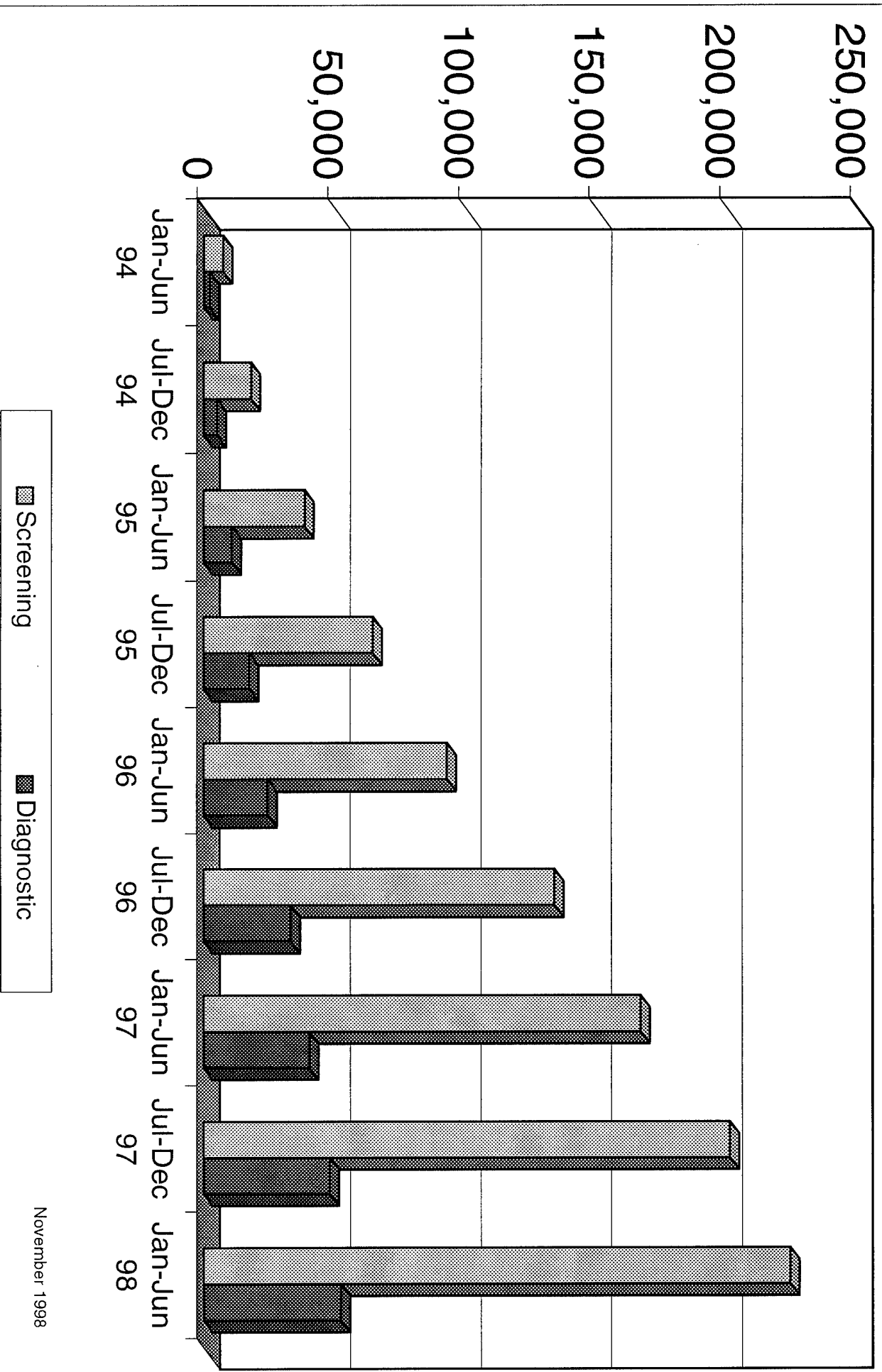
**Figure 5: Cumulative Growth of North Carolina Facilities in the Carolina Mammography Registry**



**Figure 6: Cumulative Growth of Records in the Carolina Mammography Registry**

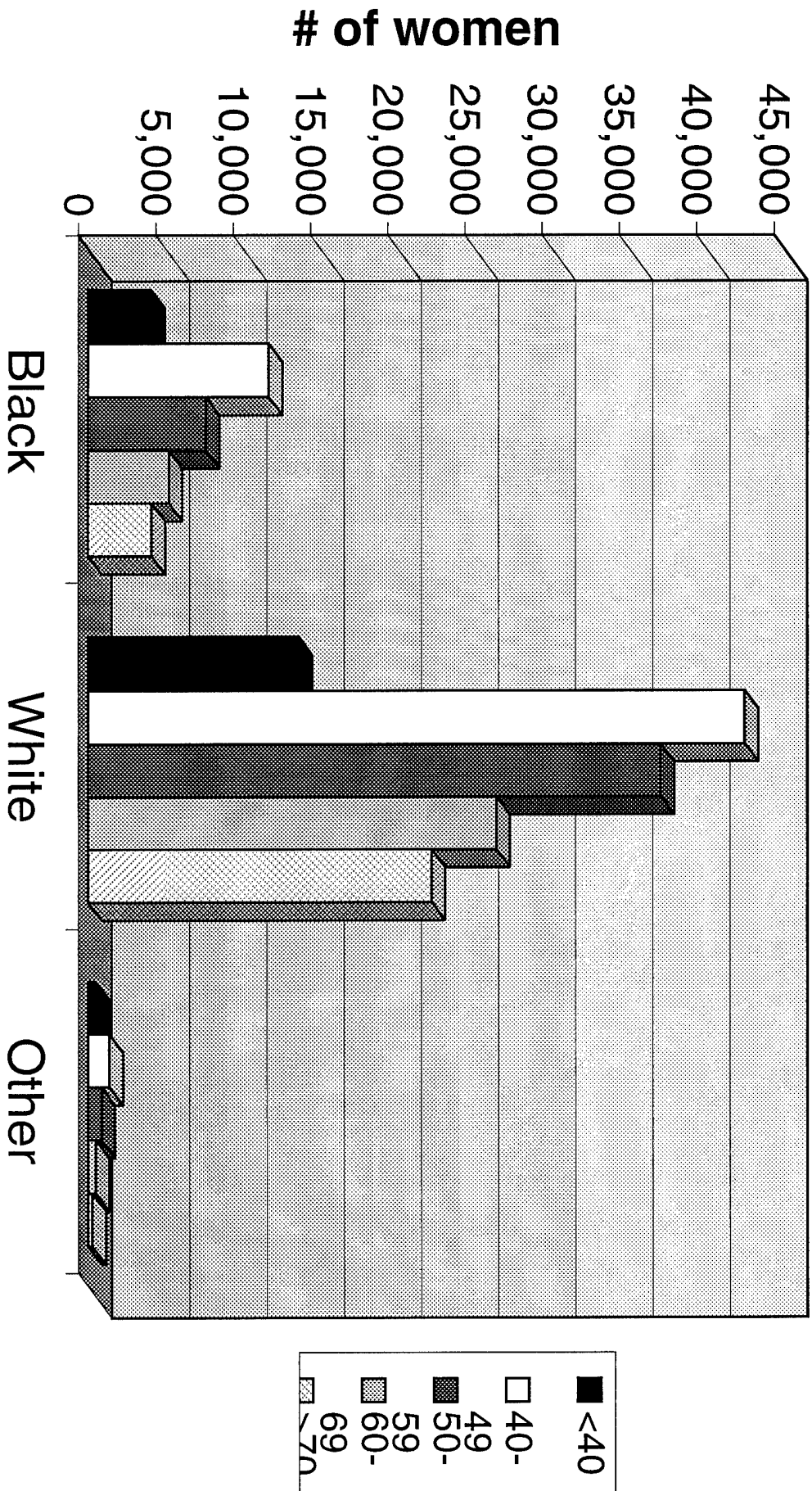


**Figure 7: Cumulative Distribution of Screening and Diagnostic Mammograms**



November 1998

**Figure 8: Age Distribution by Race**  
 Women Residing in North Carolina



November 1998

Table 1: North Carolina Facilities in the Carolina Mammography Registry

PARTICIPATING FACILITIES

ORIGINAL 24 COUNTY AREA		
Facility Type	start up date	County
S	10/6/93	Alamance
S	7/1/98	Alamance
+	5/31/95	Beaufort
+	1/30/97	Beaufort
+	8/30/95	Bertie
+	5/8/97	Chatham
+	7/20/93	Durham
+	7/20/93	Durham
+	7/20/93	Durham
+	2/26/97	Durham
S	2/26/97	Durham
S	2/26/97	Durham
S	2/26/97	Durham
S	2/26/97	Durham
S	6/6/97	Durham
S	2/26/97	Durham
S	12/3/96	Greene
+	10/7/96	Hertford
S	5/21/97	Jones
+	7/26/97	Lee
+	4/8/97	Lenoir
+	3/5/96	Martin
+	6/1/95	Moore
S-van	6/1/95	Moore
+	7/7/95	Nash
+	10/1/95	Nash
+	11/6/97	Nash
+	1/1/94	Orange
+	1/1/94	Orange
+	1/1/94	Orange
+	3/26/96	Orange
S	8/1/95	Orange
S	11/5/93	Pitt
S	10/6/95	Pitt
+	7/29/96	Pitt
+	4/15/96	Wake
+	7/31/96	Wake
+	7/31/96	Wake
S	7/31/96	Wake
S	7/31/96	Wake
+	1/1/96	Washington
+	5/31/95	Wayne
+	10/23/95	Wilson
S	10/23/95	Wilson
S	8/14/97	Wilson

