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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)* Breast cancer survivors compose the largest group of cancer survivors in the United States. As heterogeneity exists within stages and between races in breast cancer survival, it is important to develop a better understanding of prognostic factors. Tumor estrogen and progesterone receptors are one of the more important prognostic factors in breast cancer patients. However, currently in clinical practice hormone receptor status is treated as either being present or absent and is treated similarly in all groups. The dichotomization of hormone status may lead to loss of valuable information and hormone receptor status may not have the same effect in African Americans and Whites. This historical cohort study evaluates quantitative differences in tumor hormone receptors in African Americans and Whites and determines whether survival effects differ between the two groups. This study also assesses whether a dose-response relationship, linear or nonlinear, exists between hormone receptors and survival. Findings of this study may lead to better prediction of survival and to identification of subsets of patients at higher risk that may have gone unrecognized by the application of a single cutpoint. Our preliminary findings indicate that African American breast cancer patients have more estrogen receptor negativity and a worse survival.

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Breast cancer survival, African American, estrogen receptor, Progesterone receptor, quantitative analysis

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INTRODUCTION

Breast cancer survivors compose the largest group of cancer survivors in the United States today. As considerable heterogeneity exists within stages and between racial groups in breast cancer survival it is important to develop a better understanding of prognostic factors. Estrogen and progesterone receptors in breast tumor tissue are regarded to be one of the more important prognostic factors in breast cancer patients. However, currently in clinical practice hormone receptor status is treated as either being present or absent and is treated similarly in all race/ethnic groups. The dichotomization of hormone status may lead to loss of valuable information and hormone receptor status may not have the same effect in African Americans and Whites. This historical cohort study evaluates quantitative differences in estrogen and progesterone receptors in the breast tumors of African Americans and Whites and determines whether survival effects differ between the two groups. This study will also assess whether a dose-response relationship, linear or nonlinear, exists between quantitatively assessed hormone receptors and survival, as opposed to the currently popular dichotomized assessment of receptor status. Findings of this study may lead to better prediction of survival and to identification of subsets of patients needing particular clinical attention that may have gone unrecognized by applying one cutpoint to all patients.

BODY

Year one of this three-year study has been completed and the items in the *Statement of Work* that should have been undertaken and/or completed are summarized in Table 1.

Table 1. Progress on items in the *Statement of Works*

	Description	*Planned time*	*Progress*
Task 1	Initial establishment of study team, approach and issues	1 to 4 months	Completed
	Staff training	1 to 4 months	Completed
	Preparation of computer programs and study database	1 to 4 months	Completed
Task 2	Establish and Characterize Cohort	4 to 8 months	Completed
	Abstraction of Patient / Tumor Data From	4 to 16 months	
	Computer Databases		Ongoing
	Medical Record Abstraction		Underway
	Hormone Receptor Log Book		Completed
Task 3	SES estimates based on 1990 US Census data	12 to 24 months	Underway
Task 4	Survival Data Collection From		
	Henry Ford Health System Tumor Registry	12 to 24 months	Underway
	SEER	18 to 24 months	Underway
	Michigan State Tumor Registry	18 to 24 months	Underway
Task 5	Attend breast cancer conference	Year two	1 Attended

A study team has been put into place. Ms. Christine Neslund-Dudas, an Epidemiologist I, is helping manage the study, Mr. Richard Krajenta is in charge of the computer databases and data preparation, and Ms. Cheryl Spoutz heads a team of research abstractors who have a minimum of a two-year college degree in Health Information Management (HIM), have passed National Accreditation Examinations and are credentialed Registered Health Information Technicians (RHIT). Currently, Dr. Tammemagi is carrying out all statistical analyses.

All available estrogen and progesterone hormone receptor data (quantitative data) for breast cancer patients from 1982 to 1990 have been manually transcribed from the laboratory notebooks of the Department of Clinical Biochemistry into a Microsoft Access database. Information pertinent to this study was extracted from the Henry Ford Health System (HFHS) Tumor Registry for breast cancer patients during the same period and was placed into another Microsoft Access file.

Survival data has been collected from the HFHS Tumor Registry. Survival and other relevant clinicopathologic data have been collected from the Detroit Surveillance, Epidemiology and End Results (SEER) Tumor Registry. Also, death data for the breast cancer cohort has been downloaded from the Michigan Death Registry files and includes deaths up until the year 1999. These data have been placed in another Access database.

Socioeconomic status (SES) data was estimated for breast cancer patients (1982-1990) in the HFHS Tumor Registry based on patient's address at diagnosis and the block group medium household income (BGMHI) derived from the 1990 US Census. So far we have obtained SES stimates for approximately 70% of individuals, which is below what we have obtained in several past studies. We will be investigating alternative computer algorithms for collecting these data, including attempting to collect SES data for individuals living outside of the Metropolitan Detroit area.

As these databases are completed and cleaned up they will be merged. One issue that we are addressing is conflicting survival follow-up data. The HFHS Tumor Registry is usually current to up to within 6 months, whereas the SEER Tumor Registry is usually about 1 year behind in updating its files. Thus, one would expect the HFHS Tumor Registry to be preferred, however, the SEER Tumor Registry and the Michigan Death Registry data may capture survival

events lost to follow-up in the HFHS, and the latter will provide specific causes of death data. Each conflicting survival case will be assessed individually.

