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13. ABSTRACT *(Maximum 200 Words)*

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.

14. SUBJECT TERMS	15. NUMBER OF PAGES
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Table of Contents

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/ethnic 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 racial/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 a single cutpoint to all patients.

BODY

Year two 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* (Changes from the 2001 annual report are in bold face type.)

	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 28 months	
	Hormone receptor log book data		Computer entry completed
	Medical record abstraction		**815 patients completed (~85%)**
	Construction of computer entry system for record abstracted data		**Microsoft Access database entry forms written**
	Data entry into computer databases		**Records for 114 individuals have been entered**
Task 3	**SES estimates based on 1990 US Census data**	**12 to 28 months**	**Continuing**
Task 4	**Survival Data Collection From**		
	Henry Ford Health System Tumor Registry	**12 to 28 months**	**Initial completed, ongoing**
	SEER	**18 to 28 months**	**Initial completed, ongoing**
	Michigan Death Index	**18 to 28 months**	**Initial completed, ongoing**
Task 5	**Attend breast cancer conference**	**Year two**	**1 Attended / DoD upcoming**

The current study staff consists of the following:

Project Staff
C. Martin Tammemagi – Principal Investigator
Chris Neslund-Dudas – Project Manager
Mary Ellen Frebes – Tumor registrar and quality assurance audits
Jonathon Mitchell- Database manager/programmer
Rick Krajenta – Programmer/ tumor registry data specialist

Medical Record Abstractors (Coordinator Ms. Cheryl Spoutz)
Roseanne Rose
Karen Gerula
Mary Beland
Kay McGlynn

Data Entry
Roseanne Rose
Kim Beney
Joan Broderick
Barbara Harkness

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).

In year two of this study approximately 815 patient records were requested, obtained and abstracted. Incomplete or no records were obtained for 130 individuals after three repeat attempts. We are making vigorous efforts to locate these records.

Ms. Mary Ellen Frebes has joined the study in the last year. She is a certified tumor registrar (National Cancer Registrars Association) with 15 years of experience and is also a RHIT. Her role is to assure the quality of all vital statistics and staging data. She reviews each patient's completed abstract form and verifies all questionable data and

completes incomplete data by accessing data in the Henry Ford Health System (HFHS) Tumor Registry, the Surveillance, Epidemiology and End Results (SEER) Tumor Registry and the Social Security Death Index. Dr. Tammemagi also reviews each completed abstraction form for completeness and consistency. Currently, Dr. Tammemagi is carrying out all statistical analyses.

Jonathon Mitchell, a computer programmer, has written computer data entry forms using Microsoft Access. A representative sampling is presented in Appendix 1. The initial beta version has been tested and upgraded to the mature product in current use. A team of four data entry personnel has been trained. The reliability and accuracy of data entry was evaluated initial and will be re-evaluated at regular intervals. To date, the abstracted data of 114 patients have been entered into the computer database.

The study staff meets biweekly to discuss any issues, problems or concerns. Dr. Tammemagi or Ms. Neslund-Dudas is available to all staff to provide immediate responses to problems as they arise.

All available estrogen and progesterone hormone receptor data for breast cancer patients 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 HFHS Tumor Registry 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 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.

Socioeconomic status (SES) data was estimated for breast cancer patients 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 estimates for approximately 70% of individuals, which is below what we have obtained in several past studies. We are currently assessing updated versions of MapMarker® and MapInfo® geocoding programs useful in providing census-based aggregate estimates of SES. It is anticipated that these programs will provide more complete data as well as a wider range of SES estimators.

We are on track to having all data collection and clean up completed by fall of 2002, whence analysis will begin. Statistical analysis, writing of manuscripts and dissemination of study results are expected to be completed by the end of the third study year, as planned.

This year Dr. Tammemagi attended and presented the following:

Tammemagi CM, C. Neslund-Dudas, M. Simoff, P. Kvale. Comorbidity explains some of the race difference in lung cancer survival. National Institutes of Health / American Cancer Society's Cancer Survivorship: Resilience across the lifespan. June 2, 2002, Washington, D.C.

Although these findings concerns lung cancer survival, they deal with a topic pertinent to the current study of racial/ethnic differences in breast cancer survival. Valid survival studies must take into consideration the effects of important prognostic factors in addition to the one under study. We have recently shown that comorbidity is the third most important predictor of survival in lung cancer patients, following stage and treatment, and it in part explains some of the racial/ethnic difference in lung cancer survival (Appendix 2). We have augmented the data collection procedures for this study to include comorbidity data to make possible assessment and adjustment for comorbidity (Appendix 3).

Dr. Tammemagi will be attending the Era of Hope meeting in September 2002.

KEY RESEARCH ACCOMPLISHMENTS: NA.

REPORTABLE OUTCOMES: NA.

CONCLUSIONS

It is too early into the study to draw any substantive or methodologic conclusions.

APPENDIX 1. Sample of Computer Database Entry Forms (Microsoft Access)

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID [redacted]

ADDITIONAL INFORMATION/SUMMARY

If the chart information was incomplete or insufficient, choose 'Yes' and specify below [ ] *0 = Nul 1 = Yes*

Comments

What is the date on the first record for this patient (not limited to the abstraction period) 04/19/1982

In the 5 years prior to diagnosis, for how many years were records abstracted 4

In the 5 years prior to diagnosis, for how many months were records abstacted 7

If the records in the last 5 years had a gap > 2 years, was it becuase the patient:

Was healthy and did not need to see a doctor? [ ] *0 = Nul 1 = Yes*

Was being seen elsewhere? [ ] *0 = Nul 1 = Yes*

Don't know the reason? [ ] *0 = Nul 1 = Yes*

What is the date on the last record for this patient (not limited to the abstraction pelord) 12/14/1990

In the 3 years post diagnosis, for how many years were records abstracted 2

In the 3 years post diagnosis, for how many months were records abstracted 7

Record any additional comments about this case:

THIS CHART IS A "RE-DO" OF THE ORIGINAL, DONE IN 10/01. SOME DATE DISCREPANCIES WERE NOTED ON THE ORIGINAL - CHART WAS REORDERED AND RE-REVIEWED.