44 facilities

19 counties

OUTSIDE ORIGINAL 24 COUNTY AREA		
Facility Type	start up date	County
+	11/12/97	Cherokee
+	2/1/98	Forsyth
S	10/6/93	Gaston
S	10/1/97	Gaston
S	7/1/98	Gaston
S	9/13/95	Graham
+	10/6/93	Guilford
S	10/6/93	Guilford
+	8/4/98	Henderson
+	11/13/97	Jackson
+	10/6/93	Johnston
+	10/1/96	Macon
+	8/18/97	McDowell
S-van	11/17/97	McDowell
+	9/20/95	Mecklenburg
S	9/20/95	Mecklenburg
S	9/20/95	Mecklenburg
S	9/20/95	Mecklenburg
S	9/20/95	Mecklenburg
+	4/11/96	Mitchell
S	8/1/95	Orange
+	12/1/96	Surry
+	11/13/97	Swain
+	8/7/98	Transylvania
S-van	8/7/98	Transylvania

25 facilities

16 counties

S	- Screening Only
+	- Screening and Diagnostic Services
S-van	- Mobile Mammography Van

**Table 1 (cont') : NC Facilities in the Carolina Mammography Registry**

**FACILITIES IN PROCESS**

<b>ORIGINAL 24 COUNTY AREA</b>		
<b>Facility Type</b>	<b>Status</b>	<b>County</b>
S	in process	Durham
+	in process	Edgecombe
+	in process	Johnston
S	in process	Nash
S	in process	Orange
+	in process	Pitt
+	in process	Wake
+	in process	Wake
+	in process	Wake
+	in process	Wake
+	in process	Wake
+	in process	Wake
+	in process	Wake
+	in process	Wake
+	in process	Wake
S	in process	Wake
S	in process	Wake
S	in process	Wake
S	in process	Wake
S	in process	Wake

20 facilities

<b>OUTSIDE ORIGINAL 24 COUNTY AREA</b>		
<b>Facility Type</b>	<b>Status</b>	<b>County</b>
+	in process	Craven
+	in process	Henderson
+	in process	Mecklenburg
S	in process	Mecklenburg
S	in process	Mecklenburg
S	in process	Mecklenburg
+	in process	Robeson
+	in process	Swain

8 facilities

	<b>facilities*</b>
reporting data	69
in process	28
	97

\*a few prtices may represent many facilities  
 These are mostly large sites where we are interfacing with existing data systems. It takes a long time to bring these practices into the Registry, but we get data back to the beginning of 1996 in most cases

Table 2: Distribution of women in the Registry by age and race.

Race →	White	Black	Other	Total
N= →	107,461	23,944	2,499	133,904
Age Group	%	%	%	%
<40	7.6	9.9	9.9	8.1
40-49	30.2	37.2	41.4	31.5
50-59	27.7	24.1	25.6	26.9
60-69	19.2	16.5	14.9	18.6
≥70	15.3	12.2	8.2	14.8



Table 3: Number of annual screening mammography records in the Registry by age and race.

Age Group	Race	N=	Number of Scening Mammograms		
			1 %	2 %	≥3 %
<40	W	7,536	95.9	3.8	0.2
	B	2,188	96.0	3.7	0.3
40-49	W	30,569	85.4	13.5	1.1
	B	8,534	87.1	12.2	0.7
50-59	W	29,335	68.9	26.6	4.4
	B	5,711	74.3	22.8	2.8
60-69	W	20,313	64.9	28.8	6.2
	B	3,899	71.7	24.9	3.4
≥70	W	16,958	67.1	25.9	7.0
	B	2,951	75.0	21.2	2.8

Table 4: Number of months between repeat screening mammography exams in the Registry by age and race.

Age Group	Race	N=	Number of months		
			9-18 %	19-24 %	>24 %
<40	W	279	75.3	16.7	14.0
	B	83	71.1	15.7	13.2
40-49	W	4,566	68.5	13.7	17.7
	B	1,143	62.5	17.8	19.8
50-59	W	8,601	85.5	7.2	7.2
	B	1,442	80.5	10.5	9.1
60-69	W	6,663	87.0	6.9	6.1
	B	1,096	8307.0	9.6	6.7
≥70	W	5,372	82.9	7.6	9.5
	B	721	76.1	13.2	10.7
Total	W	25,481	82.2	8.4	9.4
	B	4,485	75.8	12.6	11.6

Table 5: Number of facilities visited per woman

Race	One facility		Two facilities		Three facilities	
	n	%	n	%	n	%
White	99,739	93.7	6,638	6.2	65	0.06
Black	22,524	95.5	1,044	4.4	8	0.03
Other	2,370	96.1	96	3.9	1	0.04
Total	124,633	94.1	7,778	5.9	74	0.06

Table 6: Distribution of Mammography Interpretation for Initial Screening Study.

Interpretation	<40		40-49		50-59		60-69		≥70		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Needs further evaluation	465	4.2	1,942	4.1	1,630	3.4	1,157	3.3	681	2.4	5,875	3.5
Normal	7,982	72.6	33,018	70.5	33,292	70.2	24,432	70.6	19,238	69.2	117,962	70.3
Benign Finding	1,872	17.0	9,147	19.5	10,036	21.1	7,174	20.7	6,376	22.9	34,605	20.6
Probably benign	630	5.7	2,475	5.3	2,195	4.6	1,564	4.5	1,231	4.4	8,095	4.8
Suspicious abnormality	38	0.3	264	0.6	288	0.6	253	0.7	216	0.8	1,059	0.6
Suspicious for Malignancy	-	0.0	8	0.02	12	0.03	24	0.07	39	0.14	83	0.05

Table 7: Distribution of Mammography Interpretation for End of the Screening Radiologic Work-up.

Interpretation	<40		40-49		50-59		60-69		≥70		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Needs further evaluation	113	0.9	484	0.9	391	0.7	320	0.8	227	0.7	1,535	0.8
Normal	9,068	75.4	39,552	73.9	40,393	73.8	29,612	74.3	22,997	72.5	141,622	73.8
Benign Finding	2,026	16.8	10,356	19.3	11,068	20.2	7,807	19.6	6,756	21.3	38,013	19.8
Probably benign	749	6.2	2,781	5.2	2,501	4.6	1,788	4.5	1,412	4.4	9,231	4.8
Suspicious abnormality	66	0.5	343	0.6	331	0.6	304	0.8	258	0.8	1,302	0.7
Suspicious for Malignancy	2	0.02	14	0.03	29	0.05	41	0.1	54	0.17	140	0.07

Table 8: Cancer Incidence by Age Group

Age	Cancer Incidence per 1,000	Total Cancers n	Ductal Carcinoma in - situ		Invasive Cancer	
			n	%	n	%
<40	2.4	28	6	21.4	22	78.6
40-49	3.4	155	39	25.2	116	74.8
50-59	6.1	238	40	16.8	198	83.2
60-69	8.8	239	44	18.4	195	81.6
≥70	9.1	197	25	12.7	172	87.3
Total	5.9	857	154	18.0	703	82.0

## REFERENCES

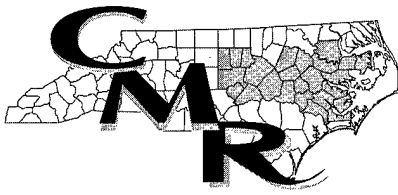
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## APPENDICES

- A. Newsletters produced for practices participating in the project. (Supported by NCI U01-CA-70040)
- B. Copy of a practice annual report sent to practices on their data. One is produced for the entire Registry for comparison.

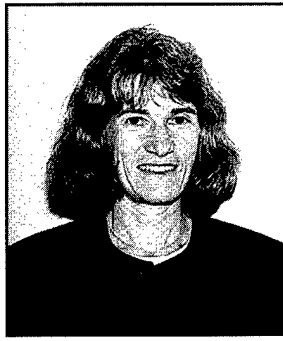
Appendix A: CMR Newsletters

# CAROLINA MAMMOGRAPHY REGISTRY



# Rapport

The Carolina Mammography Registry is growing at a rapid pace thanks to all the practices that have become members in this collaborative project. We currently have over 110,000 records in the registry! The main purpose for a newsletter is to communicate efficiently and to establish rapport with all of the professionals who are connected with the Registry. We will work to keep it short and relevant, with information about enhancements to our data system, tips to make our service to you more effective, and information about the research that will result from all of our efforts. We have a large staff working hard to serve you and serve the needs of the registry. We introduce them briefly in our first issue so that you will know a little more about us, and we will introduce them in more depth one at a time in future issues.



Bonnie Yankaskas, PhD

The CMR is part of the National Breast Cancer Surveillance Consortium. Now that we have a national Public Health Certificate of Confidentiality to protect all of our data across state lines, we will be contributing anonymous data to the national database for research questions that require large numbers to investigate. In the future, we will use this newsletter to report activities of this group to you.

See Kara's column for clarification on some issues related to data entry and edit reports. Maria has outlined the new features coming very soon in our software upgrade. We have included a short piece to remind you of the care we take to assure quality data and confidentiality of the data in the registry. If you have specific suggestions for what you would like to see in this publication, please let us know. Your ideas are always welcome. Good communication is essential to any large operation. We hope this publication assists us in keeping open the communication lines with all of you and our staff here at the CMR.

## Upgrade Highlights:

### Reduce Data Entry Time and Improve Reporting

The following changes to our software are included in an upgrade which you will receive soon:

**Multiple users in different locations** may now access the database simultaneously.

**Revised Positive Mammogram listing** will include only women whose mammogram interpretation code is 0,4,5 OR who have a follow-up time of less than 6 months. The current listing includes mamcodes of 0,3,4,5 or a recommended follow-up time of less than 12 months.

**Pathology data collection and reporting system** has new design, new interface, and expanded reporting.

Now you can generate an outcome report for all patients who have been recommended for a biopsy but DO NOT yet have path reports on file.

**New navigational tools and internal validations** reduce data entry time. For example, if you answer no to recommended follow-up tests on screen 6 you will save 12 keystrokes!

- You no longer have to enter something for each recommended follow-up test.
- When editing a record, the new pick lists allow you to move through each screen without having to designate a selection each time.

#### Double Read Activity Report

has been added to the Report Menu.

**New progress bars** exist for the reindexing and downloading processes.

**Electronic data transmission and remote diagnosis capability** will save time and effort by transmitting data to us electronically. We can problem solve program glitches electronically. Please see the back of the newsletter for details.