A good deal of effort in the last year has gone into developing and testing the *Data Abstraction Form*. A copy is provided in Appendix 1. It has gone through four cycles of testing and re-writing and re-testing. It has recently undergone a reliability test in which several abstractors abstracted four sets of medical records. The abstraction process demonstrated a high degree of consistency. The average time to complete the abstraction of one patient's medical records was 1.5 hours. Our recent studies in cancer survival have found that comorbidity may play an important role, and that its distribution may differ by race. To ensure adequate adjustment in analysis and attempt to better understand the racial differences in breast cancer survival we have incorporated a section on comorbidity into the abstraction form. Intensive medical record abstraction is about to commence and we hope to complete the majority of it by the end of year two. Dr. Tammemagi will review each abstraction form for completeness and consistency within one week of the abstraction and prior to data entry, so as to allow immediate handling of problems or issues.

Dr. Tammemagi attended the Summit Meeting Evaluating Research on Breast Cancer in African American Women, in Washington, DC, September 8-10, 2000.

To enhance analytic capabilities Dr. Tammemagi purchased S-Plus 2000 (Insightful Corporation, Seattle, WA), and CART (classification and regression tree) and MARS (multivariate adaptive regression spline) (Salford Software Inc., San Diego, CA) software packages. Dr. Tammemagi attended a three-day training course on the use of the latter two programs in Toronto, in October 2000. Dr. Tammemagi also met with Dr. Michael LeBlanc in

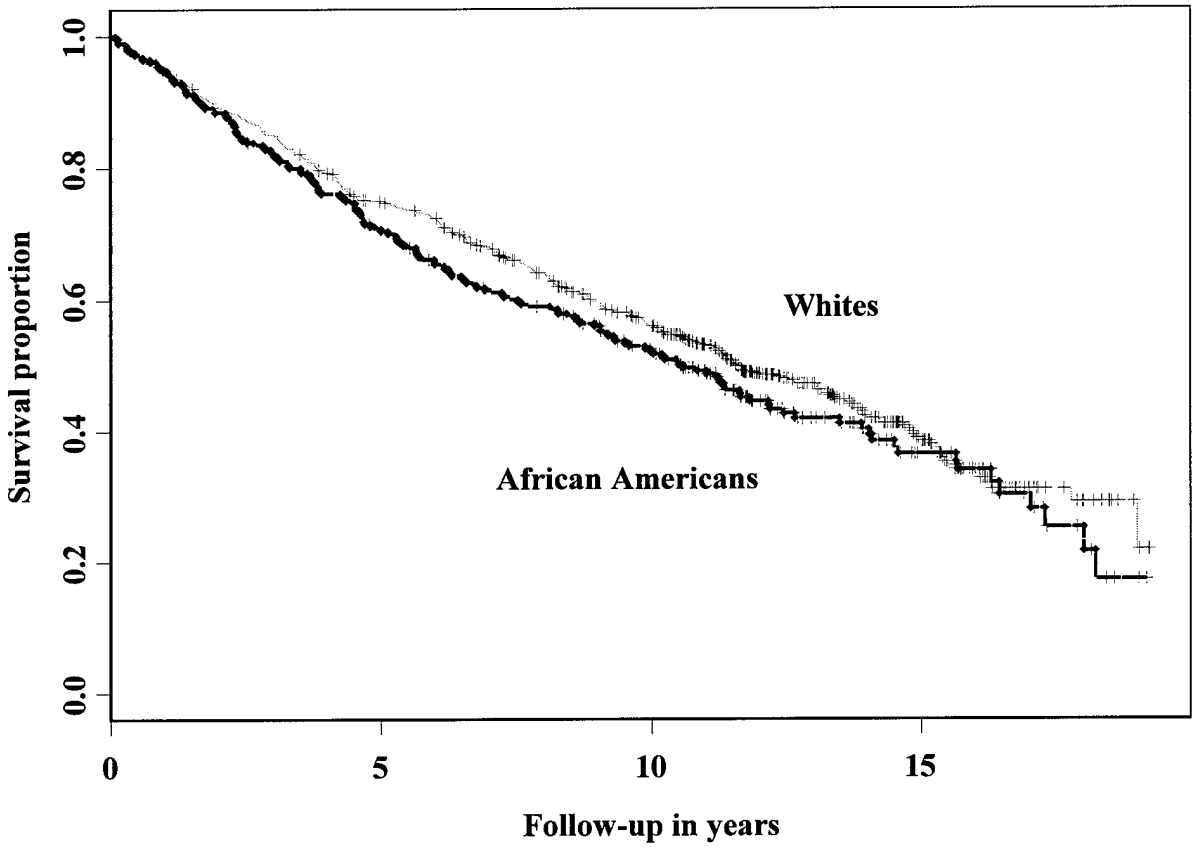
Seattle, WA, and had Dr. LeBlanc's tree-based survival software installed on his laptop computer and received instruction on its use.

Preliminary Study Findings

Although the study is still in the early stages, an impression of the study population and data is offered. It must be emphasized that the data presented are preliminary and are likely to change – datasets are not complete and data has not been "cleaned".