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID [redacted]

ADDITIONAL INFORMATION/SUMMARY

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID [redacted]

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/mth) 1 = Mild use (past or present) (1-13 drinks/month) 2 = Moderate use (past or present) (4-14 drinks/wk) 3 = Past heavy use (>14 drinks/wk) 4 = Current heavy use (>14 drinks/wk) 5 = Heavy use, not otherwise specified (>14 drinks/wk) 7 = Alcohol was consumed by not quantified 8 = record shows "0" 9 = No alcohol data were available	Date: 09/20/1982 Code # 7	Date: Code #	Date: Code #	Date: Code #
	Date: Code #	Date: Code #	Date: Code #	Date: Code #

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID [redacted]

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

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID [redacted]

(4) DISEASES OF THE BLOOD AND BLOOD-FORMING ORGANS (ICD 280-289)

CM59-Deficiency and other or unspecified anemi		*0 = No, 1 = Yes*
CM60-Acute post-hemorrhagic anemi		*0 = No, 1 = Yes*
CM61-Sickle cell anemia		*0 = No, 1 = Yes*
CM62-Coagulation and hemorrhagic disorder		*0 = No, 1 = Yes*
CM63-Diseases of white blood cell		*0 = No, 1 = Yes*
CM64-Other hematologic conditions, including spleen disorder		*0 = No, 1 = Yes*

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 002[redacted]

BODY SIZE INFORMATION (exclude data during pregnancy)

Maximum Height (inches)		Date:	
Pre-diagnosis weight closest to diagnosis date (pounds)		Date:	

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03673810

PATIENT HISTORY OF BREAST LESIONS BEFORE THE INDEX BREAST CANCER

Breast Biopsy History throughout patient records [9] 0 = No 1 = Yes 9 = Unknown

If yes, complete table below:

Dates:	Results (specify L/R)		
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right
			Specify Left or Right

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

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 2425377

CASE DESCRIPTION AND EPIDEMIOLOGIC DATA

CONFIRMATION OF CASE STATUS

Is there evidence in the chart that the patient was diagnosed with 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 [ ] 0 = No, 1 = Yes

If Yes, record original JFCC diagnosis date here: [ ]

If No, do alternative breast cancer diagnosis dates exist? [ ] 0 = No, 1 = Yes

Alternative diagnosis date1 [ ]

Alternative diagnosis date2 [ ]

Alternative diagnosis date3 [ ]

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

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03673810

(7) DISEASES OF THE CIRCULATORY SYSTEM (ICD 390-459)

CM96-Heart valve disorders [ ] *0 = No, 1 = Yes*

CM97-Peri-, endo-, and myocarditis, cardiomyopathy (except that caused by tuberculosis or ST [ ] *0 = No, 1 = Yes*

CM98-Essential hypertensio [1] *0 = No, 1 = Yes*

CM99-Hypertension with complications and secondary hypertensio [ ] *0 = No, 1 = Yes* CM99-If yes, specify [ ]

CM100-Myocardial infractio [ ] *0 = No, 1 = Yes* CM100-How long ago was most recent MI? - years [ ]

CM100-How long ago was most recent MI? - months [ ]

CM101-Coronary atherosclerosis and other heart diseas [ ] *0 = No, 1 = Yes*

CM102-Angina (non-specific or non-angina chest pain is coded under #322 [ ] *0 = No, 1 = Yes*

CM103-Pulmonary heart disease (cor pulmonal [ ] *0 = No, 1 = Yes*

CM104-Other or ill-defined heart diseas [ ] *0 = No, 1 = Yes*

CM105-Conduction disorder [ ] *0 = No, 1 = Yes*

CM106-Cardiac dysrhythmias/ arrhythmia [ ] *0 = No, 1 = Yes*

CM107-Cardiac arrest or ventricular fibrillatio [ ] *0 = No, 1 = Yes*

CM108-Congestive heart failur [ ] *0 = No, 1 = Yes*

CM109-Acute cerebrovascular disease [ ] *0 = No, 1 = Yes*

CM110-Occlusion or stenosis of precerebral arterie [ ] *0 = No, 1 = Yes*

CM111-Other and ill-defined cerebrovascular diseas [ ] *0 = No, 1 = Yes*

CM112-Transient cerebral ischemi [ ] *0 = No, 1 = Yes*

CM113-Late effects of cerebrovascular disease, i.e., plegia or hemiplegi [ ] *0 = No, 1 = Yes*

CM114-Peripheral and visceral atherosclerosi [ ] *0 = No, 1 = Yes*

CM115-Aortic, peripheral, visceral artery aneurysm [ ] *0 = No, 1 = Yes*

CM115B-Aortic, peripheral, visceral artery aneurysms - If yes, where was it locate [ ]

CM115C-Aortic, peripheral, visceral artery aneurysms - What was its size? ___ c [ ]

CM115D-Aortic, peripheral, visceral artery neourysms - Was it surgically corrected [ ] *0 = No, 1 = Yes*

CM116-Aortic and peripheral arterial embolism or thrombo [ ] *0 = No, 1 = Yes*

CM117-Other circulatory disease, including hypertensio [ ] *0 = No, 1 = Yes*

CM118-Phlebitis, thrombophlebitis and thromboembolis [ ] *0 = No, 1 = Yes*

CM119-Varicose veins of lower extremit [ ] *0 = No, 1 = Yes*

CM120-Hemorrhoid [ ] *0 = No, 1 = Yes*

CM121-Other diseases of veins and lymphatic [ ] *0 = No, 1 = Yes*

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03673810

Diagnosis date month 11 Diagnosis date year 1986 Initials HZ Last 3-digits of MRN 810

COMORBIDITIES

Please document all the commorbiditie **(Indicate Yes"=1")** that the patient had a history of in their record from 3 years prior to diagnosis to 6 months following diagnosis or until the first treatment, which ever
regardless of when comorbidities actually occurred. The commorbidity did not have to have been present during this period, it just needed to be documented in the medical records during this time period.
If any information is given as t **when the commorbidity or sign/symptom was diagnosed or occured** and its duration, please write it down beside its listing on the abstraction form.

For **diagnosis/occurrence,** please specify the year or date.

For **duration** please specify the number of years/months.