Maria Paschall



## Data Collection Notes



Kara Gasink

### **A record based on a biopsy only:**

Screen 5 of our software prompts users for mammographic findings even if a biopsy is the only type of

study indicated on the data sheet. We are currently addressing this inconsistency, and ask that in the meantime you enter 'no findings' on screen 5.

### **Query System Output Printing:**

Within our current software, if you initially send your query results to the screen, the query system does not allow you to print your results (though the screen prompts lead you to believe that it does). Until we distribute the next upgrade, there are two ways to sidestep this:

(1) select #1 *Output to Printer* from the Report Options Menu (your query results will subsequently appear on your screen with a prompt to initiate printing);

(2) select #3 *Output to File* and print your file once you've exited CMDS. Please call us if you need further assistance.

### **Edit Reports:**

Our qc inconsistency report flags as *potential errors* women with lumps who have once had screening mammograms. Users have explained that many women present with histories of specific breast lumps but their visits are still considered screens because these lumps have been followed unchanged for several years. These calls from users have been frequent enough that we will now flag as errors only those asymptomatic mammograms where the woman has stated the lump as the reason for scheduling her mammogram.



Front row: (L to R) Renée Kemske, Bonnie Yankaskas, Kara Gasink. 2nd row: Marilyn Hill, Brian Springer, Maria Paschall, Richard Kwok, Frankie Harvey. Back row: Ann Chamberlin, Jennifer David.

## Who's Who at CMR?

**Bonnie Yankaskas, PhD** is the Principal Investigator of the project. She is an associate professor of Radiology and adjunct associate professor of Epidemiology at UNC-CH. She has spent her entire career working in cancer epidemiology, with special emphasis in mammography and breast cancer for the past 6 years.

**Timothy Aldrich, PhD** is the Associate Principal Investigator. He is the former Director of the NC Central Cancer Registry and adjunct faculty member in the Department of Epidemiology at UNC-CH.

Other investigators on the project include: **Susan Maygarden, MD**, pathologist, **Elizabeth McKinley, MD**, general internist, and **Lynne Dressler, MS**, Research Assistant Professor of Medicine and Research Associate in Pathology at the Lineberger Comprehensive Cancer Center (LCCC), and **Michael Schell, PhD**, a Research Associate Professor in Biostatistics also at the LCCC. We are advised by a group of radiologists including **Richard Clark, MD** of the Department of Radiology at UNC-CH, and **Drs. David Desrochers, Richard Bird, George Crawley, and Bruce Schroeder** in practices around the state.

The staff who make the Project successful on a day to day basis include:

**Kara Gasink**, our Project Director who visits practices to introduce the project and promote participation;

**Marilyn Hill**, who handles all the data from each facility, cleans it, and prepares it for input into the registry;

**Maria Paschall**, who maintains and improves the data system that many practices choose to use, and who trouble shoots any computer-related problems;

**Sharon Schiro, PhD**, who is responsible for our data management programming;

**Jennifer David, MS**, a graduate student in epidemiology who is our data analyst;

**Brian Springer**, a graduate student in public health administration who provides support for us as our part-time secretary and Associate Editor of our newsletter;

**Ann Chamberlin, MPH**, Associate Editor of our newsletter and Assistant Project Director in charge of follow-up;

**Rich Cooke, MS**, a graduate student in biostatistics who provides SAS programming assistance and statistical consultation;

**Frankie Harvey, CCR**, a certified cancer registrar who oversees our pathology coding and reporting;

**Dianne Vann**, Grant Coordinator for the North Carolina Central Cancer Registry, who gathers the NCCCR fast report pathology data for us.

## How our Pathology Linking System Works for You!

Under a fast-report pathology system, the CMR receives all newly diagnosed breast cancer cases in 24 counties in eastern North Carolina. For patients with cancers diagnosed at facilities outside of our 24 counties, we are able to provide pathology outcome when we receive complete statewide reporting from the Central Cancer Registry (NCCCR). We have complete statewide NCCCR data for 1994 and 1995. We anticipate having the 1996 annual statewide data by June of 1997.

The NC Central Cancer Registry began the process of fast report for benign pathology in February of 1996. Two-thirds of the targeted facilities are presently reporting benign pathology to either the NCCCR or directly to the CMR.

Our compilation of benign and malignant pathology data will assist you in tracking your patients and provide outcome measures of screening performance. We are now generating pathology outcome reports for your practice on a regular basis. Each time we receive a download disk from your facility, we will run your composite dataset against our pathology database and send you a report of all the new matches found. For this reason, we encourage you to download your data *monthly* if you are not already doing so. For those of you sending us data on paper, we will automatically be generating this pathology outcome report for you on a monthly basis, unless you indicate a wish to receive it less frequently.

## Who's Who at CMR? ...continued

Meet our students who assist our staff in running the CMR smoothly:

**Renée Kemske**, a senior from New Bern majoring in biology;

**Amy Huang**, a senior from Raleigh majoring in international studies and political science;

**Richard Kwok**, a senior from Atlanta majoring in history and environmental sciences;

**Octavia Powers**, a sophomore from Lumberton majoring in political science;

**Ashwini Rode**, a junior from Evans, GA majoring in health policy and economics.

**The only good data is accurate data.** We work hard at quality control of the data. Here is a quick overview:

- At data entry there are builtin data entry controls and checks.
- Data are checked for errors when received at the CMR; including checking range of dates sent on disk; searching for exact duplicate records, listing missing essential data, inconsistent data, and implausible dates. We also do simple frequencies of the data to identify any obvious questionable data.
- Data are sent back to the practices for editing; data can be corrected or verified as correct.
- When annual reports are run, we check actual distributions of outcomes compared to those expected.

**Confidentiality of the data** is a primary concern of ours at all times. We have the following protections in place:

- Radiologist and Technologist codes are assigned by the practice. We receive the codes, not the names, thus the CMR does not have a link from these codes to actual names.
- Pathologist names or codes are not used anywhere in the system.
- Practices are assigned random alphanumeric codes which are used in place of practice names on all correspondence, reports, and in the registry data.
- All data are sent via Federal Express.
- Downloaded data on disks can only be read by our data system software.
- All disks received at the CMR are stored in a locked, fireproof, steel reinforced file cabinet.
- All data, including pathology data, are stripped of identifiers (name, street address, SSN, and phone number) and assigned a unique identifying number for all future use. Mammogram data is linked to pathology data through this unique ID. This ID enables us to track a woman through the system, or from one practice to another.
- Only one copy of the linked unique ID file is kept. It is stored on a remote server, and is password protected.
- Data is linked by unique ID for data analysis, then unlinked for storage. Files that have mammogram data linked to pathology outcome data are never saved. The separate mammogram and pathology files are stored on a remote server and are password protected.
- No copies of reports sent to practices are kept at the CMR.
- We are protected by the NC state public record law, and have a United State Public Health Service Certificate of Confidentiality which protects the data here in NC and when it is shared with the National Breast Cancer Surveillance Consortium.
- All data shared with the consortium is with unique IDs only, with no access to the identifying data which has been stripped.

Our protection does not carry over to your offices. You have reports linking women to their data, and the outcomes of your performance. You can choose to save these data, or destroy them after editing for us and recording what you need for MQSA.

**There is still TIME!!!**

Please respond to our questionnaire on positive mammograms. We want to know how you define a positive mammogram.

If you did not receive this questionnaire, please call (919) 966-0492.

**Completing follow-up on every woman with a positive mammogram can be challenging.**

We can help you follow up women who do not return in the recommended time frame or who go elsewhere for their care. Let us know if you'd like us to do this for you.

**Registry Progress**

At last count we had over 72,000 records of clean, edited data in the registry.

There are an additional 30,000 records that have been sent back for editing and have not yet been returned. Please send your edits to us.

**Send us your data easily over the phone lines!**

The Carolina Mammography Registry has grown and matured to the point where we are modernizing our approach to data transmission. For many of our participating practices it may save time and effort to transmit data to us electronically. Electronic transmission will allow us to problem solve any program glitches without visiting your site. We would like your feedback on the proposal described below.

We propose to assist practices in setting up their computers so that data downloads would happen over the phone lines. Our staff could then diagnose any problems over these same communication lines. Once set up, you would be saved the hassle of downloading to disk, packaging the disk, and getting it in the mail or to Federal Express. Likewise, we would be able to transmit upgrades and special request outputs to you immediately via the same route.

What equipment do you need to make this happen?

- 486 or later model personal computer (IBM compatible);
- Direct computer access to a dedicated or non-rollover phone line;
- Windows operating system of 3.1 or greater;
- A Fax/Modem communication card for your computer.

While CMR cannot provide the phone line support, if there is enough interest, we may be able to provide the modem cards and the necessary software.

If you already have a fax/modem card and communication software, it is possible that we could begin functioning electronically immediately. If you have the necessary computer but no fax modem, you would need to install the phone line, and we will consider taking care of the remainder, i.e. purchasing the software and the fax/modem card for your computer. If you already have a fax line and this is near your computer, you may be able to piggyback the modem for your computer to this line.

**Please take a minute and let us know your level of interest in sending us your data over the phone lines, and what your needs would be to come on-line. Please fax this information to us at (919) 966-0525.**

Name of Practice: \_\_\_\_\_

Contact Person: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

I am interested, but don't really understand the process, please call me.

I am interested and have the following: (please check all that apply)

Windows 3.1 or higher

Fax/Modem Card

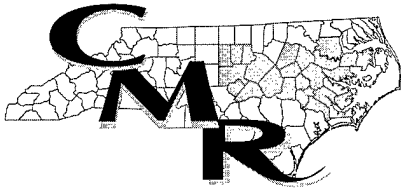
Direct available phone line for connection to Fax/Modem

I am not interested, would prefer to continue the Fed Ex/current mail system.