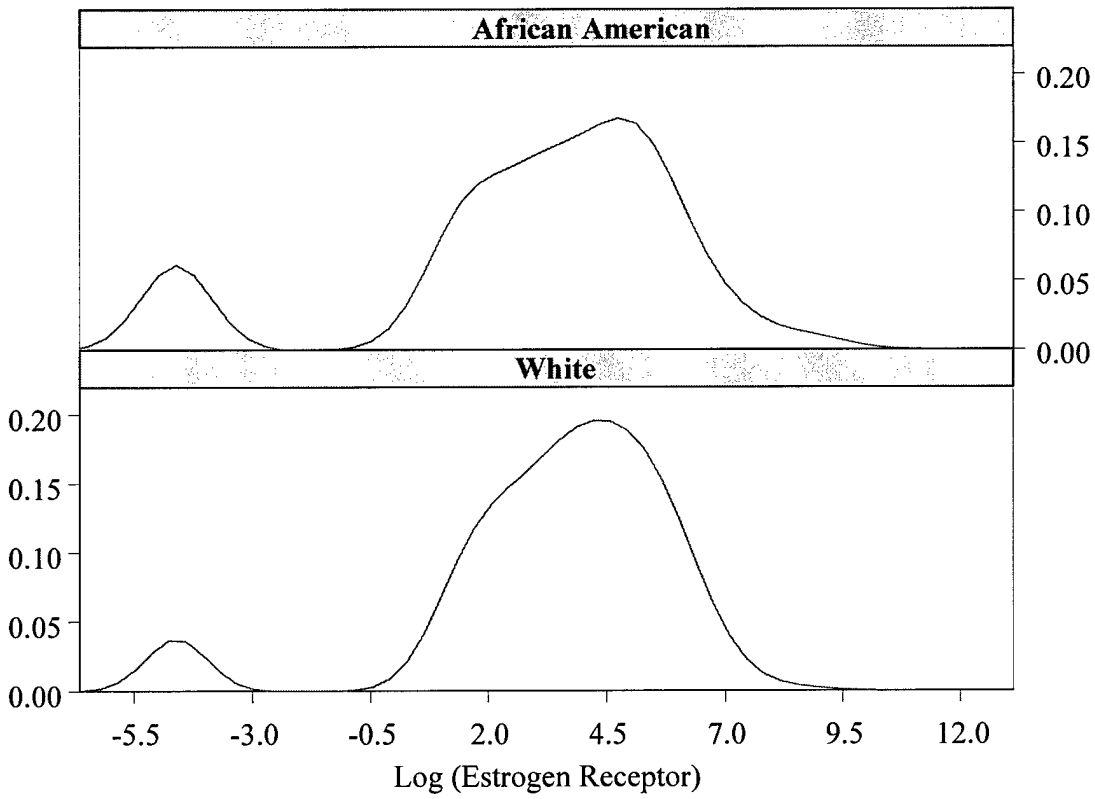
The non-finalized dataset includes 1161 patients of whom 824 (71%) are whites and 337 (29%) are Black. The mean patient age is 60.1 years (SD 14.2) and the minimum, median and maximum ages are 24, 61, 94 years, respectively. The median follow-up of the breast cancer cohort is 11.4 years (95% CI 10.6-12.5). The median survival for African Americans was 10.6 (95% CI 9.1-12.2) years versus 11.6 (95% CI 10.6-13.3) years for Whites. A Kaplan-Meier survival plot describing the survival experience for these two groups is presented in Figure 1.

Figure 1. Kaplan-Meier survival plot describing the survival experience of 956 breast cancer patients diagnosed in the HFHS (1982-1990)



The hormone receptor data presented here are for 1041 individuals. The overall geometric mean for estrogen receptors is 26.84, and for African Americans is 19.74 and for Whites is 30.54. These preliminary data together with the density distribution plot for log(estrogen receptor) (Figure 2) suggest that African Americans have more receptor negative tumors and possibly more positive tumors with lower counts.

Figure 2. Density distribution plot of log (estrogen receptor) stratified by race



KEY RESEARCH ACCOMPLISHMENTS: NA.

REPORTABLE OUTCOMES: NA.

CONCLUSIONS

It is too early into the study to draw any substantive or methodologic conclusions. However, the study is progression on schedule and within budget, and expects to present a more exciting report next year.

APPENDIX 1. JFCC – *Hormone Receptors & Breast Cancer Survival Study Abstraction Form*

Study ID #: _____
Abstraction Date: __/__/____ **Abstraction Time:** _____
Abstractor ID: _____ (use month/day/ year throughout)

CASE DESCRIPTION & EPIDEMIOLOGIC DATA

CONFIRMATION OF CASE STATUS

Is there evidence in the chart that the patient was diagnosed with invasive breast cancer or suspicion of invasive breast cancer on the same date (or within 2 weeks of the date) as it appears as the "Diagnosis Date" for the Josephine Ford Cancer Registry?

If Yes➔ Continue.
Record original JFCC dx date here: __/__/____

If No ➔ Do alternative breast cancer diagnosis dates exist?
Please enter the dates here:

1. __/__/____
2. __/__/____
3. __/__/____

If you are unable to confirm diagnosis of invasive breast cancer, **STOP REVIEW** and consult with investigator.

SOCIODEMOGRAPHIC DATA (Complete only if it differs from that provided, i.e., JFCC Tumor Registry data)

Date of Birth: ____/____/____

Race

1 = White
2 = Black / African American
3 = American Indian or Alaskan Native
4 = Asian
5 = Pacific Islander or Native Hawaiian
6= Other, specify_____
9 = Unknown

Ethnicity 0= Non-Hispanic 1 = Hispanic

Marital Status at diagnosis

1= Married or living as married
2 = Not married 2a = Single (never married)
2b = Divorced or legally separated
2c = Widowed
9= Unknown

BODY SIZE INFORMATION (exclude data during pregnancy)

Maximum Height (inches): _____ Date: __ __ / __ __ / __ __ __ __

Weight closest to **diagnosis date** (pounds): _____ Date: __ __ / __ __ / __ __ __ __

REPRODUCTIVE / ENDOCRINE HISTORY

Age at menarche (years) _____

Menopausal status at diagnosis.
01= Pre-menopausal
02= Peri-menopausal (Transition between pre- & post-menopause. Menstrual cycles irregular, hot flashes.)
03= Post-menopausal When did menopause occur? _____Year/age/years ago?
04= Hysterectomy. Number of ovaries removed? _____ Date of surgery: __ __/__ __/__ __ __
99=Undetermined