The systems are listed in the following order:

(1) Infectious and Parasitic Diseases		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(2) Previous Neoplasms		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(3) Endocrine, Nutrional/Metabolic Diseases, Immunity Disorders		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(4) Diseases of the Blood and Blood-Forming Organs		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(5) Mental Disorders		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(6) Diseases of the Nervous System Sense Organs		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(7) Diseases of the Circulatory System		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(8) Diseases of the Respiratory System		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(9) Diseases of the Digestive System		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(10) Diseases of the Genitourinary System		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(11) Complications of Pregnancy, Childbirth, and the PuerPerium		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(12) Diseases of the Skin and Subcutaneous Tissue		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(13) Diseases of Musculoskeletal and Connective Tissue		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(14) Congenital Anomalies		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month
(15) Certain Conditions Originating in the Perinatal Period		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and months
(16) Injury/Trauma Poisoning		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and months
(17) Symptoms and Signs of the index cancer, and ILL-DEFINED CONDITIONS		0 = Null 1 = Yes	Diagnosis/Occurrence-Date and year	Duration-years and month

StudyID 03673810

(14) CONGENITAL ANOMALIES (ICD 740-759)

CM213-Cardiac and circulatory anomalie		*0 = No, 1 = Yes*
CM214-Digestive congenital anomalie		*0 = No, 1 = Yes*
CM215-Genitourinary congenital anomalie		*0 = No, 1 = Yes*
CM216-Nervous system congenital anomalie		*0 = No, 1 = Yes*
CM217-Other congenital anomalie		*0 = No, 1 = Yes*

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03673810

(9) DISEASES OF THE DIGESTIVE SYSTEM (ICD 520-579)

CM135-Intestinal infectio [ ] *0 = No, 1 = Yes*

CM136-Disorders of teeth and ja [ ] *0 = No, 1 = Yes*

CM137-Diseases of mouth, excluding denta [ ] *0 = No, 1 = Yes*

CM138-Esophageal disorder [ ] *0 = No, 1 = Yes*

CM139-Gastroduodenal ulcer (except hemorrhage [ ] *0 = No, 1 = Yes*

CM140-Gastritis and duodeniti [ ] *0 = No, 1 = Yes*

CM141-Other disorders of stomach and duodenu [ ] *0 = No, 1 = Yes*

CM142-Appendicitis and other appendiceal conditions [ ] *0 = No, 1 = Yes*

CM143-Abdominal herni [ ] *0 = No, 1 = Yes*

CM143-If yes, was it accompanied by obstruction or gangrene? [ ] *0 = No, 1 = Yes*

CM144-Regional enteritis and ulcerative colitis, including inflammatory bowel diseases, such as Crohn's disease ulcerative colitis [ ] *0 = No, 1 = Yes*

CM145-Intestinal obstruction without hernia, e.g., paralytic ileus, impaction, adhesion [ ] *0 = No, 1 = Yes*

CM145-If yes, specify [ ]

CM146-Diverticulosis and diverticuliti [ ] *0 = No, 1 = Yes*

CM147-Anal and rectal conditions [ ] *0 = No, 1 = Yes*

CM148-Peritonitis and intestinal absces [ ] *0 = No, 1 = Yes*

CM149-Biliary tract disease, e.g., cholecystitis, cholelithiasisi [ ] *0 = No, 1 = Yes*

CM150-Liver disease, alcohol-relate [ ] *0 = No, 1 = Yes*

CM151-Other liver diseases, e.g., liver disease or cirrhosis without mention of alcohol, liver abscess, ascit [ ] *0 = No, 1 = Yes*

CM152-Pancreatic disorders (not diabetes [ ] *0 = No, 1 = Yes*

CM153-Gastrointestinal hemorrhag [ ] *0 = No, 1 = Yes*

CM153-If yes, specify: [ ]

CM154-Noninfectious gastroenteriti [ ] *0 = No, 1 = Yes*

CM155-Other gastrointestinal disorders, e.g., constipation, dysphagi [ ] *0 = No, 1 = Yes*

CM155-If yes, specify: [ ]

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03673810

(1) INFECTIOUS AND PARASITIC DISEASES (ICD 001-139) **No = 0 the default, YES = 1**

CM1 Tuberculosis *No = 0, Yes =1* Is this a recent infection (< 3 years old) or an active infection under treatment? *No = 0, Yes =1*

CM2 Septicemia (except in labor) *No = 0, Yes =1*

CM3 Bacterial infection, unspecified site *No = 0, Yes =1*

CM4 Mycoses *No = 0, Yes =1*

CM5 HIV infection/AIDS *No = 0, Yes =1*

CM6 Hepatitis (infectious, not primarily alcohol-related, see #150) *No = 0, Yes =1* Hepatitis virus: A,B,C,D,E,G, or othe *0=A, 1=B, 2=C, 3=D, 4=E, 5=G, 6=Other*

CM7 Viral infection (not hepatitis) *No = 0, Yes =1*

CM8 Other infections, including parasitic *No = 0, Yes =1*

CM9 Sexually transmitted infections = STD (not HIV or hepatitis) *No = 0, Yes =1*

CM10 Immunizations and screening for infectious disease *No = 0, Yes =1* If yes, specify immunizatio

CM248 Gangrene *No = 0, Yes =1*

Back Next

StudyID 03673810

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 why it was given	Estimate usage 1 = Short term (< 6 months) 2 = Long term (>= 6 months) 9 = unknown
ALDACTAZIDE	HTN	2
ZYLOPRIM	9	2
NALFON	KNEE PAIN	1
CLINORIL	BURSITIS	9
NAPROSYN	JOINT PAIN	1

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03673810

(15) CERTAIN CONDITIONS ORIGINATING IN THE PERINATAL PERIOD (ICD 760-779)

CM218-Liveborn		*0 = No, 1 = Yes*
CM219-Short gestation, low birth weight, and fetal growth retardatio		*0 = No, 1 = Yes*
CM220-Intrauterine hypoxia and birth asphyxi		*0 = No, 1 = Yes*
CM221-Respiratory distress syndrom		*0 = No, 1 = Yes*
CM222-Hemolytic jaundice and perinatal jaundic		*0 = No, 1 = Yes*
CM223-Birth traum		*0 = No, 1 = Yes*
CM224-Other perinatal condition		*0 = No, 1 = Yes*

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID [redacted]

(8) DISEASES OF THE RESPIRATORY SYSTEM (ICD 460-519)

CM122-Pneumonia (except that caused by tuberculosis or sexually transmitted diseas [ ] *0 = No, 1 = Yes*

CM123-Influenza [ ] *0 = No, 1 = Yes*

CM124-Acute and chronic tonsilitis [ ] *0 = No, 1 = Yes*

CM125-Acute bronchitis [ ] *0 = No, 1 = Yes*

CM126-Other upper respiratory infection [ ] *0 = No, 1 = Yes* CM126-If yes, specify: [ ]

CM127-Chronic obstructive pulmonary disease bronchiectasi [ ] *0 = No, 1 = Yes*

- CM127B-COPD otherwise not specifie [ ] *0 = No, 1 = Yes*
- CM127C-Emphysem [ ] *0 = No, 1 = Yes*
- CM127D-Chronic bronchiti [ ] *0 = No, 1 = Yes*
- CM127E-Bronchiectasis [ ] *0 = No, 1 = Yes*