The CMR Report is a publication of the CMR, Department of Radiology, University of North Carolina at Chapel Hill. CMR is jointly funded by the Department of Defense and the National Cancer Institute. Co-editors are Brian Springer and Ann Chamberlin, MPH. (919) 966-0492



# CAROLINA MAMMOGRAPHY REGISTRY

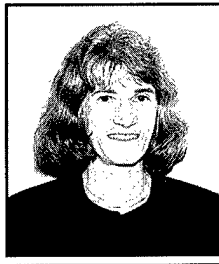


# Rapport

## Changes at the CMR

It is summertime, and being in an academic setting, we annually have staff changes at this time of year. We are sad to announce that Kara Gasink, our Project Director for the last two years has moved on. She returned to her home in the north-east in late July. She has been a joy to work with for all of us and has done an exceptional job keeping this project moving. It is a juggling act at all times, and she has performed above and beyond our wildest expectations. Thank you Kara, and we wish you well.

Kara worked so hard, it will take two people to replace her. Beginning August first, the Project Director will be



Bonnie Yankaskas, PhD

Molly Blackley. We introduce her to you on the next page. Promoted to Associate Project Director and working along side Molly will be Renée Kemske. Renée has been working with the CMR during her 4 years as a Carolina student. She graduated in May and is now with the Registry full-time. We will introduce her to you more fully in our next newsletter. I am confident that Molly and Renée will be able to develop the rapport that Kara so successfully created with our facilities. Please do not hesitate to call on either one.

The other change I am happy to report is that we are finally in a position to commit to sending you regular reports from your data, and will have a more streamlined reporting system for follow-up pathology. These are described below.

## Reports For Participating Practices

### Summary Reports

The registry has reached a point of maturity where we are now ready to commit to a regular schedule of reports for our participating practices. We know this has taken a long time and appreciate your patience. We have created a report which will display summary statistics for your practice over a period of time. This report will include descriptive data and graphs of the demographics of your population served and the distribution of mammography volume over time. The report also has summary outcome data on the recommendations and the results of screening mammograms. We will be sending these reports out in order of the date that a practice enrolled in the CMR. Please look over the report and give us feedback as to its content. If you would like a personal visit to explain any of the data, or just to discuss better ways to present these data, please call. We are more than happy to visit any practice. The initial reports will cover data for your practice from the date you began sending data through 30 March 1997. *If you have data from this time period that was returned for editing and has yet to be returned to us, we will hold your report until we receive your edits.*

*We do not want to report on incomplete data. After this initial round of reports, the reports will become an annual event, and will cover rolling 2 year periods; 1996 and 1997 in early 1998, 1997-1998 in early 1999, and so on. This will give you a periodic look at your data, without having numbers that are so small as to be of little value.*

### Pathology Reports

We are poised to renew our periodic reporting of the pathology we have that matches your mammography data. We plan to send a pathology report to all practices sending us data. This report will list the women whose mammography record links with a pathology record from our pathology database. You will receive the report on a schedule that corresponds to how often you send us data (monthly or bimonthly). At this same time, we will also send you a listing of the women recommended for biopsy for whom we have no match in our database and a list of women recommended for immediate or short-term radiologic follow-up who after 6 months have not returned.

A description of our pathology database, and more details of our follow-up reporting system follows on page 2.

## Data Collection Notes



Kara Gasink

**Has your mother, a sister, or a daughter had breast cancer before age 50?:** Please only enter Y as the answer to this question if 1) the

relative is the patient's mother, sister, or daughter; 2) if the relative's breast cancer occurred BEFORE age 50. So if a patient writes "Aunt, age 65" next to this question, you would enter N for two reasons: 1) the relative is not the patient's mother, sister, or daughter; 2) the relative's age of diagnosis was not before age 50. We are going to change the way we collect this history information in our next upgrade, but until that time, it is VERY important for our data analysis that you record this family history information correctly.

### Entering first names and

**middle initials:** In order to assign your patients unique identifiers so they

are protected (i.e. unidentifiable) in our registry database, it is extremely important that the patient's first name only goes in the "First Name" field and only the middle initial is entered in the "Middle Initial" field. Our unique ID program has trouble identifying Jane A. Doe as the same woman when her first name appears in the "First Name" field as "Jane" in some instances, "Jane A." in others.

**Immed. Health/Immed. Tech (or Repeat Tech):** What's the difference in these recommended follow-up time choices? Immediate Tech (or Repeat Tech, depending upon the wording on your data sheet) should only be checked if a patient's films need to be redone because of poor image quality. Therefore, if your radiologist wants a patient to come back for additional views or an ultrasound (based upon what he or she has seen on the initial mammogram), Immed. Health should be checked off as the recommended follow-up time.

## CMR Spotlight



Molly Blackley

The CMR welcomes Molly Blackley as our new Project Director. Molly is a native North Carolinian, born in Chapel Hill and raised in Elkin.

She graduated from UNC-Chapel

Hill in 1996 with a Bachelor of Science degree in Biology. After spending a summer in Seattle, Washington, Molly moved to Atlanta, Georgia where she worked at a Children's Medical Center with general pediatrics and residency programs. Outside of work, Molly enjoys hiking, biking, sailing, planning her next travel adventure, or relaxing with a book and an enormous cup of coffee. Welcome Molly!

**REMINDER:** When a woman returns for an ultrasound, extra views (or other procedure) as part of a continued work-up please fill out a separate data sheet!! The patient data (screen 1) and history (screen 2) are automatically filled in from the previous visit.

## Pathology Database Has Malignant And Benign Data.

Pathology data is received from radiology facilities (when sites actually enter this information), from a fast-report system of breast pathology delivered to us weekly by the Central Cancer Registry, and from the annual Central Cancer Registry data that we receive approximately 6 months after the close of the year.

The fast report data includes all new malignant breast pathology reports within our originally designated 24 counties. It does not include biopsies where the pathology is sent to a laboratory outside of our 24 counties. If your practice is outside our original targeted study area, we will have to wait for the annual state data to give you the outcome data. We also are receiving benign breast pathology as fast report from most pathology sites in the study area. We are working toward making this complete. The fast report, though delivered to us weekly does have a lag time. Thus we prefer to run pathology matches beginning 3 months after the date of the recommended biopsy. If we do not find an outcome pathology

report for a patient, it may be that insufficient time has elapsed for us to receive the data. The annual data which covers the entire state has a much longer lag time than the weekly fast report data. We have not yet received the 1996 data but are expecting it sometime this summer. The edited 1995 data is in our pathology database.

We know that cancer reporting to the Central Cancer Registry is not 100% complete. They are continually working to reach this goal. Until they do, it is out of our immediate control to provide guaranteed 100% follow-up information. We have instituted a follow-up system, which a few practices have agreed to, where we will follow up on records where there was a recommendation for biopsy and after 3 months, there is no pathology report. We do this by sending a questionnaire to the referring physician, not the patients. We are happy to send you a copy of the questionnaire we use. (We never contact women directly!) If you would like our help, please contact Ann Chamberlin at (919) 966-0492.

## Explanation of Mammogram Impression Using the ACR Breast Imaging and Reporting System

A screening mammogram will either result in an incomplete assessment or a complete assessment. If, following a screening mammogram, further radiologic evaluation is necessary to render an impression, then the assessment is incomplete, and the impression code should = '0'.

If no further radiologic work-up is required or recommended, then the assessment is complete. When the assessment is complete, the ACR code should equal one of the following:

- 1 = normal mammogram**
- 2 = benign finding**
- 3 = highly likely benign, but want a shorter return time for next mammogram**
- 4 = suspicious for malignancy and a biopsy is warranted without further evaluation**
- 5 = highly suspicious for malignancy and appropriate action recommended**

The codes 1-5 are only to be used if radiologic assessment is complete! If there is any concern that requires further radiologic evaluation then the assessment code should be '0', which specifically indicates a need for further radiologic evaluation. The '0' is only appropriate following a screening mammogram or in the rare case where a third radiologic study is necessary after interpreting a second radiologic study. At the end of the diagnostic work-up (extra views, US or other radiologic study, NOT including biopsy) the assessment should be complete and the patient should fall into one of three groups:

- Normal or benign finding, routine return for next screening mammogram; *these are coded as '1' or '2'.*
- Probably benign finding, short term return for mammogram; *these are coded as '3'.*

- Suspicious or highly suspicious and biopsy recommended (or surgical consult); *these are coded as '4' or '5'.*

Practically speaking, for the CMR data system this means that if a woman has a screening mammogram followed by further examinations *on the same visit*, the interpretation code should be a final assessment, and should equal '1', '2', '3', '4' or '5'.

If a woman has a screening mammogram which requires further evaluation, and she is asked to come back *at a later time for the continued work-up* then the interpretation code at the time of the screening mammogram should reflect that further evaluation is necessary and should therefore = '0'. When the woman returns for her continued work-up, the assessment should be complete and the data at this continued work-up time should reflect a final interpretation code, i.e. a code equal to '1', '2', '3', '4' or '5'.

Thus, it follows that:

- If biopsy is recommended, there should be a code of '4' or '5' (occasionally a '3'). At the point that biopsy is recommended, the radiologic assessment is complete.
- If a surgical consult is recommended, there should be a code of '4' or '5' (or possibly '3'), as the radiologic assessment is complete.
- If the patient is asked to return in 6 months to follow a benign finding, there should be a code of '3', as the radiologic assessment is complete.
- If the recommendation is for routine return, 1 year, 2 years, or at age 40, there should be a code of '1' or '2', as the radiologic assessment is complete.
- If after a screening mammogram, immediate return is recommended for further radiologic work-up, there should be a code of '0', as the radiologic assessment is incomplete.

### Upgrade Highlights: Automated Zip Code Saves Time

New Automated Zip Code Feature reduces data entry time. Now instead of typing in City, State, Area Code and County information on Screen 1, our software automatically directs you to type in the five-digit zipcode. Once the zip code is entered, the cursor automatically moves to the completed city field. As you continue to press <Enter>, the state, telephone area code and county are filled in, saving you keystrokes and time!