Parity (# of live births) as of the diagnosis date. __ __

If pre-menopausal, record the number of post-diagnosis live births __ __

Did the patient use hormone contraceptives? 0=No 1=Yes 9=Unknown

Start date of use: __ __ / __ __ / __ __ __ __ Type : 1=Birth Control Pills
Length of time (years): _____ 2=Shots or Injections
Product Name: _____ 3=Subdermal Implants

Start date of use: __ __ / __ __ / __ __ __ __ Type: 1=Birth Control Pills
Length of time (years): _____ 2=Shots or Injections
Product Name: _____ 3=Subdermal Implants

Start date of use: __ __ / __ __ / __ __ __ __ Type: 1=Birth Control Pills
Length of time (years): _____ 2=Shots or Injections
Product Name: _____ 3=Subdermal Implants

Did the patient use hormone replacement therapy? 0=No 1=Yes 9=Unknown

Start date of use: __ __ / __ __ / __ __ __ __ 1=Estrogen Alone
Length of time (years): _____ 2=Estrogen plus Progesterone
Product Name: _____ 3=Progesterone Alone

Start date of use: __ __ / __ __ / __ __ __ __ 1=Estrogen Alone
Length of time (years): _____ 2=Estrogen plus Progesterone
Product Name: _____ 3=Progesterone Alone

Start date of use: __ __ / __ __ / __ __ __ __ 1=Estrogen Alone
Length of time (years): _____ 2=Estrogen plus Progesterone
Product Name: _____ 3=Progesterone Alone

FAMILY HISTORY OF BREAST CANCER

Is there a family history of breast cancer?	1= Yes, there is a noted family history 2= No, there is a noted negative family history 8 = record shows Ø 9=Undetermined, not documented

MAMMOGRAPHY HISTORY

Mammography History from 3 years prior to first treatment: 0=No 1=Yes 9=Unknown

If yes, complete the following table

	Dates:	Results:
1.	__ __/__ __/__ __ __ __	_____
2.	__ __/__ __/__ __ __ __	_____
3.	__ __/__ __/__ __ __ __	_____
4.	__ __/__ __/__ __ __ __	_____
5.	__ __/__ __/__ __ __ __	_____
6.	__ __/__ __/__ __ __ __	_____
7.	__ __/__ __/__ __ __ __	_____
8.	__ __/__ __/__ __ __ __	_____
9.	__ __/__ __/__ __ __ __	_____
10.	__ __/__ __/__ __ __ __	_____
11.	__ __/__ __/__ __ __ __	_____
12.	__ __/__ __/__ __ __ __	_____
13.	__ __/__ __/__ __ __ __	_____
14.	__ __/__ __/__ __ __ __	_____
15.	__ __/__ __/__ __ __ __	_____
16.	__ __/__ __/__ __ __ __	_____

Results Key:

1= Negative

2= Benign/Negative

3= Probably Benign

4= Suspicious

5= Highly Suspicious

8= Incomplete/Inconclusive

9= Unknown

PATIENT HISTORY OF BREAST LESIONS *BEFORE* THE INDEX BREAST CANCER

Breast Biopsy History throughout patient records

0=No 9=Unknown

1=Yes If yes, complete table below

Dates	Results
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____
__ __/__ __/__ __ __ __	_____

Key to Results:

1. Benign Breast Disease (BBD)
2. Ductal Carcinoma In Situ (DCIS)
3. Lobular Carcinoma In Situ (LCIS)
4. Both BBD and CIS/Cancer
5. Invasive Carcinoma (specify histopathologic type)
6. Lumpectomy or Mastectomy (unilateral or bilateral) not further specified
7. Cosmetic Breast Reduction
8. Cosmetic Breast Enlargement
9. Other Breast Biopsy (epithelial biopsy of breast skin, nipple, fat, axillary lymph nodes, etc.)
99. Incomplete/Inconclusive Unknown

SYMPTOMS AND LEAD-UP TO THE DIAGNOSIS OF BREAST CANCER

When was the first time that a suspicion of breast cancer for this index case of breast cancer was documented in medical records or indicated by a medical procedure? __ __ / __ __ / __ __ __ __

Did patient report breast symptoms?

- ❑ 01=Yes → If yes, please continue with the next question.
- ❑ 02=No. Explicit mention of no symptoms → If no, skip to next box.
- ❑ 99=No comment about symptoms → Skip to next box.

Patient Reported Breast Symptoms *(Indicate all that apply.)*

L	R	Unk		Date Documented	Duration
❑	❑	❑	01=Lump or mass	________	____
❑	❑	❑	02=Pain *Specify:* ________	________	____
❑	❑	❑	03=Nipple discharge	________	____
❑	❑	❑	04=Visual change	________	____
❑	❑	❑	05=Odor	________	____
❑	❑	❑	88=Other, *specify:* ________	________	____
❑	❑	❑	99=Unspecified		

PATHOLOGY SUMMARIES of the specimens related to the index breast cancer.
If cytology, biopsy and surgical excision were involved, please complete for each procedure.