CM128-Asthm [ ] *0 = No, 1 = Yes*

CM304-Pulmonary fibrosis/intestinal lung disease [ ] *0 = No, 1 = Yes*

CM129-Aspiration pneumonitis, food/vomitu [ ] *0 = No, 1 = Yes*

CM130-Pleurisy, pneumothorax, pulmonary collapse (atelectasi [ ] *0 = No, 1 = Yes*

CM131-Respiratory failure, insufficiency, arrest (adul [ ] *0 = No, 1 = Yes*

CM132-Lung Disease due to external agents, including pneumoconioses, e.g., anthracosis, silicosis, asbestosis, berylliosis, siderosis, stannosis, barito [ ] *0 = No, 1 = Yes*

CM133-Other lower respiratory diseas [ ] *0 = No, 1 = Yes*

CM134-Other upper respiratory diseas [ ] *0 = No, 1 = Yes*

Back Next

JFCC - Hormone Receptors & Breast Cancer Survival

Abstraction Form, V. Feb. 27, 2002

StudyID 03679810

(12) DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE (ICD 680-709)

CM197-Skin and subcutaneous tissue infections, e.g., cellulitis or abscess		*0 = No, 1 = Yes*
CM198-Other inflammatory condition of ski		*0 = No, 1 = Yes*
CM199-Chronic ulcer of skin		*0 = No, 1 = Yes*
CM200-Other skin disorder		*0 = No, 1 = Yes*

Back Next

APPENDIX 2.

Comorbidity Explains Some of the Race Difference in Lung Cancer Survival

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BACKGROUND

Lung cancer, the commonest cause of cancer death in North America, generally has a grave prognosis, which is worse in Blacks compared to Whites. The purpose of this study was to determine whether comorbidity explains some of the race difference in survival.

METHODS

A historical cohort study was carried out of 1155 lung cancer patients diagnosed at the Henry Ford Health System (HFHS) between 1995 and 1998. Sociodemographic, exposure, clinicopathologic, treatment and survival data were collected by abstraction of medical records and from the HFHS Tumor Registry. Fifty-six comorbidities were studied.

RESULTS

19 comorbidities were associated with survival: HIV/AIDS, tuberculosis, previous metastatic cancer, thyroid/glandular diseases, electrolyte imbalance, anemia, other blood diseases, dementia, neurologic disease, congestive heart failure, chronic obstructive pulmonary disease, asthma, pulmonary fibrosis, liver disease, gastrointestinal bleeding, renal disease, connective tissue disease, osteoporosis and peripheral vascular disease. Only the latter was protective. The occurrence of at least one of the 18 deleterious comorbidities occurred in 64.0% of women and 59.9% of men ($p = 0.16$), and 65.4% of Blacks and 59.0% of Whites ($p = 0.03$). The unadjusted hazard ratio for race (Black vs. White) was 1.203 (95% CI 1.05-1.38, $p = 0.008$) and adjusted for all 19 predictive comorbidities was 1.156 (95% CI 1.00-1.33, $p = 0.05$), a decline of 23.1%.

CONCLUSION

The higher prevalence of deleterious comorbidities in Blacks explains some of their overall poorer lung cancer survival.

APPENDIX 3. Revised 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 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)

Name Last:_____ **First:** _____ **Middle Initial:** _____

Address at diagnosis: Street Address _____

City State ZIP Code _____ _____ _____

Current address, if different from diagnosis address

Street Address _____ _____ _____

City State ZIP Code _____ _____ _____

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: __ __ / __ __ / __ __ __ __

Pre-diagnosis weight closest to **diagnosis date** (pounds): _____ Date: __ __ / __ __ / __ __ __ __

REPRODUCTIVE / ENDOCRINE HISTORY (Mark NA if data are not available)

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 <u>hormone contraceptives</u>? 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 <u>hormone replacement therapy</u>? 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
4=Other

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

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

FAMILY HISTORY OF BREAST CANCER

Is there a family history of breast cancer? (BRCA)

1= Yes, there is a noted family history
2= No, there is a noted negative family history of BRCA
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: Left	Results: Right
1.	__/__/____		
2.	__/__/____		
3.	__/__/____		
4.	__/__/____		
5.	__/__/____		
6.	__/__/____		
7.	__/__/____		
8.	__/__/____		
9.	__/__/____		
10.	__/__/____		
11.	__/__/____		
12.	__/__/____		
13.	__/__/____		
14.	__/__/____		
15.	__/__/____		

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** (specify L/R)
__/__/____	
__/__/____	
__/__/____	
__/__/____	
__/__/____	
__/__/____	
__/__/____	
__/__/____	
__/__/____	

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 (mths)
❑	❑	❑	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	L	R	Unk	Results
(Indicate all that apply for each breast.)	❑	❑	❑	01= Atypical hyperplasia
	❑	❑	❑	02= Ductal hyperplasia
Date of procedure: __ __ / __ __ / __ __ __ __	❑	❑	❑	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
Photocopy report masking patient identifiers	❑	❑	❑	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	L	R	Unk	Results
(Indicate all that apply for each breast.)	❑	❑	❑	01= Atypical hyperplasia
	❑	❑	❑	02= Ductal hyperplasia
Date of procedure: __ __ / __ __ / __ __ __ __	❑	❑	❑	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
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	❑	❑	❑	18= Invasive cancer, NOS
	❑	❑	❑	19= Cystosarcoma phyllodes
	❑	❑	❑	88= Other, *specify:*_____
	❑	❑	❑	99= Undetermined

STAGING (Please flag any conflicting pathology, staging, treatment or follow-up data, & discuss with investigators)

	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 ❒ Multifocal
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) # LN positive _____ # LN tested _____	❒ 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 LNs, >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	❒ GX= cannot be assessed ❒ G1= well differentiated ❒ G2= moderately differentiated, ❒ G3= poorly differentiated ❒ G4= Undifferentiated ❒ G9 = Unknown

TREATMENT

Did the patient receive 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) 5 = lumpectomy +/- node removal
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? (other than tamoxifen) **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? _____

Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY <u>other than tamoxifen</u>? **0 = no 1 = yes** If yes, what was the start date? __ __/__ __/__ __ __ __

If yes, which of the following apply? (If no mention is made assume the default of "0")

Ovarian ablation by surgery No = 0 Yes = 1

Ovarian ablation by radiation No = 0 Yes = 1

Luteinizing-releasing hormone antagonist No = 0 Yes = 1

Progestins (eg. megesterol acetate or medroxyprogesterone acetate) No = 0 Yes = 1