Maria Paschall

### CMR Advisory Committee meets in Chapel Hill

The advisory committee for the CMR met in mid-June in Chapel Hill. The Committee members in attendance represented radiologists, pathologists, tumor registrars, the State Department of Health and Human Services, and breast cancer survivors. The committee was updated on the progress of the project. We had a fruitful discussion on the informed consent issues for obtaining benign pathology tissue for research and any use of the CMR data beyond the original research goals. The committee was impressed with our progress and our attention to detail in protecting confidentiality of our data. Our next meeting will be in the fall.

**Send us your data edits!**

The only good data is accurate data. We routinely check all data for errors and return it to you to correct or verify as correct. Timely return of data edits is vital to the registry.

**BCCCP Mammogram Reports**

If you have patients participating in the Breast and Cervical Cancer Control project, you may submit the CMR data form to document mammogram results in place of the BCCCP form.

**Registry Progress**

At last count we had over 140,041 records of clean, edited data in the registry. There are an additional 40,000 records that have been sent back for editing and have not yet been returned.

**A Big Thank You to Cancer Registrars and Others**

The CMR staff and especially I would like to thank all of the Cancer Registrars and others participating in the Carolina Mammography Registry and the Carolina Breast Cancer Study. While I was a part of a Cancer Registry which reported to the Carolina Breast Study, I filled out the face sheet which both studies need for identification, and I am very aware of the time it takes from your day. For a busy registrar, this important job may at times seem fruitless. Be assured that you are helping in two important studies of breast cancer. These studies have already contributed to articles that will increase our understanding of breast cancer. With the addition of benign breast cancer pathology, we may begin to understand and trace what benign pathology becomes breast cancer, how long it takes, and the age groups that develop cancer.

The CMR study is designed to track all mammograms through software programs supplied to the mammography facilities. At the CMR we match the mammography data to the malignant or benign pathology data and report this information back to the facilities. This reporting meets the required MQSA (FDA) guidelines.

A patient for whom an excisional biopsy is recommended may have the surgery performed in a different hospital, possibly in a different county than the place where the mammogram was performed. As a result, matching the mammogram to the pathology requires the collection of breast pathology, both benign and malignant, throughout the state. Therefore our thanks go to all Cancer Registrars and others who are supplying us with the needed pathology.

*Frankie Harvey, CTR*

**National Breast Cancer Surveillance Consortium Meets in NC**

The CMR was the host for the National Breast Cancer Surveillance Consortium's (BCSC) semi-annual meeting in Chapel Hill in April. The BCSC brings together investigators from the CMR and 8 other mammography registry projects, located throughout the United States, to set a national research agenda for the large mammography database that will be created by shared data from all 9 sites. In addition to the CMR in North Carolina, the other 8 sites are in the states of Washington (2 sites), California, New Mexico, Colorado, Iowa, Vermont, and New Hampshire. This group has agreed on the core data to be shared and has outlined several research projects that will go forward as soon as the national database is created. Each site will be sending data (without any identifying information as to woman, physician or practice) to a central statistical coordinating center. Some of the research questions that will be addressed include: 1) What is the regional variation of mammography performance?; 2) What is the variation in the use of the American College of Radiology (ACR) lexicon (established by the ACR for the purpose of standardizing reporting of mammograms)?; 3) Is there a difference in the recommended follow-up interval, following a positive mammogram for women from different geographic areas based on urban/rural residence, race or educational level, or type of site where mammography is done?; and 4) How do variations in the definitions of positive screening mammograms (such as length of time used to define a true or false outcome) affect mammography performance reporting? The existence of the national database will have sufficient numbers of mammography records to allow future research to look at subgroups of women, such as women 40-45 years of age. The April meeting also included presentations by investigators from the Breast and Cervical Cancer Control Program of the CDC and the MQSA program of the FDA. The next meeting of the BCSC will be in October in Vermont.

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CAROLINA MAMMOGRAPHY REGISTRY

CMR Rappport



Bonnie Yankaskas, PhD

CMR continues to flourish as we grow at a steady rate, both in number of facilities reporting to the registry as well in the number of mammograms. We have had a busy schedule since the last newsletter. As is noted in an article in this issue, we have expanded to the point that we no longer consider this a registry for 24 counties in N.C. We have been welcomed into facilities in the western part of the state and several others across the center of the state. By the time you receive this newsletter, you should have received your first outcome report from us. This has been a major effort to enable us to routinely report to you the patients who are now linked to pathology outcomes, and the patients for whom we have no follow-up recommended for further work-up.

The latest update to our software will be out soon. The enhancements should delight you. Maria has outlined them in this issue. As always, we welcome your comments and feedback on any changes or improvements we make. Over the next six months, we will complete our first cycle of research papers and will summarize our findings in the upcoming newsletters. We continue to enjoy our relationship with each of you, and look forward to sharing some results from all our hard work soon.

Carolina Mammography Registry Facilities

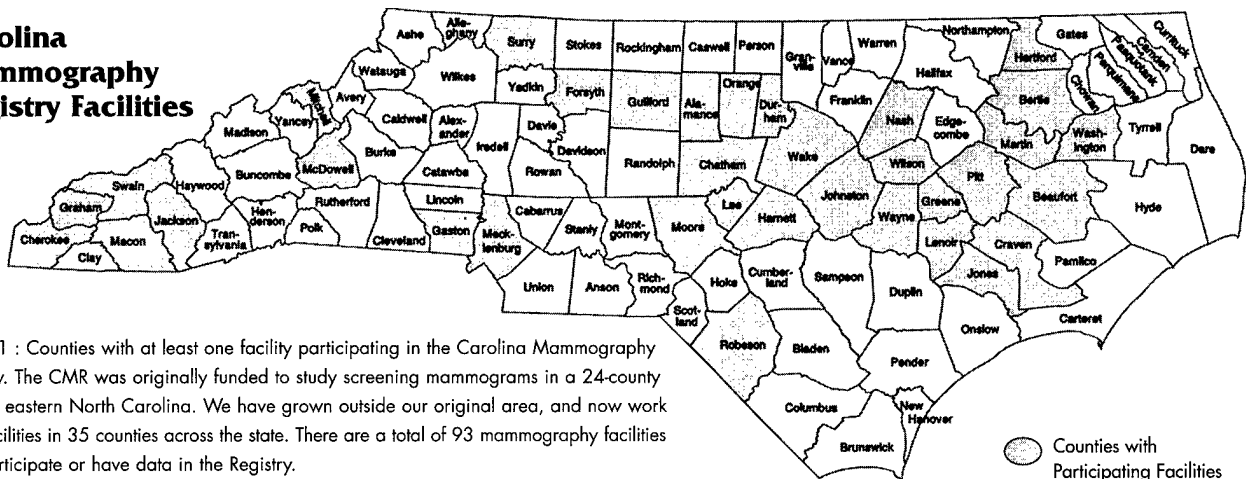


Figure 1 : Counties with at least one facility participating in the Carolina Mammography Registry. The CMR was originally funded to study screening mammograms in a 24-county area in eastern North Carolina. We have grown outside our original area, and now work with facilities in 35 counties across the state. There are a total of 93 mammography facilities that participate or have data in the Registry.

Carolina Mammography Registry Outcome System  
New Reports Available from CMR

The Carolina Mammography Registry has implemented an outcome system that will help facilities by providing follow-up information for their patients. The CMR pathology database has all breast pathology reported to the North Carolina Central Cancer Registry both on a fast report (weekly) and on an annual basis as well as all pathology entered by the facilities. Our Outcome System will provide each facility with the following reports: 1) A full listing of any pathology reported for women receiving their screening mammogram in your facility regardless of

where their pathology procedure was performed, and 2) a listing of women who were recommended for further tests either radiologic or non-radiologic and who do not have results in our database. The referring physician will be listed to enable your facility to resolve what follow up the patient had. All facilities will receive reports on a regular basis. The initial reports will be for all records from 1997. We will work with you to obtain complete follow up information on your patients and to incorporate this new information into your database.



## CMR Spotlight

Renée Kemske began working with us as a research assistant in May of 1994, as a freshman at UNC-Chapel Hill. Upon her graduation with a Bachelor of Science in Biology in May 1997, she began working with the CMR full-time as the Associate Project Director. Renée works closely with Molly Blackley to assure that each participating facility is running smoothly and to answer any questions that may arise concerning the CMDS. She is responsible for building and maintaining the CMR pathology database and has recently helped develop the new outcome system. Outside of work, Renée enjoys exercising, hiking, nature, drawing, art, and relaxing with friends.



Renée Kemske  
Associate Project Director

## Screening vs. Diagnostic Mammograms

On the second side of the data form in the first block, you are asked to note the reason for the visit. It is intended here that you will note whether this is a screening mammogram or a diagnostic mammogram (i.e., there is a known breast problem that is to be worked up) from the radiologist's perspective. This might not agree with the information that is completed by the patient on the front of the form. The patient is asked if she is having problems with her breasts, and whether or not that is the reason she has come for her mammogram. We are aware of the fact that even though the patient may have a complaint, the examination may still be the standard 2-view screening mammogram. In this case, the woman may report symptoms, and the 'reason for visit' may be asymptomatic screening mammogram.

## Expanded Coverage of Screening Benefits Under Medicare

U.S. Congress recently mandated an expansion in the screening benefits provided under the Medicare plan. These expansions went into effect on January 1, 1998, and include the coverage of annual mammography for all women with Medicare who are age 40 and over. These changes reflect the growing acceptance of mammography as an important tool in early detection of breast cancer.

## Changes in Your Staff or Locations?

If you have new mammography technologists or radiologists working for your facility or if you open new facilities or close old ones, please give us a call and let us know. We will work with you to make the necessary changes to your data sheet and to the pick-list in the data system.

## Data Collection Notes - Addition of Ultrasound Module to CMDS



Molly Blackley  
Project Director

The recent upgrade to the CMDS includes a module for the collection of information on patients who have an ultrasound as part of a continued work-up following a positive mammogram. The **ULTRASOUND REPORT** is incorporated into Box 5 of the new data sheet and is to be completed by the radiologist (see below for example of data sheet addition). For all ultrasounds, the radiologist should assign a **final assessment code (0-5) based on the combination of the mammogram and ultrasound studies**. If the radiologist reports that the ultrasound was "normal", the system will assume that the final code for this patient should be a "1". This final code will resolve a patient in the data system who had a mammogram that was interpreted as indeterminate prior to the ultrasound.

For example, if a patient has a positive mammogram, is recommended for an ultrasound, and is found to

<b>ULTRASOUND REPORT</b>		MD code _____	Date _____								
<b>Image:</b>	<input type="checkbox"/> Right Only	<b>Normal?</b>	<input type="checkbox"/> Yes	<b>Right Left</b>							
	<input type="checkbox"/> Left Only	<input type="checkbox"/> No	Cyst	<input type="checkbox"/> <input type="checkbox"/>							
	<input type="checkbox"/> Both Breasts	Solid Mass		<input type="checkbox"/> <input type="checkbox"/>							
<b>Assessment after Ultrasound:</b>											
RIGHT BREAST			LEFT BREAST								
0	1	2	3	4	5	0	1	2	3	4	5

have a benign cyst, this patient will no longer be listed as "needs follow-up" by the CMDS. The same data sheet can be used for a mammogram and an ultrasound study for a particular episode, regardless of the day that the ultrasound was performed. In Box 5 of the data sheet, the "Reason for Visit" should be *Continued Work-up Post Screen* and both *Mammogram* and *Ultrasound* should be checked under "Type of Study".

If the ultrasound is performed on a different day, the date of the ultrasound should be recorded separately in the Ultrasound Report box; *Continued Work-up Post Screen* would still be checked, but "ultrasound" would be the only exam.

# Upgrade 1998

It is time once again for an upgrade to the Carolina Mammography Data System. We have been working diligently over the last year to incorporate suggestions and practice needs into Upgrade 1998, and we will do our best to deliver it to all of our practices as soon as possible. We hope that these improvements to the data system will continue to assist in the collection of quality data and will aid in patient tracking in a more efficient manner. Upgrade 1998 will be gradually distributed to all participants using the CMDS in the upcoming months. The Upgrade will include the following:



Maria Paschall  
CMDS Programmer

- Changes in the collection of **"Family History of Breast Cancer?"** with the ability for the patient to document more than one immediate relative with breast cancer.
- Expansion of the Ethnic Group classification to add of "Hispanic Origin? (Y/N)" (capturing data on race separately from categories of Hispanic origin), and new classification of Native Americans to specify Cherokee, Lumbee or Other.
- Creation of a data entry process for records for which you are waiting for outside films. In addition, we have created a **"Pending Films Report"** mechanism to print a listing of all patients whose outside films have not been received.
- Addition of the ability to mark a patient's record as "Inactive", or "Deceased", to assist in tracking and to allow the printing of letters only to patients who continue to be active patients.
- Enhancement of "Next Recommended Follow-Up" by the capture of two separate follow-up times: one for the "Next Recommended Action Date" (for immediate follow-up studies following an abnormal mammogram) and another for the "Next Recommended Mammogram Date". This feature enables the practice to track patients who go outside of the practice for continued work-up so that they may be contacted for their next routine mammogram.
- Creation of an Ultrasound Report module and corresponding report that will appear on screen 4 of the CMDS. Additionally, the positive mammogram report will include ultrasound results when used as a diagnostic tool as part of a continued work-up. Please see the Data Collection Notes article on page 2 for more information on this new module.
- Addition of a Patient History Report for each patient, including a listing of all visits at the facility and all pathology data entered.
- Development of an Online Help System, which can be accessed from any screen to assist with data entry.
- Improvements to the Query System, creating a more powerful and simple system for practice-initiated queries of data.

## Early Results from CMR Registry Data

Cumulative Growth of Records

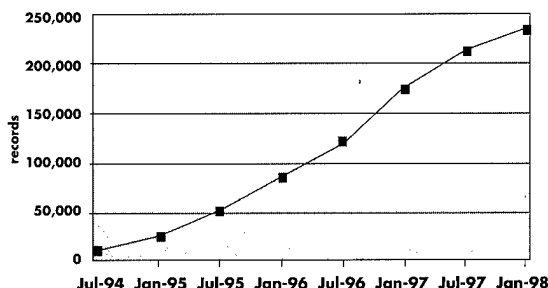


FIGURE 2: At last count, we had over 238,282 records of edited data in the registry, representing 164,385 women across North Carolina.

Age by Race of Women in the Registry

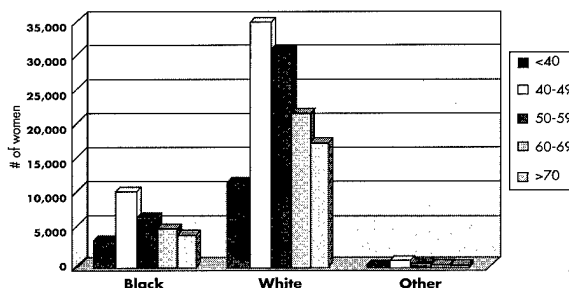


FIGURE 3: At this time, the racial distribution of the entire registry is 79% white, 19% black and 2% other.

Cancer Following Screening Mammogram Within 12 months

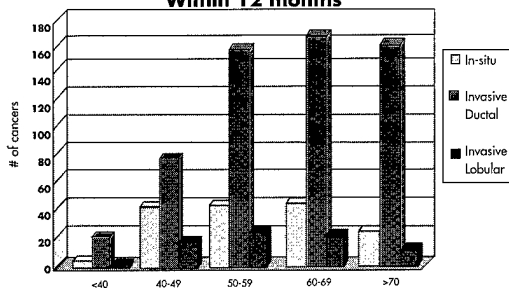


FIGURE 4: Number of cancers found within 12 months following a screen, by age group.

Cancer Following Screening Mammogram Within 12 months

Race	N	Incidence /1,000	Ductal	Invasive	Invasive
			In-situ %	Ductal %	Lobular %
Black	137	4.2	25.5	67.2	7.3
White	634	4.2	16.4	74.1	9.5
Other	10	3.0	30	70.0	0.0
Total	781	4.2	18.2	72.9	9.0

FIGURE 5: Number of cancers found within 12 months following a screen by race.



## Please send us your edits!

The only good data is accurate data. We routinely check all data for errors and return it to you to correct or verify as correct. Timely return of data edits is vital to the registry.

## Backing Up Your Files

It is extremely important to make back-up copies of your mammography database to keep at your facility in case of a power surge or loss of memory on site. When you "back-up" your databases, you are making a copy of all the information stored in your databases. **"Backing up"** is NOT the same as **"downloading"** to CMR! A "download" is a transfer of your information in an encrypted form to our site in Chapel Hill. Please contact one of us if you are not backing up or if you have any questions about these two important processes.

## CMDS Security Features - Password Protection

In an ongoing effort to protect data at each facility and maintain utmost patient confidentiality, CMDS now offers password protection. When the system is started, the first screen prompts for a user ID and password. These values are assigned on-site by a technical administrator, who is appointed by each facility to have full access and control at each site. Should you decide not to utilize this feature, you can simply press <Page Down> and accept the system default values. This bypasses the need for a password. We have also implemented some 'behind the scenes' changes to enhance our pathology tracking and printing routines. There are no changes in the user interface but, in the end, the user will notice a more efficient processing time to generate output.

## CMR Facility Highlight

## PUNGO DISTRICT HOSPITAL

Our project wouldn't be possible without the support and hard work of our participating locations across North Carolina. In this edition of the *Rapport*, we are proud to highlight Pungo District Hospital in Belhaven, NC. Pungo has been a CMR participant since January 1997. The radiologists at Pungo are Drs. David DesRochers, Marshall Taylor, and Elizabeth Jones. Shown at right are the staff members in the radiology department who proudly serve the women of Beaufort County and the surrounding area.

(From L to R): **Noell Morris**, transcriptionist; **Wanda Allen**, RTR, M; **Sandy O'Neal**, RTR, M, ARDMS, Dept. Manager; **Deannie Wallace**, RTR, M, ARDMS; **Robin Coltrain**, RT, R, ARDMS. (not pictured: **Loretta Johnson**, RT, R)



## <http://cmr.unc.edu>

We are developing a web page accessible to all facilities participating in the CMR for helpful hints from our staff. The web site will include an active area for questions about CMR from our sites. We will answer your questions quickly and post frequently asked questions that might be helpful to other sites. Once active, we hope that you will come visit our home on the Internet and give us some feedback on this service! We are located at <http://cmr.unc.edu> and should be active soon.

The CMR *Rapport* is a publication of the CMR, Department of Radiology, University of North Carolina at Chapel Hill School of Medicine. CMR is jointly funded by the Department of Defense and the National Cancer Institute. Edited by Molly P. Blackley, (919) 966-0492.

## Interval Cancer Film Review Exercise

On the 24th of January 1998, five of our advisory radiologists (Richard Bird, David DesRochers, Bryan Koon, Claire Poyet, and Cheryl Viglione) generously gave up a Saturday to review films for the first CMR Film Review of Interval Cancers. This was a blinded review of a mixture of films that preceded interval cancers and other films randomly chosen from the same practices, for the time period 1994, 1995, and 1996. We would like to thank all of you who collaborated by sharing your films. As soon as we have analyzed the data, we will issue a report of our overall findings to all facilities. We will repeat the review session for the 1997 films in January 1998.

## Appendix B:

### Definitions used for analysis of **initial screening** and **screening work-up** statistics

- (1) **Initial screening mammography:** The interpretation code for the initial screening mammography examination is defined as the result of the screening exam only without the further radiologic work-up. (In a few cases where the patient has more than a screening mammography at the initial visit, the screening mammography alone is recoded as zero to denote that further work-up was required.)
- (2) **Screening Work-up Final Interpretation:** The interpretation code for the end of the radiologic work-up is defined as the result of the screening process which begins with the screening mammography examination includes further radiology work-up and ends when the patient is recommended for biopsy or given a follow-up time of 6 months or greater.
- (3) **Positive screening mammography** is defined as a mammographic interpretation code of 0, 4, or 5 or an interpretation code of 3 (if the recommended follow-up time is less than 6 months or if there is a recommendation for biopsy or surgical consult).
- (4) **Positive screening mammography recommended for biopsy:** is defined as a mammographic interpretation code of 4, or 5 or any mammography study that results in a recommendation for biopsy or surgical consult.
- (5) **False positive mammography** result is when the mammography interpretation is positive, and the patient does not have a diagnosis of cancer within 12 months of the mammography. A **true positive** is when the mammography is positive and there is a cancer diagnosis within 12 months of the mammography.
- (6) **False negative mammography** result is when the mammography interpretation is negative and the patient has a diagnosis of cancer within 12 months of the mammography. A **true negative** mammography is when there is no cancer diagnosis within 12 months following the mammography examination.
- (7) **Sensitivity** is the proportion of the diagnosed cancers that had a positive mammography interpretation.
- (8) **Specificity** is the proportion of the women with no diagnosis of cancer who had a negative mammography interpretation.
- (9) **Positive Predictive Value** is the proportion of the positively interpreted mammography examinations where the woman has cancer diagnosed within 12 months of the mammography
- (10) **Negative predictive value** is the proportion of the negatively interpreted mammography examinations where the woman remains without a diagnosis of cancer for 12 months following the mammography.

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We have included the 95% confidence intervals to demonstrate that when the number of cancers is small, the sensitivity and predictive value of a positive mammography are inexact estimates. Until your database gets very large (several years of data), you are best just looking at your individual false negatives and false positive absolute numbers, and not paying much attention to the sensitivity and predictive value.

Index: The attached graphs and tables are for the Registry data from your practice except where noted.

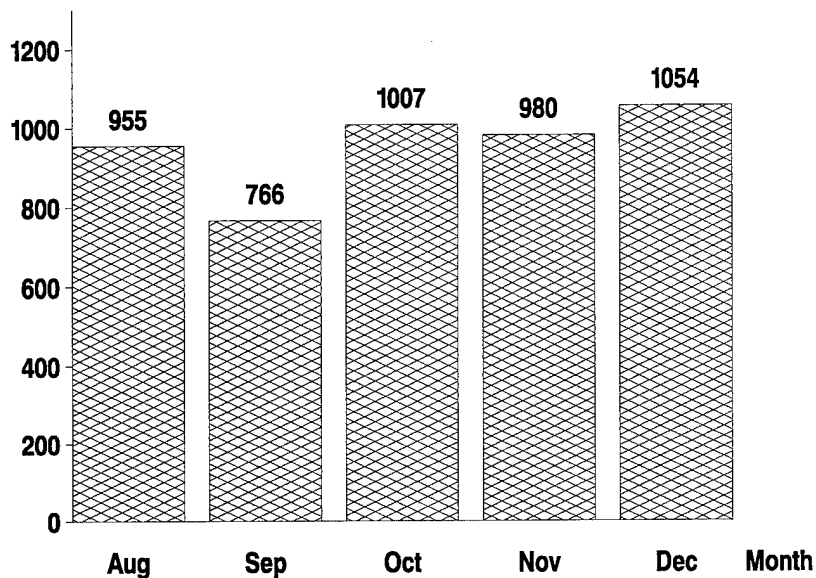
1. Volume of Mammograms by Month – for Years 1994 through 1997
  - a. Screening
  - b. DiagnosticThese graphs display the volume by month for screening and diagnostic mammograms for each year of data in the Registry.
2. Table 1: Age by Race Distribution of Women at First Screen  
This is a table showing the frequency distribution of your women by age and racial groups.
3. Table 2: Number of Screens per Women in Registry  
This displays how many of your women have 1 record in the Registry, 2 etc.
4. Table 3: Outcomes by Final Interpretation Code  
This table displays the pathology linkage to mammography records by the assessment at the end of the radiologic work-up. The cancer path % is the probability of cancer being diagnosed within a year of the various assessments.
5. Table 4: Pathology Outcomes
  - a. From Initial Screening Exam
  - b. From End of Work-up/Recommendation for BiopsyThese two tables give the cancer occurrence by age, with the breakdown for DCIS and invasive cancer. Table 4a is calculated by the assessment at the initial screening study, and Table 4b is calculated at the end of the radiologic work-up.
6. Table 5: Cancer Following Screening Mammography (Within 12 Months)  
This table gives cancer incidence within a year of the screening mammography, reported as number of cancers per 1,000 screening mammography studies for each age group.
7. Table 6: Performance Statistics
  - a. For Initial Screening Mammography
  - b. For End of Work-up, restricted.
  - c. For End of Work-up (includes incomplete mammography work-up)These three tables present sensitivity, specificity and predictive values with the 95% confidence intervals. If your practice data is still small, and the number of cancers few in number, the limits will be wide. These are interpreted to mean that the true value for your practice has a 95% probability of being within these limits. We have given you these estimates for the assessment at the initial screen, and at the end of the radiologic work-up. Table 6a is performance measures presented for the initial screening mammography. Table 6b is for the end of radiologic work-up excluding women with incomplete radiologic work-up. Table 6c is

calculated including all women, classifying women with incomplete follow-up as positive assessments.

8. **Table 7: Work-up Cancer Incidence**  
This table presents a summary for the work-up, displaying the cancer incidence related to the assessment at the initial screen, and the end of work-up.
9. **Table 8: Outcomes for Women With Positive Screens at End of Work-up**  
This table enables you to compare the distribution of your assessments at the end of the work-up with the results for the entire Registry.
10. **Table 9: Performance Statistics for All Practices Combined**  
This table presents the accuracy estimates for the total Registry. You can compare your results from table 6c to these estimates.

### Volume of Mammograms by Month

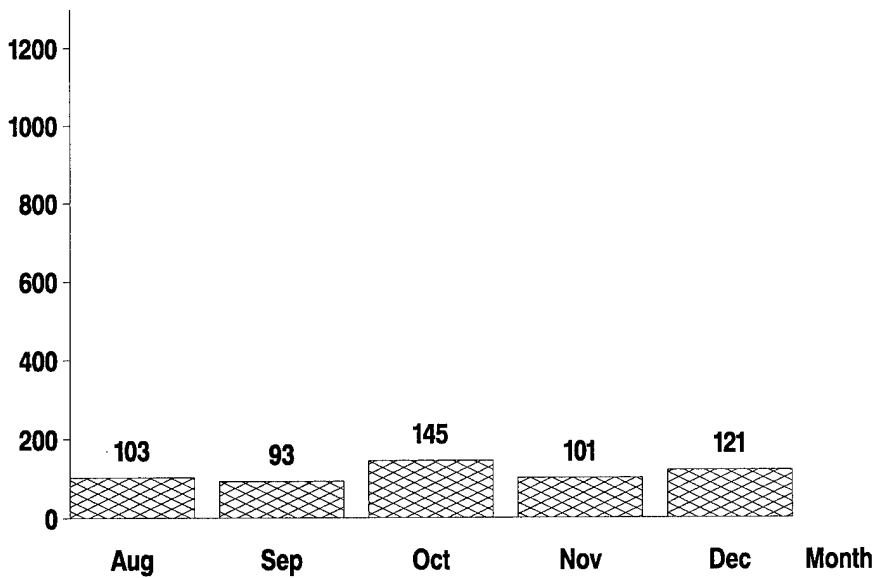
Year=1996 Type of Visit=Screening



Practice = ACB228

### Volume of Mammograms by Month

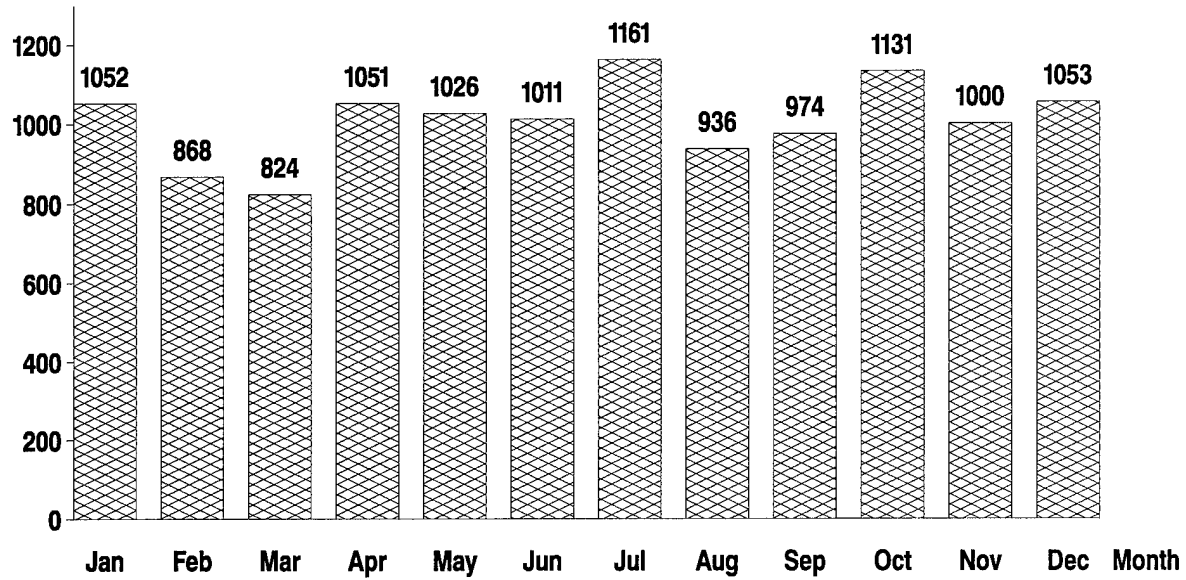
Year=1996 Type of Visit=Diagnostic



Practice = ACB228

### Volume of Mammograms by Month

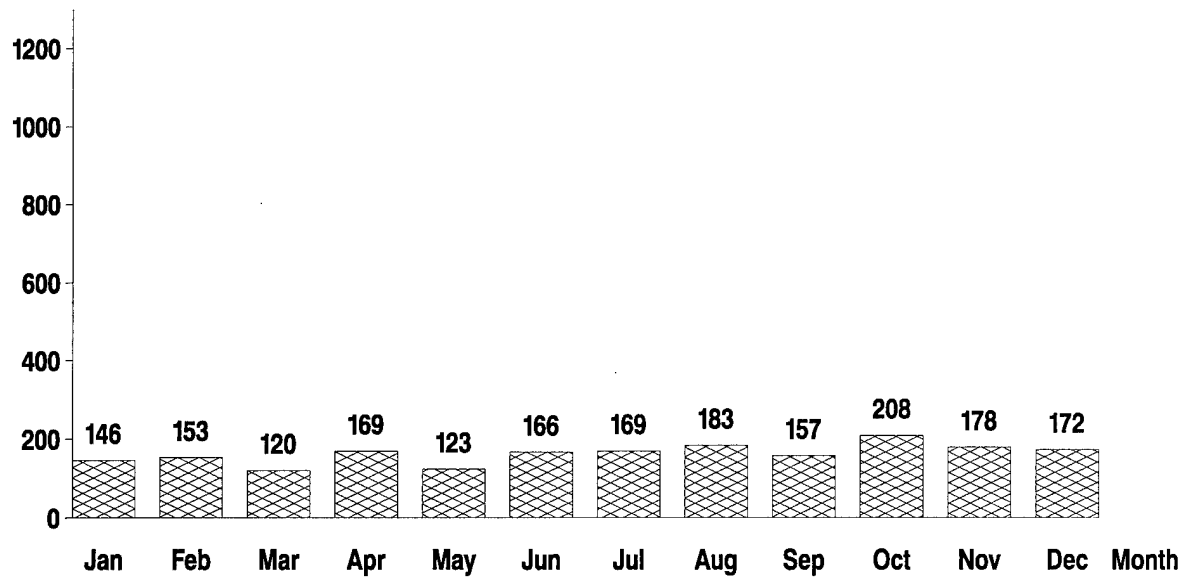
Year=1997 Type of Visit=Screening



Practice = ACB228

### Volume of Mammograms by Month

Year=1997 Type of Visit=Diagnostic



Practice = ACB228



SUMMARY REPORTS FOR PRACTICE = ACB228

Table 1: Age by Race Distribution of Women at First Screen

Age Group	White N (%)	Black N (%)	Other N (%)	Missing N (%)	Total N (%)
<-40	963 ( 7.5)	175 ( 11.9)	36 ( 11.0)	4 ( 1.8)	1,178 ( 8.0)
40-49	4,095 ( 32.0)	608 ( 41.4)	146 ( 44.5)	39 ( 17.5)	4,888 ( 33.0)
50-59	3,916 ( 30.6)	365 ( 24.8)	75 ( 22.9)	48 ( 21.5)	4,404 ( 29.7)
60-69	2,109 ( 16.5)	191 ( 13.0)	47 ( 14.3)	54 ( 24.2)	2,401 ( 16.2)
>= 70	1,709 ( 13.4)	131 ( 8.9)	24 ( 7.3)	78 ( 35.0)	1,942 ( 13.1)
Total	12,792 (100.0)	1,470 (100.0)	328 (100.0)	223 (100.0)	14,813 (100.0)

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 2: Number of Screens per Woman in Registry  
From 08/01/96 to 12/31/97

Number of Screens	Count	%
1	14,818	89.2
2	1,794	10.8
3	1	0.0

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 3: Outcomes by Final Interpretation Code

Interpretation Code	Cancer Path N (%)	Reported Benign Path N (%)	Not Applicable or No Path** N (%)	Total N (%)
Indeterminate (0)	10 ( 12.0)	3 ( 3.6)	70 ( 84.3)	83 (100.0)
Normal (1,2)	32 ( 0.2)	1 ( 0.0)	16,042 ( 99.8)	16,075 (100.0)
Prob benign (3)	13 ( 3.5)	7 ( 1.9)	352 ( 94.6)	372 (100.0)
Susp/cancer (4,5)	27 ( 32.5)	6 ( 7.2)	50 ( 60.2)	83 (100.0)

\* For Final Interpretation Code refer to definition sheet (2).

\*\* This includes studies where NO recommendation for biopsy was made.

NOTE: Pathology data may be incomplete due to incomplete reporting at the state level.

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 4a: Pathology Outcomes From Initial Screening Exam

	Age Group					Total N (%)
	< 40 N (%)	40-49 N (%)	50-59 N (%)	60-69 N (%)	>= 70 N (%)	
Total Screening Exams	1207	5163	5144	2853	2232	16599
All Positive Initial Screens (1)	58 ( 4.8)	275 ( 5.3)	220 ( 4.3)	124 ( 4.3)	94 ( 4.2)	771 ( 4.6)
No Cancer	57 ( 98.3)	264 ( 96.0)	204 ( 92.7)	111 ( 89.5)	86 ( 91.5)	722 ( 93.6)
Total Cancer	1 ( 1.7)	11 ( 4.0)	16 ( 7.3)	13 ( 10.5)	8 ( 8.5)	49 ( 6.4)
DCIS	-	5 ( 45.5)	2 ( 12.5)	4 ( 30.8)	-	11 ( 22.4)
Invasive	1 (100.0)	6 ( 54.5)	14 ( 87.5)	9 ( 69.2)	8 (100.0)	38 ( 77.6)

Refer to definition sheet (1).

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 4b: Pathology Outcomes From End of Workup/Recommendation for Biopsy

	Age Group					Total N (%)
	< 40 N (%)	40-49 N (%)	50-59 N (%)	60-69 N (%)	>= 70 N (%)	
All Positive Initial Screens (1)	58	275	220	124	94	771
Women With Incomplete Workup	14 ( 24.1)	102 ( 37.1)	79 ( 35.9)	42 ( 33.9)	26 ( 27.7)	263 ( 34.1)
End of Workup (2) / Recommended for Biopsy (3)	9 ( 15.5)	33 ( 12.0)	38 ( 17.3)	17 ( 13.7)	19 ( 20.2)	116 ( 15.0)
No Cancer	8 ( 88.9)	27 ( 81.8)	23 ( 60.5)	11 ( 64.7)	15 ( 78.9)	84 ( 72.4)
Total Cancer	1 ( 11.1)	6 ( 18.2)	15 ( 39.5)	6 ( 35.3)	4 ( 21.1)	32 ( 27.6)
DCIS	-	2 ( 33.3)	1 ( 6.7)	1 ( 16.7)	-	4 ( 12.5)
Invasive	1 (100.0)	4 ( 66.7)	14 ( 93.3)	5 ( 83.3)	4 (100.0)	28 ( 87.5)

Refer to definition sheet (1) (2) (3).

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 5: Cancer Following Screening Mammography  
(Within 12 Months)

Age	N	Incidence /1000	Ductal In-Situ N (%)	Invasive N (%)
< 40	2	1.7	1 ( 50.0)	1 ( 50.0)
40-49	18	3.5	5 ( 27.8)	13 ( 72.2)
50-59	21	4.1	3 ( 14.3)	18 ( 85.7)
60-69	20	7.0	4 ( 20.0)	16 ( 80.0)
>= 70	9	4.0	1 ( 11.1)	8 ( 88.9)
Total	70	4.2	14 ( 20.0)	56 ( 80.0)

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 6a: Performance Statistics  
for Initial Screening Mammography (1)

Screening Result	Cancer	No Cancer
Positive (3)	49	724
Negative	21	15,819
Sensitivity (7)	49/70	0.70 (0.59,0.81)
Specificity (8)	15,819/16,543	0.96 (0.95,0.96)
Pos Pred Value (9)	49/773	0.06 (0.05,0.08)
Neg Pred Value (10)	15,819/15,840	0.99 (0.99,0.99)

Refers to definition sheet (1) (7) (8) (9) (10).

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 6b: Performance Statistics  
for End of Workup (2)

Screening Result	Cancer	No Cancer
Positive*	32	84
Negative	27	16,207
Sensitivity (7)	32/59	0.54 (0.42, 0.67)
Specificity (8)	16,207/16,291	0.99 (0.99, 0.99)
Pos Pred Value (9)	32/116	0.28 (0.19, 0.36)
Neg Pred Value (10)	16,207/16,234	0.99 (0.99, 0.99)

\* This does not include mammography that was positive at screen but had undetermined follow up (see table 6c for these results).  
Refers to definition sheet (2) (7) (8) (9) (10).



SUMMARY REPORTS FOR PRACTICE = ACB228

Table 6c: Performance Statistics  
for End of Workup (2)

Screening Result	Cancer	No Cancer
Positive*	43	336
Negative	27	16,207
Sensitivity (7)	43/70	0.61 (0.50,0.73)
Specificity (8)	16,207/16,543	0.98 (0.98,0.98)
Pos Pred Value (9)	43/379	0.11 (0.08,0.15)
Neg Pred Value (10)	16,207/16,234	0.99 (0.99,0.99)

\* Women with positive initial screens and incomplete workup are considered to be positive.

Refers to definition sheet (2) (7) (8) (9) (10).

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 7: Workup Cancer Incidence

Initial Screening Assessment	End of Radiologic Workup	Cancer Outcome	N	Cancer Incidence per 1,000
Negative	Negative	No Cancer	15,819	
Negative	Negative	Cancer	21	1.3
Total			15,840	
Positive	Negative	No Cancer	388	
Positive	Negative	Cancer	6	15.2
Total			394	
Positive	Positive	No Cancer	336	
Positive	Positive	Cancer	43	113.5
Total			379	

SUMMARY REPORTS FOR PRACTICE = ACB228

Table 8: Outcomes for Women With Positive Screens  
at End of Workup (2)

End Of Workup Status	For the Individual Practice N (%)	For All Practices N (%)
Negative	394 (51.0)	6,069 (61.0)
Positive	116 (15.0)	2,173 (22.0)
Incomplete	263 (34.0)	1,741 (17.0)

Definition reference (2).

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