CYTOLOGY

(Indicate all that apply for each breast.)
Date of procedure: __ __ / __ __ / __ __ __ __

Photocopy report masking patient identifiers

L	R	Unk	Results
❑	❑	❑	00=Insufficient sample
❑	❑	❑	01=Normal cells
❑	❑	❑	02=Atypical cells
❑	❑	❑	03=Abnormal cells
❑	❑	❑	04=Malignant cells, specify type ________
❑	❑	❑	88=Other, *specify:* ________
❑	❑	❑	99=Undetermined

(Indicate all that apply for each breast.)
Date of procedure: __ __ / __ __ / __ __ __ __

Photocopy report masking patient identifiers

L	R	Unk	Results
❑	❑	❑	00=Insufficient sample
❑	❑	❑	01=Normal cells
❑	❑	❑	02=Atypical cells
❑	❑	❑	03=Abnormal cells
❑	❑	❑	04=Malignant cells, specify type ________
❑	❑	❑	88=Other, *specify:* ________
❑	❑	❑	99=Undetermined

(Indicate all that apply for each breast.)
Date of procedure: __ __ / __ __ / __ __ __ __

Photocopy report masking patient identifiers

L	R	Unk	Results
❑	❑	❑	00=Insufficient sample
❑	❑	❑	01=Normal cells
❑	❑	❑	02=Atypical cells
❑	❑	❑	03=Abnormal cells
❑	❑	❑	04=Malignant cells, specify type ________
❑	❑	❑	88=Other, *specify:* ________
❑	❑	❑	99=Undetermined

Continued, PATHOLOGY SUMMARY of the specimens related to the index breast cancer. If cytology, biopsy & surgical excision were involved complete for each procedure.

HISTOPATHOLOGY FROM BIOPSY (Indicate all that apply for each breast.) Date of procedure: __ __ / __ __ / __ __ __ __ Photocopy report masking patient identifiers	L	R	Unk	**Results**
	❑	❑	❑	01= Atypical hyperplasia
	❑	❑	❑	02= Ductal hyperplasia
	❑	❑	❑	03= Fibroadenoma
	❑	❑	❑	04= Intraductal carcinoma in situ (DCIS)
	❑	❑	❑	05= Lobular carcinoma in situ (CIS)
	❑	❑	❑	06= CIS not otherwise specified
	❑	❑	❑	**07= Invasive ductal carcinoma (DC)**
	❑	❑	❑	08= Invasive DC with DCIS
	❑	❑	❑	09= Invasive lobular carcinoma
	❑	❑	❑	10= Mucinous carcinoma
	❑	❑	❑	11= Medullary carcinoma
	❑	❑	❑	12= Papillary carcinoma
	❑	❑	❑	13= Tubular carcinoma
	❑	❑	❑	14= Adenoid cystic carcinoma
	❑	❑	❑	15= Secretory (juvenile) carcinoma
	❑	❑	❑	16= Apocrine carcioma
	❑	❑	❑	17= Paget's disease of the nipple
	❑	❑	❑	18= Invasive cancer, NOS
	❑	❑	❑	19= Cystosarcoma phyllodes
	❑	❑	❑	88= Other, *specify:*_____
	❑	❑	❑	99= Undetermined

HISTOPATHOLOGY -- SURGICAL EXICISION (Indicate all that apply for each breast.) Date of procedure: __ __ / __ __ / __ __ __ __ Photocopy report masking patient identifiers	L	R	Unk	**Results**
	❑	❑	❑	01= Atypical hyperplasia
	❑	❑	❑	02= Ductal hyperplasia
	❑	❑	❑	03= Fibroadenoma
	❑	❑	❑	04= Intraductal carcinoma in situ (DCIS)
	❑	❑	❑	05= Lobular carcinoma in situ (CIS)
	❑	❑	❑	06= CIS not otherwise specified
	❑	❑	❑	07= **Invasive ductal carcinoma (DC)**
	❑	❑	❑	08= Invasive DC with DCIS
	❑	❑	❑	09= Invasive lobular carcinoma
	❑	❑	❑	10= Mucinous carcinoma
	❑	❑	❑	11= Medullary carcinoma
	❑	❑	❑	12= Papillary carcinoma
	❑	❑	❑	13= Tubular carcinoma
	❑	❑	❑	14= Adenoid cystic carcinoma
	❑	❑	❑	15= Secretory (juvenile) carcinoma
	❑	❑	❑	16= Apocrine carcioma
	❑	❑	❑	17= Paget's disease of the nipple
	❑	❑	❑	18= Invasive cancer, NOS
	❑	❑	❑	19= Cystosarcoma phyllodes
	❑	❑	❑	88= Other, *specify:*_____
	❑	❑	❑	99= Undetermined

STAGING

	PLEASE PHOTOCOPY PATHOLOGISTS REPORTS minus patient identifiers
Primary Tumor (T)	❒ TX Primary tumor cannot be assessed ❒ TO No evidence of primary tumor ❒ Tis Carcinoma in situ ❒ T1 Tumor ≤2 cm in greatest dimension ❒ pT1mic Microinvasion 0.1 cm or less in greatest dimension ❒ T1a Tumor >0.1 to ≤0.5 cm in greatest dimension ❒ T1b >0.5 to ≤1 cm in greatest dimension ❒ T1c >1cm to ≤2 cm in greatest dimension ❒ T2 Tumor >2 cm to 5 cm ❒ T3 Tumor >5 cm ❒ T4 Tumor of any size with direct extension to chest wall or skin ❒ T4a Extension to chest wall ❒ T4b Edema or ulceration of the skin or satellite skin nodules confined to same breast ❒ T4c Both T4a and T4b ❒ T4d Inflammatory carcinoma Paget's disease associated with a tumor is classified by size of the tumor
Regional Lymph Nodes (N)	❒ NX Regional LN cannot be assessed (e.g., previously removed or were not sampled) ❒ N0 No regional LN metastasis ❒ N1 Spread to movable ipsilateral axillary LN(s) ❒ N2 Spread to ipsilateral axillary LN(s) fixed to one another or to other structures ❒ N3 Spread to ipsilateral internal mammary LN(s)
Pathologic Classification (pN)	❒ pNX Regional LNs cannot be assessed ❒ pNO No regional LN metastasis ❒ pN1 Metastasis to movable ipsilateral axillary LN(s) ❒ pN1a Only micrometastasis (none larger than 0.2 cm) ❒ pN1bi Metastasis in 1 to 3 LMs, >0.2 to <2cm in greatest dimension ❒ pN1bii Metastasis to 4 or more LNs, >0.2 to <2cm in greatest dimension ❒ pN1biii Extension of tumor beyond capsule of a LN <2 cm in greatest dimension ❒ pN1biv Metastasis to LN ≥2 cm in dimension ❒ pN2 Metastasis to ipsilateral axillary LNs that are fixed to other LN(s) or structures ❒ pN3 Metastasis to ipsilateral internal mammary LN(s)
Distant Metastasis	❒ MX ❒ M0 ❒ M1 (includes metastasis to ipsilateral supraclavicular LN(s) If M=1, what are the number of metastatic organ sites? _____ Specify sites (which organs) _____
What was the TNM stage group, if provided?	❒ 0 (TIS) ❒ I ❒ II ❒ IIA ❒ IIB ❒ III ❒ IIIA ❒ IIIB ❒ IV ❒ Stage X (cannot be determined) ❒ Not provided
Histopathologic GRADE: _____	❒ GX= cannot be assessed ❒ G1= well differentiated ❒ G2= moderately differentiated, ❒ G3= poorly differentiated ❒ G4= Undifferentiated ❒ G9 = Unknown