Estrogens No = 0 Yes = 1

Androgens No = 0 Yes = 1

Adrenalectomy No = 0 Yes = 1

Hypophysectomy No = 0 Yes = 1

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 9= unknown If yes, Histopathologic dx? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes 9= unknown If yes, Histopathologic dx? _____ Date? __ __ / __ __ / __ __ __ __
Did the patient develop other types of primary cancer? 0=no 1=yes 9= unknown If yes, type of cancer? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes 9= unknown If yes, type of cancer? _____ Date? __ __ / __ __ / __ __ __ __
Did the patient develop another type of cancer, but unknown if it is 2nd primary or metastasis? 0=no 1=yes 9= unknown If yes, type of cancer? _____ Date? __ __ / __ __ / __ __ __ __ 0=no 1=yes 9= unknown If 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/mth) 1 = Mild use (past or present) (1-13 drinks/month) 2 = Moderate use (past or present) (4-14 drinks/wk) 3 = Past heavy use (>14 drinks/wk)	Date	Date	Date	Date
4 = Current heavy use (>14 drinks/wk) 5 = Heavy use, not otherwise specified (>14 drinks/wk) 7 = Alcohol was consumed by not quantified 8 = record shows "Ø" 9 = No alcohol data were available	Code #	Code #	Code #	Code #

Drinks/time is a guideline. Drink ~ 1 bottle beer ~ 1 glass wine ~ 1 shot of liquor

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 were 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.

If smoking data were not available for the specified time period, then use available smoking data from any time period.

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**
__/__/____								
__/__/____								
__/__/____								
__/__/____								
__/__/____								
__/__/____								
__/__/____								
__/__/____								
__/__/____								
__/__/____								

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 why it was 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 insufficient, check box and specify below. ❑ 01=Yes

Comments:

What is the date on the first record for this patient (not limited to the abstraction period)? __/__/__

In the 5 years prior to diagnosis, for how many years/months were records abstracted yrs __ mths __

If the records in the last 5 years had a gap > 2 year, was it because the patient

Was healthy and did not need to see a doctor? 1 = yes (circle 1 if appropriate)

Was being seen elsewhere? 1 = yes

Don't know the reason 1 = yes

What is the date on the last record for this patient (not limited to the abstraction period)? __/__/__

In the 3 years post diagnosis, for how many years/months were records abstracted yrs __ mths __

Record any additional comments about this case:

COMORBIDITIES

Please document all of the comorbidities (**Circle and indicate Yes "= 1"**) that the patient had a history of in their records from 3 years prior to diagnosis to 6 months following diagnosis or until the first treatment, which ever comes first, regardless of when the comorbidities actually occurred. The comorbidity did not have to have been present during this period, it just needed to be documented in the medical records during this time period. If any information is given as to **when the comorbidity or sign/symptom was diagnosed or occurred** and its duration, please write it down beside its listing on the abstraction form.

For **diagnosis/occurrence**, please specify the year or date.

For **duration**, please specify the number of years/months.

The systems are listed in the following order:

(1) INFECTIOUS AND PARASITIC DISEASES

(2) PREVIOUS NEOPLASMS

(3) ENDOCRINE, NUTRITIONAL/METABOLIC DISEASES, & IMMUNITY DISORDERS

(4) DISEASES OF THE BLOOD AND BLOOD-FORMING ORGANS

(5) MENTAL DISORDERS

(6) DISEASES OF THE NERVOUS SYSTEM & SENSE ORGANS

(7) DISEASES OF THE CIRCULATORY SYSTEM

(8) DISEASES OF THE RESPIRATORY SYSTEM

(9) DISEASES OF THE DIGESTIVE SYSTEM

(10) DISEASES OF THE GENITOURINARY SYSTEM

(11) COMPLICATIONS OF PREGNANCY, CHILDBIRTH, AND THE PUERPERIUM

(12) DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE

(13) DISEASES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE

(14) CONGENITAL ANOMALIES

(15) CERTAIN CONDITIONS ORIGINATING IN THE PERINATAL PERIOD

(16) INJURY / TRAUMA & POISONING

(17) SYMPTOMS & SIGNS of the index cancer, & ILL-DEFINED CONDITIONS

(1) INFECTIOUS AND PARASITIC DISEASES (ICD 001-139) No = 0 the default, YES = 1

CM1 **Tuberculosis** Is this a recent infection (< 3 years old) or an active infection under treatment? Yes / No
CM2 **Septicemia** (except in labor)
CM3 **Bacterial infection**, unspecified site
CM4 **Mycoses**
CM5 **HIV infection / AIDS**
CM6 **Hepatitis** (infectious, not primarily alcohol-related, see #150) *Circle*: Hepatitis virus A, B, C, D, E, G, or other.
CM7 **Viral infection** (not hepatitis)
CM8 **Other infections, including parasitic**
CM9 **Sexually transmitted infections** = STD (not HIV or hepatitis)
CM10 **(Immunizations and screening for infectious disease,** If yes, specify _____)
CM248 **Gangrene**

(2) PREVIOUS NEOPLASMS (ICD 140-239)

Cancer (CA) of	A. Present No=0, Yes=1	B. Metastasis No=0, Yes=1	C. Stage	D. Histology	E. Yr of diagnosis
CM11 Head & neck					
CM12 Esophagus					
CM13 Stomach					
CM14 Colon					
CM15 Rectum & anus					
CM16 Liver & intrahepatic bile duct					
CM17 Pancreas					
CM18 Other gastrointestinal organs, peritoneum					
CM19 Bronchus, lung					
CM20 Other respiratory & intra-thoracic					
CM21 Bone & connective tissue					
CM22 Melanomas of skin					
CM23 Other non-epithelial cancer of skin					
CM24 Breast					
CM25 Uterus					
CM26 Cervix					
CM27 Ovary					
CM28 Other female genital organs					
CM29 Prostate					
CM30 Testis					
CM31 Other male genital organs					
CM32 Bladder					
CM33 Kidney and renal pelvis					
CM34 Other urinary organs					
CM35 Brain and nervous system					
CM36 Thyroid					
CM37 Hodgkin's disease					
CM38 Non-Hodgkin's lymphoma					
CM39 Leukemias					
CM40 Multiple myeloma					
CM41 Other and unspecified primary					
CM42 Secondary malignancies					
CM43 Malignant neoplasm, unspecified site					
CM44 CA, unspecified/uncertain nature or behavior					
CM45 Maintenance chemotherapy, radiotherapy		N/A	N/A	N/A	N/A
CM46 Benign neoplasm of uterus, i.e., fibroids (leiomyoma; myoma; fibromyoma)		N/A	N/A		
CM47 Other and unspecified benign neoplasm		N/A	N/A		

(3) ENDOCRINE, NUTRITIONAL/METABOLIC DISEASES, & IMMUNITY DISORDERS (ICD 240-279)

CM48 **Thyroid disorders** e.g., goiter, hyperthyroidism, hypothyroidism, thyroiditis. If yes, specify _____

CM49 **Diabetes mellitus without complication.** If yes, is it insulin-dependent? Yes / No

CM50 **Diabetes mellitus with complications.** If yes, specify, e.g., ketoacidosis or uncontrolled diabetes, renal, ophthalmic, neurologic, circulatory, or other/unspecified complications. _____
If yes, is it insulin-dependent? Yes / No

CM51 **Other endocrine disorders**, e.g., parathyroid, pituitary and its hypothalamic control, adrenal or polyglandular disorders, premature ovarian failure (menopause <40years). If yes, specify _____

CM301 **Obesity / hyperalimentation** documented by physician/clinician/nurse in medical records

CM52 **Nutritional deficiencies (specific).** If yes, specify _____

CM52B **Under-nutrition/malnutrition** (general/unspecified)

CM53 **Disorders of lipid metabolism**, e.g., hypercholesterolemia, hyperlipidemia. If yes, specify _____

CM54 **Gout and other crystal arthropathies, If yes, which of the following apply?**

- **CM54B** Gout, mild or not further specified
- **CM54C** Gout with nephropathy
- **CM54D** Gout with other specific manifestations
- **CM54E** Other crystal arthropathy

CM55 **Fluid and electrolyte metabolic disorders**, If yes, please specify on table below (Circle and indicate Yes = 1)

Water balance	**CM55B Dehydration**	**CM55C Over-hydration**
Extracellular fluid volume	**CM55D Contraction**	**CM55E Expansion / Overload**
Sodium (Na)	**CM55F Hyponatremia**	**CM55G Hypernatremia**
Potassium (K)	**CM55H Hypokalemia (hypopotassemia)**	**CM55I Hyperkalemia (hyperpotassemia)**
Calcium (Ca)	**CM55J Hypocalcemia**	**CM55K Hypercalcemia**
Phosphate (P)	**CM55L Hypophosphatemia**	**CM55M Hyperphosphatemia**
Magnesium (Mg)	**CM55N Hypomagnesemia**	**CM55O Hypermagnesemia**
Acid-Base Metabolism	**CM55P Metabolic Acidosis** **CM55R Respiratory Acidosis**	**CM55Q Metabolic Alkalosis** **CM55S Respiratory Alkalosis**
Others, specify	**CM55T** _____	_____

CM302 **Disorder of mineral metabolism**, including iron, iodine, fluorine, zinc, chromium, selenium, manganese, molybdenum, & copper. If yes, specify _____

CM56 **Cystic fibrosis**

CM57 **Immunity disorders**, If yes, specify _____

CM253 **Allergic reactions**

CM303 **Amyloidosis**

CM58 **Other nutritional, endocrine, and metabolic disorders,** If yes, specify _____

(4) DISEASES OF THE BLOOD AND BLOOD-FORMING ORGANS (ICD 280-289)

CM59 **Deficiency and other or unspecified anemia**

CM60 **Acute post-hemorrhagic anemia**

CM61 **Sickle cell anemia**

CM62 **Coagulation and hemorrhagic disorders**

CM63 **Diseases of white blood cells**

CM64 **Other hematologic conditions, including spleen disorders**

(5) MENTAL DISORDERS (ICD 290-319)

CM65 **Mental retardation**

CM66 **Alcohol-related mental disorders**, including acute intoxication, dependency or abuse.

CM67 **Substance-related mental disorders**, including barbiturate, amphetamine, hallucinogen, opioid, cocaine or other or mixed drug dependence or abuse. Specify which drugs were used _____

CM68 **Senility and organic mental disorders**, including senile and arteriosclerotic dementia, Alzheimer's disease.

CM69 **Affective disorders**, including depressive disorder, bipolar affective disorder, manic-depressive psychosis.

CM70 **Schizophrenia and related disorders**

CM71 **Other psychoses**

CM72 **Anxiety, somatoform, dissociative, and personality disorders**

CM73 **Preadult disorders**

CM74 **Other mental conditions**

CM75 **Personal history of mental disorder, mental & behavioral problems, observation/screening for mental condition**

(6) DISEASES OF THE NERVOUS SYSTEM & SENSE ORGANS (ICD 320-389)

CENTRAL NERVOUS SYSTEM

CM76 **Meningitis** (except that caused by tuberculosis or sexually transmitted disease)
CM77 **Encephalitis** (except that caused by tuberculosis or sexually transmitted disease)
CM78 **Other CNS infection and poliomyelitis** If yes, specify _____
CM79 **Parkinson's disease**
CM80 **Multiple sclerosis**
CM81 **Other hereditary & degenerative nervous system conditions**, e.g., ALS. If yes, specify _____
CM82 **Paralysis** (except that secondary to cerebrovascular diseases which goes under # 113)
CM83 **Epilepsy, convulsions**
CM84 **Headache**, including migraine
CM85 **Coma, stupor, and brain damage**

EYE

CM86 **Cataract**
CM87 **Retinal detachments, defects, vascular occlusion, and retinopathy**
CM88 **Glaucoma**
CM89 **Blindness and vision defects**
CM90 **Inflammation, infection of eye** (except that caused by tuberculosis or sexually transmitted disease)
CM337 **Near-sightedness (myopia), far-sightedness (hyperopia), astigmatism or needing reading glasses (presbyopia)**
CM91 **Other eye disorders** If yes, specify _____

AUDITORY SYSTEM & OTHERS

CM92 **Otitis media and related conditions**
CM93 **Conditions associated with dizziness or vertigo**
CM94 **Other ear and sense organ disorders** If yes, specify _____

CM95 **Other nervous system disorders** If yes, specify _____

(7) DISEASES OF THE CIRCULATORY SYSTEM (ICD 390-459)

CM96 **Heart valve disorders**
CM97 **Peri-, endo-, and myocarditis, cardiomyopathy** (except that caused by tuberculosis or STD)
CM98 **Essential hypertension**
CM99 **Hypertension with complications and secondary hypertension** If yes, specify _____
CM100 **Myocardial infarction** How long ago was most recent MI? ____ years ____months prior to cancer diagnosis.
CM101 **Coronary atherosclerosis and other heart disease**
CM102 **Angina** (non-specific or non-angina chest pain is coded under #322)
CM103 **Pulmonary heart disease** (cor pulmonale)
CM104 **Other or ill-defined heart disease**
CM105 **Conduction disorders**
CM106 **Cardiac dysrhythmias / arrhythmias**
CM107 **Cardiac arrest or ventricular fibrillation**
CM108 **Congestive heart failure**
CM109 **Acute cerebrovascular disease**
CM110 **Occlusion or stenosis of precerebral arteries**
CM111 **Other and ill-defined cerebrovascular disease**
CM112 **Transient cerebral ischemia**
CM113 **Late effects of cerebrovascular disease**, i.e., plegia or hemiplegia
CM114 **Peripheral and visceral atherosclerosis**
CM115 **Aortic, peripheral, & visceral artery aneurysms,**
CM115B If yes, where was it located? _____.
CM115C What was its size? _____ cm.
CM115D Was it surgically corrected? No = 0, Yes = 1.
CM116 **Aortic and peripheral arterial embolism or thrombosis**
CM117 **Other circulatory disease, including hypotension**
CM118 **Phlebitis, thrombophlebitis and thromboembolism**
CM119 **Varicose veins of lower extremity**
CM120 **Hemorrhoids**
CM121 **Other diseases of veins and lymphatics**

(8) DISEASES OF THE RESPIRATORY SYSTEM (ICD 460-519)

CM122 **Pneumonia** (except that caused by tuberculosis or sexually transmitted disease)
CM123 **Influenza**
CM124 **Acute and chronic tonsillitis**
CM125 **Acute bronchitis**
CM126 **Other upper respiratory infections,** If yes, specify _____
CM127 **Chronic obstructive pulmonary disease & bronchiectasis,** If yes, specify:
- CM127B **COPD otherwise not specified**
- CM127C **Emphysema**
- CM127D **Chronic bronchitis**
- CM127E **Bronchiectasis**

CM128 **Asthma**
CM304 **Pulmonary fibrosis / interstitial lung diseases**
CM129 **Aspiration pneumonitis, food/vomitus**
CM130 **Pleurisy, pneumothorax, pulmonary collapse (atelectasis)**
CM131 **Respiratory failure, insufficiency, arrest (adult)**
CM132 **Lung disease due to external agents,** including **pneumoconioses**, e.g., anthracosis, silicosis, asbestosis, berylliosis, siderosis, stannosis, & baritosis.
CM133 **Other lower respiratory disease**
CM134 **Other upper respiratory disease**

(9) DISEASES OF THE DIGESTIVE SYSTEM (ICD 520-579)

CM135 **Intestinal infection**
CM136 **Disorders of teeth and jaw**
CM137 **Diseases of mouth, excluding dental**
CM138 **Esophageal disorders**
CM139 **Gastroduodenal ulcer** (except hemorrhage)
CM140 **Gastritis and duodenitis**
CM141 **Other disorders of stomach and duodenum**
CM142 **Appendicitis and other appendiceal conditions**
CM143 **Abdominal hernia,** If yes, was it accompanied by obstruction or gangrene? No = 0, Yes = 1.
CM144 **Regional enteritis and ulcerative colitis**, including inflammatory bowel diseases, such as Crohn's disease & ulcerative colitis.
CM145 **Intestinal obstruction without hernia,** e.g., paralytic ileus, impaction, adhesions. If yes, specify _____
CM146 **Diverticulosis and diverticulitis**
CM147 **Anal and rectal conditions**
CM148 **Peritonitis and intestinal abscess**
CM149 **Biliary tract disease**, e.g., cholecystitis, cholelithiasisis
CM150 **Liver disease, alcohol-related**
CM151 **Other liver diseases**, e.g., liver disease or cirrhosis without mention of alcohol, liver abscess, ascites.
CM152 **Pancreatic disorders** (not diabetes)
CM153 **Gastrointestinal hemorrhage** If yes, specify _____
CM154 **Noninfectious gastroenteritis**
CM155 **Other gastrointestinal disorders,** e.g., constipation, dysphagia. If yes, specify _____

(10) DISEASES OF THE GENITOURINARY SYSTEM (580-629)

CM156 **Nephritis, nephrosis, renal sclerosis**, If yes, specify _____
CM157 **Acute and unspecified renal failure**
CM158 **Chronic renal failure**
CM335 **Has the patient had dialysis? If yes, earliest date** _____ **and last date** _____
CM159 **Urinary tract infections,** If yes, specify if of kidney or cystitis/urethritis : _____
CM160 **Calculus of urinary tract (urolithiasis)** If yes, specify if of kidney or ureter or bladder : _____
What is the composition?: calcium oxalate; uric acid; cystine; struvite = magnesium ammonium phosphate, other, unknown.
CM161 **Other diseases of kidney and ureters**, e.g., hydronephrosis
CM162 **Other diseases of bladder and urethra**
CM163 **Genitourinary symptoms and ill-defined conditions**, e.g., hematuria, dysuria, retention of urine.

DISEASES OF THE MALE GENITAL ORGANS

CM164 **Hyperplasia of prostate**
CM165 **Inflammatory conditions of male genital organs,** If yes, specify _____
CM166 **Other male genital disorders,** If yes, specify _____

DISEASES OF THE FEMALE GENITAL ORGANS

CM167 Nonmalignant breast conditions
CM168 Inflammatory diseases of female pelvic organs, e.g., pelvic peritoneal adhesions, cervicitis / endocervicitis, pelvic inflammatory disease (including endometritis, salpingitis and ooporitis). If yes, specify _____
CM169 Endometriosis
CM170 Prolapse of female genital organs
CM171 Menstrual disorders
CM172 Ovarian cyst
CM173 Menopausal disorders
CM174 Female infertility
CM175 Other female genital disorders

(11) COMPLICATIONS OF PREGNANCY, CHILDBIRTH, AND THE PUERPERIUM (IDC 630-677)

CM176 Contraceptive and procreative management
CM177 Spontaneous abortion
CM178 Induced abortion
CM179 Post-abortion complications
CM180 Ectopic pregnancy
CM181 Other complications of pregnancy, e.g., genitourinary infection during pregnancy, anemia during pregnancy, mental disorder during pregnancy, missed abortion, hyperemesis gravidarum, infectious/parasitic complications in mother affecting pregnancy. If yes, specify _____
CM182 Hemorrhage during pregnancy, abruptio placenta, placenta previa
CM183 Hypertension complicating pregnancy, childbirth and the puerperium, e.g., preeclampsian/eclampsia.
CM184 Early or threatened labor
CM185 Prolonged pregnancy
CM186 Diabetes or abnormal glucose tolerance complicating pregnancy, childbirth, or the puerperium
CM187 Malposition, malpresentation
CM188 Fetopelvic disproportion, obstruction
CM189 Previous cesarean section
CM190 Fetal distress and abnormal forces of labor, e.g., fetal distress, uterine inertia, precipitate labor.
CM191 Polyhydramnios & other problems of amniotic cavity. e.g., premature rupture of membranes, infection of amnion.
CM192 Umbilical cord complication
CM193 Trauma to perineum and vulva
CM194 Forceps delivery
CM195 Other complications of birth, puerperium affecting management of mother, e.g., postpartum hemorrhage, cervical incompetence, rhesus isoimmunization, interuterine death, failed induction.
CM196 Normal pregnancy and/or delivery

(12) DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE (ICD 680-709)

CM197 Skin and subcutaneous tissue infections, e.g., cellulitis or abscess.
CM198 Other inflammatory condition of skin
CM199 Chronic ulcer of skin
CM200 Other skin disorders

(13) DISEASES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE (ICD 710-739)

CM201 Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease)
CM202 Rheumatoid arthritis and related disease
CM203 Osteoarthritis
CM204 Other non-traumatic joint disorders (place gout and other crystalline metabolic arthropathic disorders in #54)
CM205 Spondylosis, intervertebral disc disorders, other back problems
CM206 Osteoporosis
CM206B Osteopenia
CM207 Pathological fracture
CM208 Acquired foot deformities
CM209 Other acquired deformities
CM210 Systemic lupus erythematosus and connective tissue disorders
CM211 Other connective tissue disease
CM212 Other bone disease and musculoskeletal deformities
CM305 Limb amputation, If yes, then check if #254 applies.
CM339 Hip replacement

(14) CONGENITAL ANOMALIES (ICD 740-759)

CM213 Cardiac and circulatory congenital anomalies
CM214 Digestive congenital anomalies
CM215 Genitourinary congenital anomalies
CM216 Nervous system congenital anomalies
CM217 Other congenital anomalies

(15) CERTAIN CONDITIONS ORIGINATING IN THE PERINATAL PERIOD (ICD 760-779)

CM218 Liveborn
CM219 Short gestation, low birth weight, and fetal growth retardation
CM220 Intrauterine hypoxia and birth asphyxia
CM221 Respiratory distress syndrome
CM222 Hemolytic jaundice and perinatal jaundice
CM223 Birth trauma
CM224 Other perinatal conditions

(16) INJURY / TRAUMA & POISONING (800-999)

CM225 Joint disorders and dislocations, trauma-related
CM226 Fracture of neck of femur (hip)
CM227 Spinal cord injury
CM228 Skull and face fractures
CM229 Fracture of upper limb
CM230 Fracture of lower limb
CM231 Other fractures
CM232 Sprains and strains
CM233 Intracranial injury
CM234 Crushing injury or internal injury
CM235 Open wounds of head, neck, and trunk
CM236 Open wounds of extremities
CM237 Complication of device, implant or graft
CM238 Complications of surgical procedures or medical care
CM239 Superficial injury, contusion
CM240 Burns
CM241 Poisoning by psychotropic agents
CM242 Poisoning by other medications and drugs
CM243 Poisoning by nonmedicinal substances
CM244 Other injuries and conditions due to external causes
CM306 Gunshot injury

(17) SYMPTOMS & SIGNS of the index cancer, & ILL-DEFINED CONDITIONS (ICD 780-799)

CM307A Prior to the index cancer under study, was the patient symptomatic. No=0, Yes=1.

CM307B If symptomatic, what was the duration of symptoms? ____ months.

If symptomatic, complete the table below.

GENERAL	**CM245 Syncope, fainting** **CM249 Shock** **CM252 Fatigue and malaise, i.e., tiredness, weakness, lethargy** **CM246 Fever**, tumor-related or of unknown origin **CM308 Chills, sweats, night sweats, diaphoresis (excess or profuse perspiration)** **CM309 Weight loss (unintentional)** How many pounds were lost? ___, Over how many months? ____. Was weight loss intentional (i.e., due to dieting)? = 0, or was it disease related? = 1
GASTRO-INTESTINAL	**CM250 Nausea, vomiting, emesis** **CM310 Anorexia, loss of appetite, decreased appetite** **CM311 Heartburn** **CM336 Jaundice, icterus**
RESPIRA-TORY / CHEST	**CM312 Upper respiratory symptoms, epistaxis** **CM313 Throat symptoms, e.g.,** dysphagia, difficulty swallowing, sore throat, swollen throat, hiccups, choking sensation, hoarseness (rough or harsh quality of voice), dysphonia (any impairment of voice, a difficulty in speaking) **CM314 Cough** **CM315 Dyspnea, shortness of breath (SOB), excertional dyspnea, orthopnea** (inability to breath except in an upright position) **CM316 Wheezing** (i.e., whistling noises, high pitch, made during breathing) or **Stridor** (a harsh sound, audible without a stethoscope and predominantly inspiratory, often from obstruction) **CM317 Respiratory congestion** **CM318 Palpitations** **CM319 Hemoptysis** (coughing up blood from the respiratory tract) **CM320 Cyanosis** **CM321 Finger clubbing**
PAIN	**CM251 Abdominal pain** **CM322 Chest pain other than angina** **CM323 Pain of the back** **CM324 Pain of the shoulder** **CM325 Other pain**, e.g., arthralgia, neuralgia, pain in extremities.
NODES, MASSES, SWELLINGS	**CM247 Lymphadenitis** **CM326 Lymphadenopathy or palpable mass** or "can feel mass". **CM327 Swelling / edema**
NEURO-MUSCULAR & MENTAL	**CM328 Headache** as a presenting sign/symptom of the index cancer **CM329 Diziness** **CM330 Eye / ophthalmic symptoms & signs**, e.g., blurred vision, diplopia, photophobia. **CM331 Dysmetria** (improper measuring of distance or range of movement in muscular action) **CM338 Insomnia** **CM332 Mental changes** as a presenting sign/symptom of the index cancer **CM333 Neurologic symptoms & signs** as a presenting sign/symptom of the index cancer
OTHER	**CM334 Alopecia, hair loss**

CM254 Rehabilitation care, fitting of prostheses, and adjustment of devices

(17) UNCLASSIFIED, continued

CM259 Residual codes, unclassified

Other: Describe _____

[Highest numbers as of Jan 30, 2002 are CM337 (myopia, hyperopia, astigmatism, presbyopia)], 338 Insomnia, 339 hip replacement]