TREATMENT

Did the patient received treatment?	1 = treatment carried out (mostly at HFHS) 2 = treatment primarily carried out elsewhere 3 = treatment interrupted / incomplete 4 = treatment advised but refused 5 = no treatment advised 6 = no treatment given, reasons unknown 9 = unknown whether treatment received
Was the breast cancer treated with SURGERY? **0 = no 1 = yes 9 = unknown**	If yes, what was the date? (1st if more than one) __ __/__ __/__ __ __ __ Surgery consisted of 1 = breast conserving surgery (lumpectomy, wide excision, partial mastectomy, segmental mastectomy or quadrantectomy) 2 = total mastectomy without axillary lymph node dissection 3 = modified radical mastectomy (simple mastectomy + lymph node dissection) 4 = radical mastectomy (includes pectoral muscle dissection)
Was the breast cancer treated with RADIATION?	**0 = no 1 = yes 9 = unknown** If yes, what was the start date? __ __/__ __/__ __ __ __
Was the breast cancer treated with CHEMOTHERAPY? **0 = no 1 = yes 9 = unknown**	If yes, what was the start date? __ __/__ __/__ __ __ __ What were the agents? _____ _____ _____ _____ _____ _____
Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY? **0 = no 1 = yes 9 = unknown**	If yes, what was the start date? __ __/__ __/__ __ __ __ What were the agents? _____ _____ _____ _____
Was **tamoxifen** given? **0 = no 1 = yes 9 = unknown**	When was it started? __ __/__ __/__ __ __ __ For what duration was it administered? _____

RESPONSE and FOLLOW-UP

Did cancer recur or spread (local or distant progression)? 0=no 1=yes 9=unknown If yes, When was it 1st noted? __ __ / __ __ / __ __ __ __ To where? _____ What was the diagnosis of recurrence/progression based on 1=pathology 2=clinical 3=both 9=not stated?
Did the patient develop one or more subsequent primary (new) breast cancers? 0=no 1=yes Histopathologic dx? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes Histopathologic dx? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes Histopathologic dx? _____ Date? __ __ / __ __ / __ __ __ __
Did the patient develop other types of primary cancer? 0=no 1=yes Type of cancer? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes Type of cancer? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes Type of cancer? _____ Date? __ __ / __ __ / __ __ __ __
Do the records indicate that the patients died? 0=no 1=yes If yes, what was the death date? __ __ / __ __ / __ __ __ __ If patient died, were causes of death described? 0 = no 1 = yes If yes, what were the causes of death? _____ _____ _____ _____
If the patient was alive at last contact, what was the date of the last contact? __ __ / __ __ / __ __ __ __

ALCOHOL USE (documented 5 years before to 3 years after diagnosis)

Regarding ALCOHOL consumption the records indicate the following:				
0 = Abstained from alcohol / No consumption 1 = Mild use (past or present) 2 = Moderate use (past or present) 3 = Past heavy use	Date	Date	Date	Date
4 = Current heavy use 5 = Heavy use, not otherwise specified 7 = Alcohol was consumed by not quantified 8 = record shows Ø 9 = No alcohol data were available	Code #	Code #	Code #	Code #

MARIJUANA/CANNIBIS USE (documented 5 years before to 3 years after diagnosis)

Regarding MARIJUANA/CANNIBIS use the records indicate the following:				
0 = Non-user 1 = Past regular use 2 = Current regular use	Date	Date	Date	Date
3 = Both past and current use 8 = record shows Ø 9 = No data were available	Code #	Code #	Code #	Code #

ILLICIT DRUG USE (documented 5 years before to 3 years after diagnosis) (e.g., cocaine, crack, heroin, or non-specified intravenous drugs, etc.)

Regarding ILLICIT DRUG use the records indicate the following:				
0 = Non-user 1 = Past regular use	Date	Date	Date	Date
2 = Current regular use 3 = Both past and current use	Type of drug	Type of drug	Type of drug	Type of drug
8 = record shows Ø 9 = No data were available	Code #	Code #	Code #	Code #

SMOKING HISTORY

Cigarette smoking data was available in the records (documented 5 years before to 3 years after diagnosis) 0=no 1=yes **?**

If yes, complete for each recording of smoking history that occurs on a different day or in a different record, even if the data appear redundant.

DATE	**Ø** smoking	**SMOKER** 0=Never 1=Ever	**SMOKER** 0=Never Smoker 2=Past Smoker 3=Current Smoker	**QUIT HOW LONG AGO?** (in years, use decimals if needed)	**INTENSITY** cigarettes/ day	**C. INTENSITY** packs/day	**D. DURATION** # of years smoked	**C x D = PACK-YEARS SMOKED**
__/__/_____								
__/__/_____								
__/__/_____								
__/__/_____								
__/__/_____								
__/__/_____								
__/__/_____								
__/__/_____								

COMORBIDITIES

Please record all of the comorbidities that the records indicate that the patient has had that are reported in the patients records from 3 years prior to diagnosis to 6 months following diagnosis or up until the first treatment, which ever comes first. The comorbidity did not have to have started during this period, it just needed to be documented in the medical records during this time period. As a default all conditions are coded 0, indicating not present. Column A provides a location to mark broader categories of comorbidity and Column B provides a site to mark more specific categories of comorbidities. Please provide as detailed information as possible, identifying (circling) comorbidities in both Columns A and B where possible.

The following systems are listed in the table below in alphabetical order:

CARDIOVASCULAR
ENDOCRINE, METABOLIC & NUTRITIONAL
- **Endocrine**
- **Water, Electrolyte, Mineral & Acid-Base Metabolism**
- **Nutritional Disorders**

GASTROINTESTINAL (descending anatomic order)
GENITOURINARY TRACT
HEMATOLOGIC / ONCOLOGIC
IMMUNOLOGIC
INFECTIONS
MUSCULOSKELETAL / CONNECTIVE TISSUE
NEUROPSYCHIATRIC & SENSORY
RESPIRATORY

- **Using the table below to document the patients comorbidities.**

CARDIOVASCULAR	
Aneurysm	
Arrhythmia	
Cardiac Arrest	
Cerebrovascular Disease (Stroke)	Cerebrovascular accident (CVA) Transient ischemic attack Plegia associated with CVA
Congestive Heart Failure	
Heart Disease /Coronary Artery Disease	Myocardial Infarct Angina Coronary Artery Bypass Graft (CABG) Angioplasty (PCTA)
Hypertension	Provide representative systolic/diastolic readings _____ Essential (primary) hypertension Secondary (renal) hypertension
Peripheral Vascular Disease	Deep vein thrombosis / Thrombophlebitis Giant cell arteritis
Pulmonary Embolism	
Valve Disease	
Other Heart	Specify: _____
ENDOCRINE, METABOLIC & NUTRITIONAL	
Endocrine	
Diabetes mellitus mild	
Diabetes mellitus Insulin-dependent	
Diabetes mellitus with end organ damage	(Nonketotic Hyperglycemic-Hyperosmolar Coma)
Diabetic Ketoacidosis	
Alcoholic Ketoacidosis	
Hyperglycemia	
Hypoglycemia	
Pituitary Disorders	**Anterior Lobe**: Hypopituitarism, Hypersecretion (Giantism & Acromegaly, Galactorrhea); **Posterior Lobe**: Diabetes insipidus (place in renal disease)
Thyroid Disorders	Hyperthyroidism Hypothyroidism Thyroiditis
Adrenal Disease	Hypofunction: Addison's disease; Hyperfunction: Adrenal virilism, Cushing's syndrome; Hyperaldosteronism Pheochromocytoma (chromaffin cells)
Parathyroid Gland	Hypoparathyroidism (see Hypocalcemia) Hyperparathyroidism (see Hypercalcemia)
Multiple Endocrine Neoplasia (MEN) Syndromes	
Polyglandular Deficiency Syndromes	
Amyloidosis	
Lipid problems	Hypercholesterolemia Hyperglyceridemia Other Hyperlipemia / Hyperlipoproteinemia
Other endocrine _____	
Water, Electrolyte, Mineral & Acid-Base Metabolism	
Disorders of Water & Na	Extracellular Fluid Volume Contraction Dehydration Extracellular Fluid Volume Expansion Hyponatremia Hypernatremia= plasma [Na]>145mEq/L)

Disorders of Potassium Metabolism:	Hypokalemia = serum [K] <3.5 mEq/L, hyperkalemia = serum [K] >5.5 mEq/L or plasma > 5.0.
Disorders of Calcium Metabolism	Hypocalcemia = total plasma [Ca] <8.8mg/dL (2.20 mmol/L) in presence of normal plasma [protein]. Hypoparathyroidism. Hypercalcemia = total plasma [Ca]> 10.4 mg/dL (2.60 mmol/L)
Disorders of Phosphate Metabolism	Hypophosphatemia = plasma [P] <2.5 mg/dL (0.81 mmol/L) Hyperphosphatemia = plasma [P] > 4.5mg/dL (1.46 mmol/L)
Disorders of Magnesium Metabolism	Hypomagnesemia = plasma [Mg] <1.4 mEq/L (0.70 mmol/L) Hypermagnesemia = plasma [Mg] >2.1 mEq/L (1.05 mmol/L)
Disorders of Acid-Base Metabolism	Metabolic Acidosis / Metabolic Alkalosis Respiratory Acidosis / Respiratory Alkalosis
Nutritional Disorders	
Malnutrition	Starvation Protein-Energy (calorie) Malnutrition Carnitine Deficiency Essential Fatty Acid Deficiency
Vitamin Deficiency, Dependency / Toxicity	**Deficiencies**: A, D, E, K, Thiamine (B1), Riboflavin (B2), Niacin, B6, Biotin, Pantothenic acid, C. **Toxicities**: A, D, E, K, B6,
Mineral Deficiency / Toxicity	Iron, Iodine, Fluorine, Zinc, Chromium, Selenium, Manganese, Molybdenum, Copper,
Obesity	"Eye-ball test" BMI men>27.8, women>27.3
Anorexia	
Other Endocrine, Metabolic, Nutritional	Specify: _____
GASTROINTESTINAL (descending anatomic order)	
Esophageal disease	
Gastroesophageal reflux disease (GERD)	
Gastritis and Ulcer	Gastritis Peptic Ulcer Disease
Liver Disease	Fatty Liver Alcoholic Liver Disease Fibrosis Cirrhosis Hepatitis (acute vs. chronic) Drug-induced Liver Damage Hepatic Granulomas Vascular Lesions
Extra-hepatic Biliary Disorders (Gall Bladder Disease)	Cholelithiasis, Cholecystitis, Choledocholithiasis, Primary Sclerosing Cholangitis, Cholesterolosis of Gallbladder, Diverticulosis of gallbladder.
Pancreatic disease	Acute Pancreatitis Chronic Pancreatitis
Diverticulitis / Diverticulosis / Hiatal hernia	
Gastroenteritis	Infectious Chemical Drug-related
Gastrointestinal Bleeding	
Gastrointestinal Polyps	
Malabsorption Syndromes	
Inflammatory Bowel Diseases	Crohn's Disease Ulcerative Colitis
Functional Bowel Diseases	Irritable Bowel Syndrome
Anorectal Disorders	
Other GIT	Specify: _____
GENITOURINARY TRACT	
Renal Disease	Acute Renal failure

	Chronic Renal Failure Dialysis Nephritis / Nephropathy / Nephrosis / Upper urinary tract, acute vs. chronic; pyelonephritis, glomerulonephritis. Diabetes insipidis (nephrogenic or pituitary gland disorder) Other Kidney: Specify_____
Urinary Tract Disease	Urotlithiasis (stones): Calcium oxalate; uric acid; cystine; struvite = magnesium ammonium phosphate (MAP).
	Lower urinary tract, acute vs. chronic; cystitis, acute vs. chronic; Incontinence
GYNECOLOGIC & OBSTETRICAL	
Menstrual Abnormalities / Abnormal Uterine Bleeding	Primary (Functional) Dysmenorrhea (painful ovulatory cycle) Secondary (Acquired) Dysmenorrhea Amenorrhea Dysfunctional Uterine Bleeding
Premature Ovarian Failure (Premature Menopause) (<40yr)	
Endometriosis	
Uterine Fibroids (leiomyoma; myoma; fibromyoma)	
Pelvic Inflammatory Disease – Infection of the upper female genital tract	Endometritis (uterus) Salpingitis (fallopian tubes) Mucopurulent cervicitis (cervix) Oophoritis (ovaries)
Vulvovaginal Infections	Specify Agent: _____
Other Gynecologic or Obstetrical	Specify: _____
HEMATOLOGIC / ONCOLOGIC	
Anemia	
Electrolyte Imbalance	
Blood Disorders	
Other Hematologic _____	
Cancer	Non-metastatic >10 years ago Non-metastatic 0-10 years ago Metastatic cancer (any time ago)
Other Hematologic / Oncologic	Specify: _____
IMMUNOLOGIC	
Major Immunologic	Systemic lupus erythematosus (SLE) Systemic sclerosis Polymyositis Sarcoidosis
Allergic Reactions to Drugs, Foods, Hay fever, Other.	Specify: _____
Toxicity or Adverse Reactions	Specify: _____
INFECTIONS	
Encephalitis / Meningitis	
HIV / AIDS	
Gastroenteritis	
Sexually Transmitted Disease (STD)	Syphilis
Septicemia	
Tuberculosis (TB)	Active and under current Rx or old, inactive case.
Other Infections _____	Chicken pox, Herpes simplex, Measles, Mononucleosis (mono), Mumps, Poliomyelitis (polio), Shingles zoster, Toxoplasmosis

MUSCULOSKELETAL / CONNECTIVE TISSUE	Arthritis Osteoarthritis/degenerative Joint disease Other Arthritis Inflammatory arthritis Rheumatoid arthritis Polymyalgia rheumatics
Arthritis – Rheumatoid	
Arthritis – Non-Rheumatoid / Non-Immune	
Osteoporosis / Osteopenia	
Adult Fractures	
Amputation	
Other Connective Tissue _____	Specify: _____
NEUROPSYCHIATRIC & SENSORY	
Ophthalmic/ Eye Problems	Cataracts Glaucoma
Hearing problems/ disorder	
Psychiatric Disorders	Depression Paranoid / residual unspecified Schizophrenia Bipolar affective disorder Manic-depressive/unspecified psychosis Paranoia Anxiety states Phobic disorders Unspecified neurotic disorders
Dementia	
Neurologic	Parkinson's disease Multiple sclerosis Amyotropic lateral sclerosis
Migraine headaches	
Seizure / Epilepsy / Convulsions	
Other Neuropsychiatric or Sensory	Specify: _____
RESPIRATORY	
Chronic Obstructive Pulmonary Disease	
Emphysema	
Chronic Bronchitis	
Asthma	
Pneumonia	Recurrent Pneumonia Post-obstructive pneumonia
Pulmonary Fibrosis	Diffuse interstitial / infiltrative / restrictive disease
Other Respiratory _____	

Please list all medications taken by the patient for 3 years prior to the breast cancer diagnosis.
Exclude the oral contraceptives & hormone replacement therapies listed previously.

Medication	Indication if given	Estimate Usage 1 = Short term (< 6 months) 2 = Long term (≥ 6 months) 9 = unknown

ADDITIONAL INFORMATION / SUMMARY

If the chart information was incomplete or otherwise insufficient, check box and specify below. ❑ 01=Yes

Comments:

Record any additional comments about this case: