

St. Joseph & Redwood Memorial Hospitals' Breast Cancer in Humboldt County Site Report for 2005



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BREAST CANCER
IN HUMBOLDT COUNTY
SITE REPORT FOR 2005

INTRODUCTION

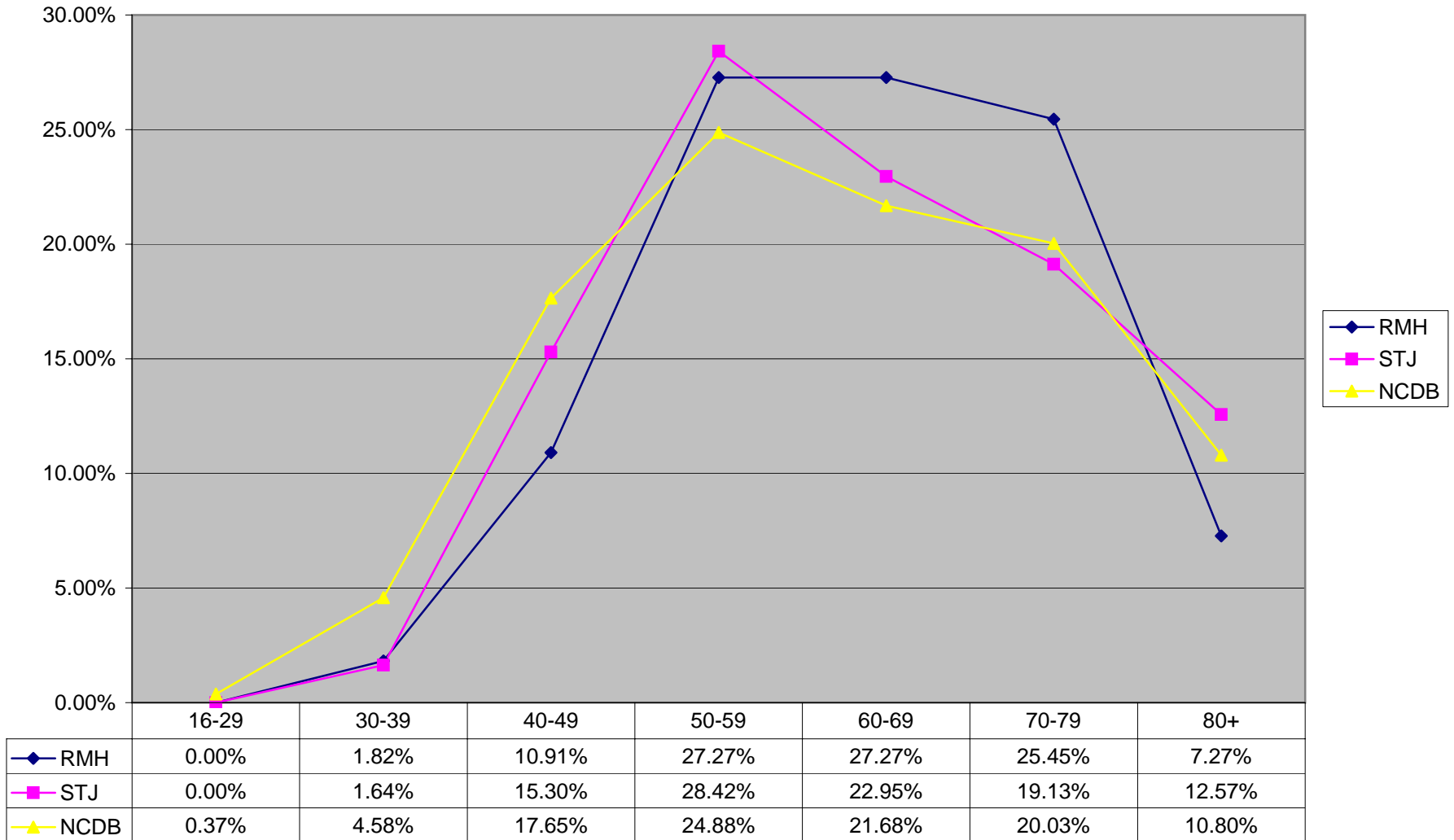
In recent years in Humboldt County there has been a rising concern that persons residing here had a greater chance of contracting breast cancer; and also a greater chance of dying from the disease than if they lived elsewhere. The Cancer Committee of St. Joseph (STJ) and Redwood Memorial (RMH) Hospitals has requested information to support or refute these suppositions. Included in this report are responses from nationally acclaimed surgeon, M. Ellen Mahoney, M.D., FACS and Brian Davis, MPH, former Epidemiologist with the County of Humboldt.

Dr. Mahoney and Brian Davis consulted with Judy Viegas, CTR, Cancer Registry Coordinator for The Cancer Program of St. Joseph and Redwood Memorial Hospitals to obtain local data and statistics during their research. Judy helped provide countywide data and specific information on age, stage of disease and county of residence regarding the individuals who were included in the mortality figures from breast cancer for the years 1999, 2000 and 2001.

Also included in this report are five charts comparing data from St. Joseph and Redwood Memorial Hospitals to the National Cancer Data Base figures for 2000 and 2001 breast cancer cases (this includes patient data for all participating cancer treatment programs in the US and Puerto Rico). In comparing survival rates by stage of disease, Stage I and II charts reflect negligible differences between the local and national averages. The stage III chart actually shows a much better survival rate for local breast cancer patients; and the Stage IV chart divergence is easily understood in light of the small number of patients comprising the hospital figures. The fifth chart, Age at Diagnosis, again reflects no significant difference between national and local hospital figures.

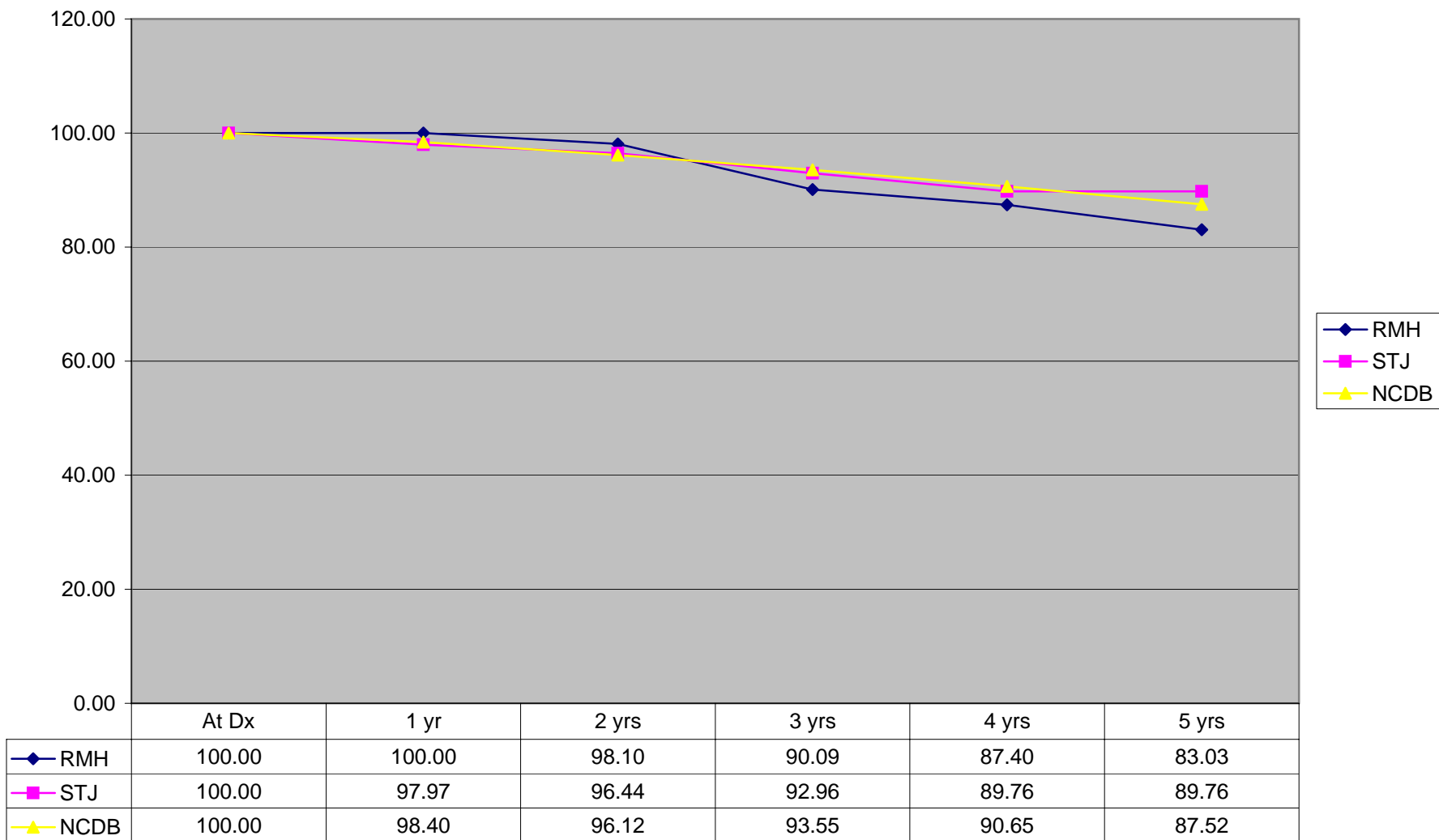
Therefore, the conclusions reached by these experts – and the raw data -- refute the aforementioned suppositions. This is due in large part to the fact that local healthcare available for breast cancer patients living in Humboldt County is excellent, even “cutting edge.”

Breast Cancer - Age at Diagnosis Comparison Chart



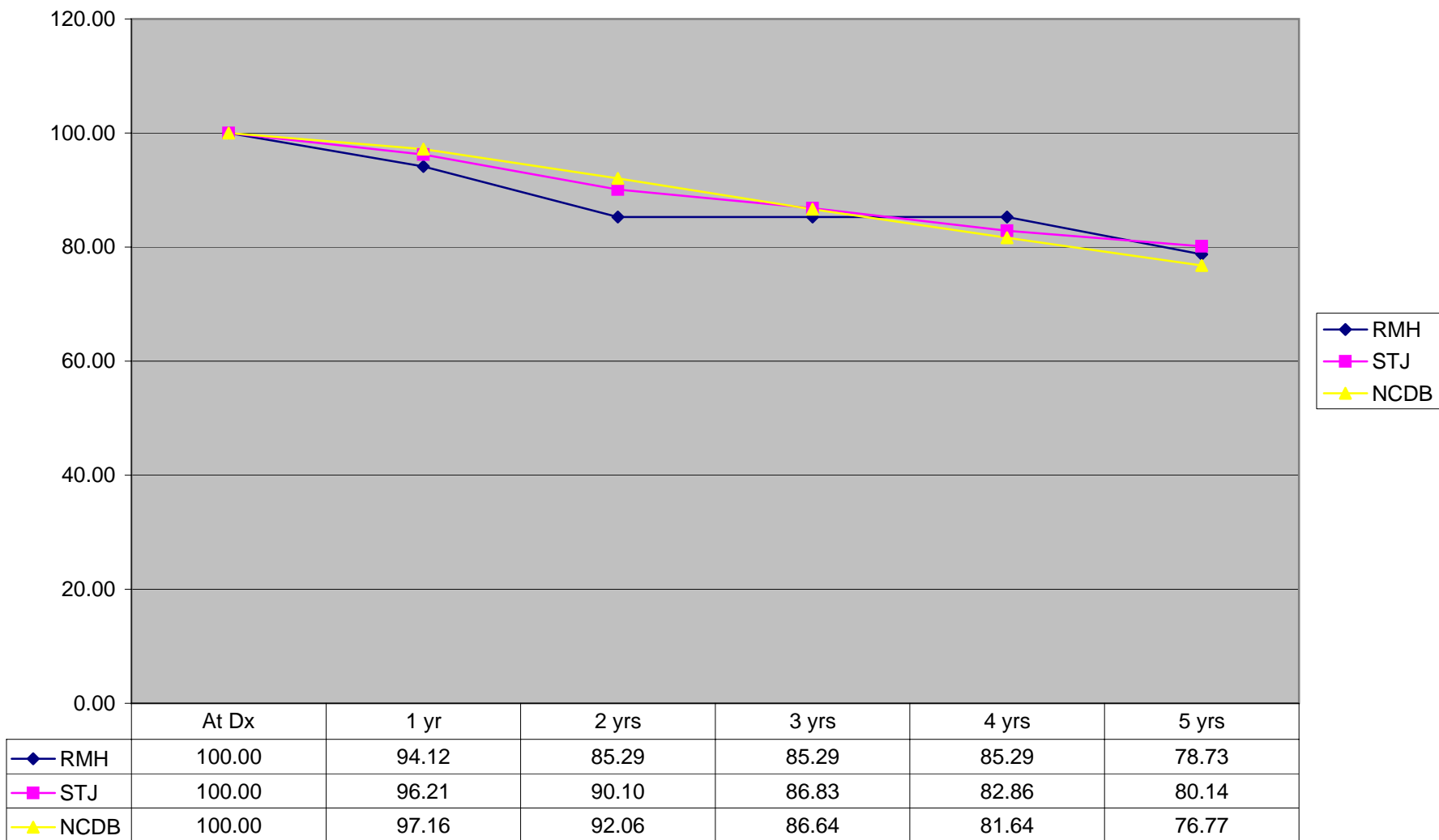
Redwood Memorial Hospital (RMH) 55 analytic cases, St. Joseph Hospital (STJ) 183 analytic cases and NCDB 324,919 cases. All cases diagnosed in 2000 and 2001.

Breast Cancer % Survival Stage I Redwood Memorial Hospital and St. Joseph Hospital vs NCDB



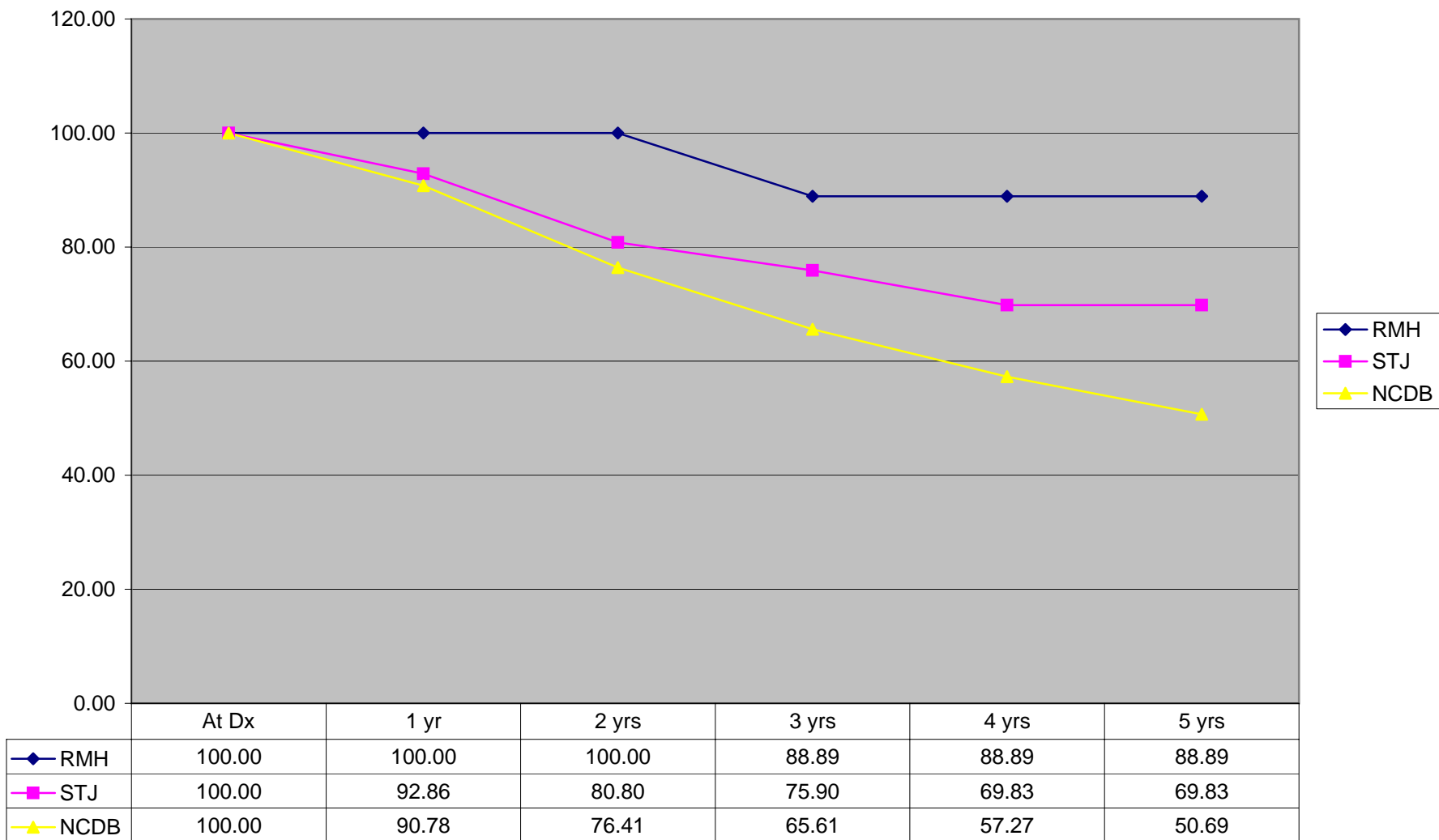
Redwood Memorial Hospital 53 analytic cases and St Joseph Hospital 198 analytic cases 1990-2000. NCDB 119,673 cases 1995-1996.

Breast Cancer % Survival Stage II Redwood Memorial Hospital and St. Joseph Hospital vs NCDB



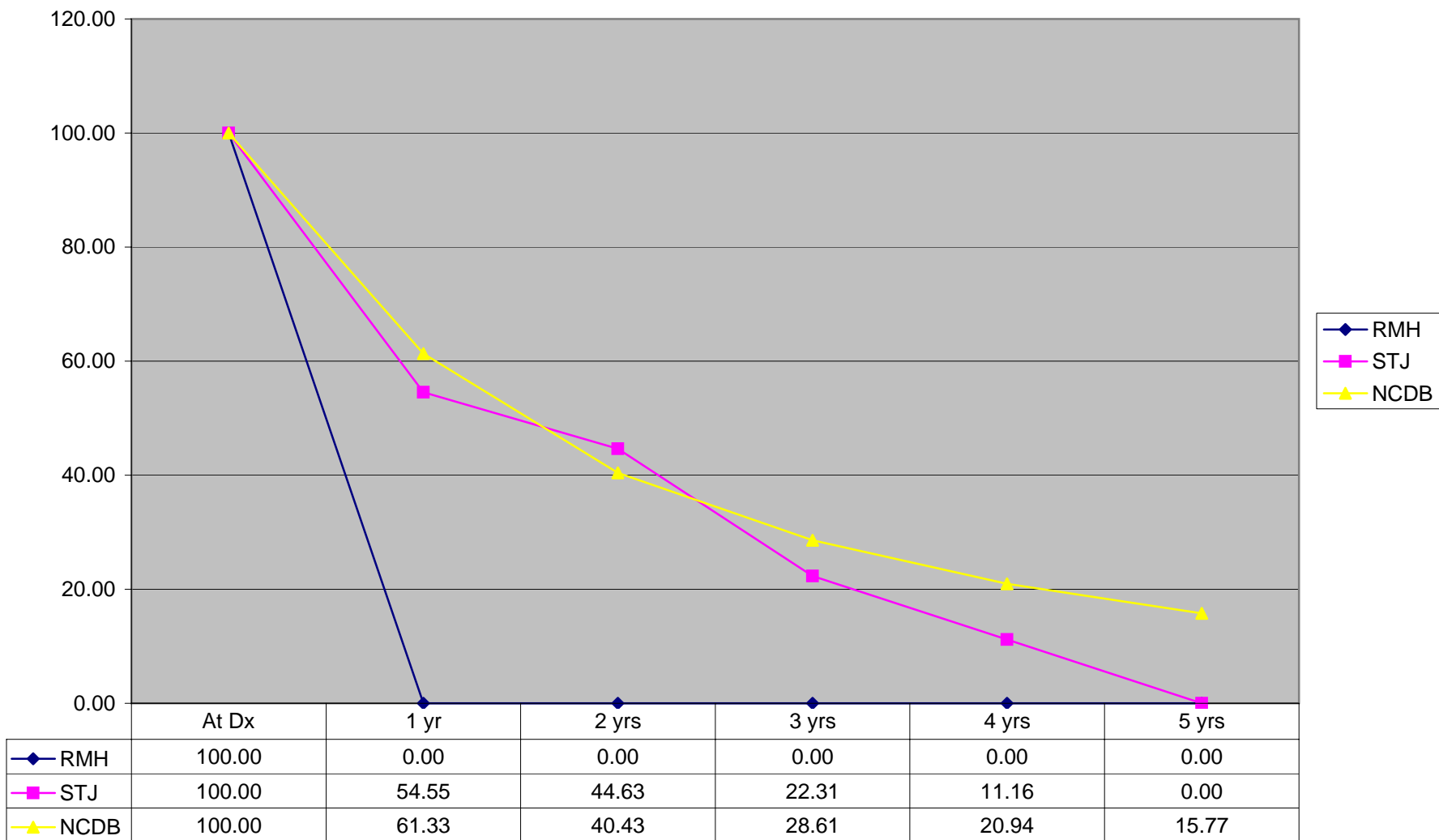
Redwood Memorial Hospital 34 analytic case and St. Joseph Hospital 132 analytic cases 1990-2000. NCDB 92,443 cases 1995-1996.

Breast Cancer % Survival Stage III Redwood Memorial Hospital and St. Joseph Hospital vs NCDB



Redwood Memorial Hospital 9 analytic case and St. Joseph Hospital 42 analytic cases 1990-2000. NCDB 21,407 cases 1995-1996.

Breast Cancer % Survival Stage IV Redwood Memorial Hospital and St. Joseph Hospital vs NCDB



Redwood Memorial Hospital 2 analytic cases and St. Joseph Hospital 11 analytic cases 1990-2000. NCDB 12,246 cases 1995-1996.

Breast Cancer – Statistics, Rate of Incidence, and Local Resources

Despite the fact that breast cancer is neither the leading cause of death for American women (cardiovascular disease) nor the leading cause of cancer death for American women (lung cancer), it remains an object of intense public fear. It is the most common invasive cancer in women worldwide. For 2005, the number of new cases of invasive breast cancer in the United States was estimated at 211,240. There has been a sharp increase in cases over the past 30 years, attributable in large part to the increase of older women, who are at higher risk of developing the disease, as a proportion of the population as a whole.

In the 1980s the incidence increased about 4% per year. Between 1987-2000 the incidence leveled off to an increase of about 0.6% per year. In the 1980s the increase was attributable to the discovery of small tumors, while the incidence of larger tumors and later stages stayed steady. This has led to the conclusion that the routine use of mammography to detect tumors at smaller sizes is responsible for the reduction in breast cancer incidence. Since the recommendations for routine mammography have become well-known and accepted widely, attention has turned to other factors that might help reduce breast cancer incidence.

Activists and physicians alike have expressed frustration at the absence of the next important advance that will make at least as large an impact in reducing the number of women who die of breast cancer. The problem with most risk factors presumed to be associated with breast cancer is that they cannot be changed practically. These include such traits as race, sex, relatives and age at first pregnancy. Their primary benefit is to guide more sophisticated research into possible mechanisms of the disease. Two factors which may be meaningful and modifiable are weight control with exercise (probably a surrogate for a constellation of healthy lifestyle choices associated with lower natural insulin levels) and judicious alcohol consumption. Consuming one to 2 drinks a day is associated with a lower risk of cardiovascular disease, the leading cause of death for American women, while consumption of over 2 drinks a day, especially in conjunction with lower folate levels, is associated with an increase in breast cancer risk.

Results of the Women's Health Initiative showed a statistically insignificant rise in breast cancer risk from a menopausal treatment of combined estrogen/progestin, and a nearly significant decrease in risk with estrogen use alone. With estrogen alone, there was no increase in the risk of breast cancer or heart disease seen up to 6.8 years, when the study was stopped. The authors conclude that there is no overall benefit of estrogen for chronic disease prevention in the general population, but support the use of the smallest effective dose for intractable menopausal symptoms for the shortest number of years, pending confirmatory studies.

The overall incidence of breast cancer is 1 in 8 women will get the disease in their lifetime. This statistic makes risk assessment difficult however, as women widely report that when they hear something “doubles” risk, or is associated with a certain percentage of increased risk, they tend to apply to the 1 in 8 figure, concluding, for instance, that a factor that doubles risk makes their risk 1 in 4. This is not true, and a better way to evaluate the influence of risk factors is to use age-specific probabilities of developing breast cancer as shown in table 6. If you are 40 years old, and exposed to something that doubles your risk of breast cancer, this means that you are looking at a 2.8% chance of developing breast cancer in the next 10 years instead of 1.4%.

Overall, the number of cases of breast cancer has been increasing each year. The most important reason is probably that the baby boomers are reaching the age when breast cancer becomes more common. Despite that, the death rate from breast cancer is *decreasing* steadily at the same time. This is partly due to improvements in mammography, which allow us to discover many tumors when they are in an earlier stage, before they could be discovered by physical examination. The increase in survival is also due to improvements in therapy. Sentinel node procedures allow us to identify patients who may benefit from a standard axillary dissection, a major improvement over subjecting every breast cancer patient to the risks associated with the bigger operation. CT planning allows the radiation oncologists to direct the beam more precisely to the breast itself rather than nearby structures in the chest. There are more and better drugs available to the oncologists, the most exciting of which target only cells which contain abnormal proteins associated with certain breast cancers. Trastuzumab (Herceptin) is one example. Our understanding of cancer at the sub-cellular level has led to the development of drugs designed to interfere with specific functions of the cell such as hormone receptors and hormone production. There is still a role for standard forms of chemotherapy, but the number of combinations has increased, as has our knowledge of the best applications for the drugs available depending on specific tumor characteristics. Over the years, supportive strategies to reduce the side effects of therapy have also improved. Although there is still much room for improvement, we are moving in the right direction. There is still a pressing need for a blood test or some other means of detecting small numbers of leftover cancer cells after surgery and radiation so that we can treat patients based on whether they actually have residual disease rather than the *probability* that they do based on large group studies.

There are three initiatives in breast cancer unique to the Humboldt County area. The Humboldt Community Breast Health Project, which has become a vital resource for women needing support and education in breast health and breast cancer, has been awarded the second in a series of community research grants by the Breast Cancer Research Program of the State of California. This prestigious award has paired the HCBHP and its counterpart in Mendocino County with UCSF for the study of decision support and consultation planning to

underserved rural communities and will result in these services, usually only available at major medical centers, becoming much more widely available.

Another initiative is the Humboldt Breast Medicine Project, funded by a grant from the California Healthcare Foundation through the IPA, which will result in an educational and decision support tool designed to be used by primary care health providers in conjunction with patients. The HBMP program will provide information on options for the evaluation and treatment of breast symptoms, along with special training, information on costs, descriptions of procedures by both physicians and patients who have undergone them, and guidance on what should be done before the patient is referred to a specialist. The emphasis will be on safe, high quality care.

The third initiative was presented to the St. Joseph Hospital Cancer Program Institutional Review Board by Drs. Ellen Mahoney and Susan Love late in 2005. Colleagues at Johns Hopkins University had shown a remarkable reduction in breast cancer in certain breeds of rats and mice developed to contract the disease 100% of the time. Our research partners at Johns Hopkins had shown that injection of medications, such as certain chemotherapeutic drugs, directly into the breast ducts was able to prevent the disease from developing. Moreover, the rodents tolerated the procedure very well, showing no evidence of toxicity. Successful application in humans might allow us to actually selectively destroy or “reset” the cells lining the ducts and lobules of the breast, the cells from which all breast cancer arises, while preserving the appearance of the breast itself, resulting in true prevention of breast cancer without breast removal. A local resident who had previously been treated for breast cancer had elected to have her uninvolved breast removed, and both breasts reconstructed at Stanford. She agreed to be the first human to undergo the ductal injection procedure so that we could see if it was as well-tolerated in humans. The plan was to inject a duct in her normal breast about eight weeks before the scheduled mastectomy. The IRB made invaluable suggestions to improve the protocol and monitoring, and after their approval, the procedure was performed at SJH in February 2005. The patient did indeed tolerate the injection well. Most importantly, blood samples drawn at regular intervals in the days following the procedure, and sent on dry ice to Johns Hopkins in Baltimore, showed no evidence of the drug in the patient’s blood stream in a sensitive assay. The work was presented at an international conference in March 2005. This has led to the approval of a larger study by the IRB of Johns Hopkins, as well as a systematic search for the best substance to use. If this procedure is ultimately proven safe and effective, the history of its beginnings will show a big role for the Cancer Program at SJH in Humboldt County, as well as for the courageous patient herself.

The Cancer Program at SJH is dedicated to the continual improvement of clinical care for all women in the area, including the earliest possible detection of breast cancer, and advances in breast cancer research and care unprecedented in a rural area, aided by links to major universities. Presented here is only a

snapshot of a portion of the work done against this disease by dedicated professionals in this area every day. We are determined to continue the progress made against this disease. So far we cannot prevent breast cancer, at least not yet, but we can continue our efforts to find it at the earliest stage, and treat it with the best evidence-based methods available while tailoring the treatment appropriately to the needs of the individual patient. We will continue as well our efforts to find less invasive methods of diagnosis and treatment, and to provide the best supportive care possible to the breast cancer patient and the important people in her life. All women are at risk, but if present trends continue, more women who do get the disease will survive to live a normal lifespan.

Table 6. Age-Specific Probabilities of Developing Breast Cancer*

| If current age is: | The probability of developing breast cancer in the next 10 years is:† | or 1 in: |
|---------------------------|--|-----------------|
| 20 | 0.05% | 1,985 |
| 30 | 0.44% | 229 |
| 40 | 1.46% | 68 |
| 50 | 2.73% | 37 |
| 60 | 3.82% | 26 |
| 70 | 4.14% | 24 |
| Lifetime risk | 13.22% | 8 |

*Among those free of cancer at beginning of age interval. Based on cases diagnosed 2000-2002. Percentages and “1 in” numbers may not be numerically equivalent due to rounding.

†Probability derived using NCI DevCan Software, Version 6.0

American Cancer Society, Surveillance Research, 2005

Tracking Breast Cancer in Humboldt County

Data Years: 1999-2003

Brian Davis, MPH
Epidemiologist

County of Humboldt
Department of Health &
Human Services
Public Health Branch

The following pages represent a condensed and edited version of Brian Davis's analysis of the Humboldt County breast cancer data for 1999-2003 as he presented it in PowerPoint format.

Highest Adjusted Mortality Rate in State

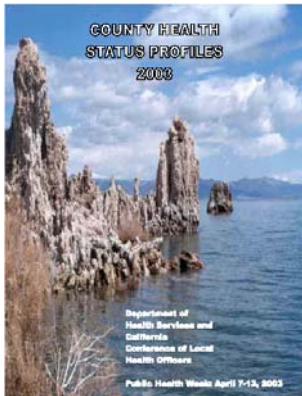
Three Year Average 1999-2001

TABLE 9
DEATHS DUE TO FEMALE BREAST CANCER
RANKED BY THREE-YEAR AVERAGE AGE-ADJUSTED DEATH RATES
CALIFORNIA COUNTIES, 1999-2001

| RANK ORDER | COUNTY | 2000 FEMALE POPULATION | 1999-2001 DEATHS (AVERAGE) | CRUDE DEATH RATE | AGE-ADJUSTED DEATH RATE | 95% CONFIDENCE LIMITS | |
|------------|-----------|------------------------|----------------------------|------------------|-------------------------|-----------------------|-------|
| | | | | | | LOWER | UPPER |
| 1 | ALPINE | 557 | 0.0 | 0.0 + | 0.0 + | - | - |
| 2 | SIERRA | 1,606 | 0.3 | 20.8 * | 8.0 * | 0.0 | 35.0 |
| 3 | DEL NORTE | 13,275 | 2.0 | 15.1 * | 11.4 * | 0.0 | 27.6 |
| 49 | SONOMA | 219,839 | 78.3 | 35.7 | 28.7 | 22.3 | 35.1 |
| 50 | SONOMA | 219,839 | 78.3 | 35.7 | 28.7 | 22.3 | 35.1 |
| 51 | GLENN | 13,415 | 4.3 | 32.3 * | 29.2 * | 1.2 | 57.1 |
| 52 | INYO | 8,753 | 3.7 | 41.9 * | 30.6 * | 0.0 | 64.2 |
| 53 | YOLO | 73,064 | 21.7 | 29.7 | 30.7 | 17.7 | 43.7 |
| 54 | TRINITY | 6,205 | 3.0 | 48.3 * | 32.0 * | 0.0 | 68.5 |
| 55 | MARIN | 118,638 | 47.0 | 39.6 | 33.4 | 23.8 | 43.0 |
| 56 | MARIPOSA | 7,867 | 4.3 | 55.1 * | 38.3 * | 1.1 | 75.5 |
| 57 | PLUMAS | 9,695 | 5.7 | 58.4 * | 38.4 * | 6.0 | 70.7 |
| 58 | HUMBOLDT | 60,541 | 30.3 | 50.1 | 41.8 | 26.8 | 56.7 |

County Health Officer, Dr. Ann Lindsay became concerned upon the release of the 2003 County Health Profile ranking of Humboldt as the county with the highest breast cancer mortality rate in the state (with an age-adjusted death rate of 41.8 deaths per 100,000 females).

County Health Status Profiles



- Published annually by DHS & CCLHO
- Selected health indicators
 - Mortality & Morbidity
- Three-year annually-averaged rates (generally)
- Ranks 58 counties

www.dhs.ca.gov/hisp/chs/OHIR/publicationindex.htm

County Health tracks health indicators, by county, throughout the state. Historically, they have presented the rates in 3-year averages – until the data-year 1999, when the standard population used to normalize the rates for intra-county comparison was changed to the 2000 Standard Population.

Other mortality indicators

Humboldt County, 1999-2001

| | |
|------------------------------|------------------|
| All deaths | 57 th |
| Motor vehicle accidents | 37 th |
| Unintentional injuries | 55 th |
| Firearm deaths* | 51 st |
| Suicides | 53 rd |
| All cancer deaths | 57 th |
| Lung cancer | 40 th |
| Coronary heart disease | 27 th |
| Cerebrovascular disease | 40 th |
| Drug related deaths | 57 th |
| Diabetes | 54 th |
| * Data not reliable, SE <23% | |

Department of Health Services and California Conference of Local Health Officers.
County Health Profiles 2003. Sacramento: 2003.

Besides Breast Cancer, the Health Profiles look at these health indicators.

As you can see, with the exception of Coronary Heart Disease, Humboldt County ranks in the lower half for all of these mortality causes.

Hypothesis:

A higher breast cancer mortality rate in Humboldt County is due to a breast cancer incidence higher than the other Northern California counties in Region 6.

I first examined the rates of breast cancer cases in Humboldt County, using the rates published by the Northern California Cancer Registry, Region 6.

Breast Cancer Incidence

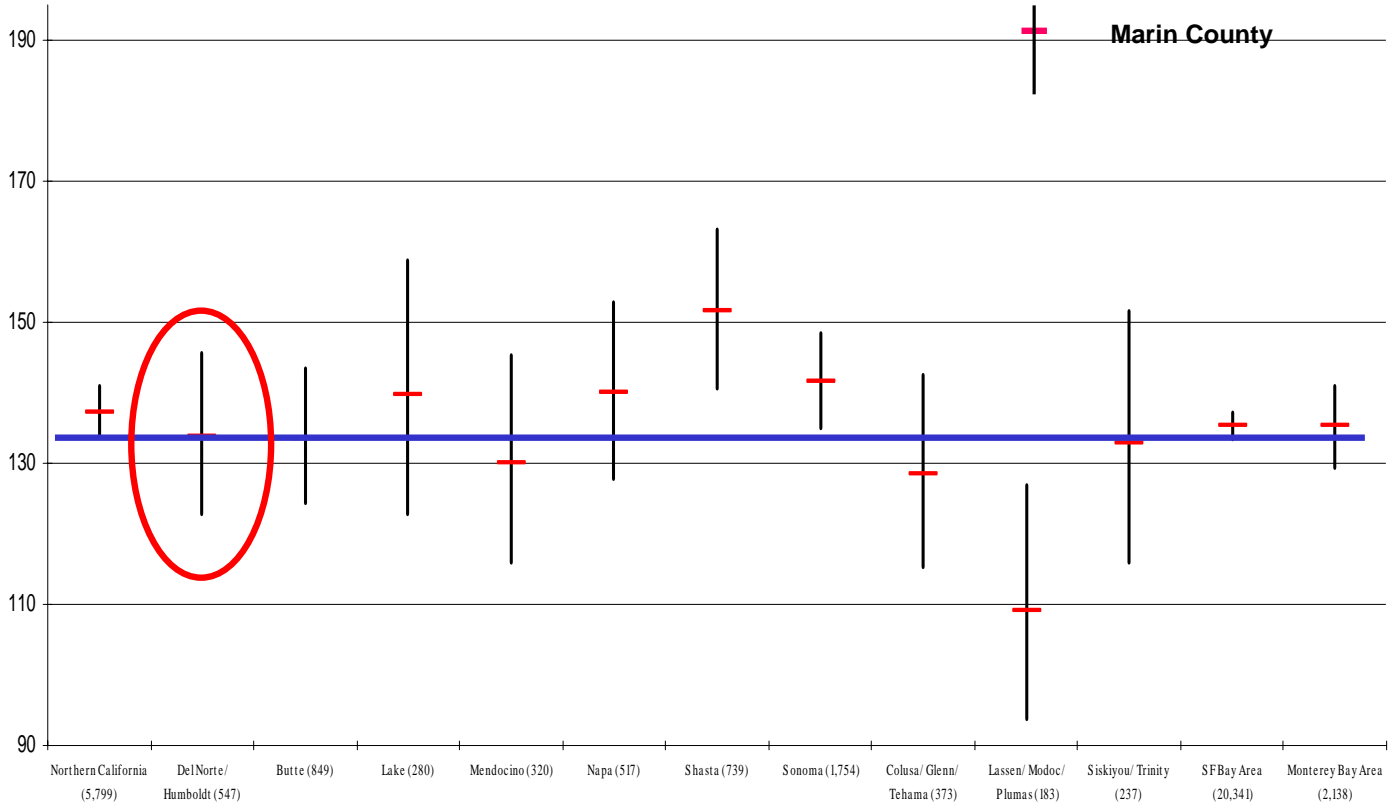
1996-2000

(Average Annual Age-Adjusted Incidence Rates/100,000 Female Population, with 95% Confidence Intervals)

| County (total cases) | Rate | CI- | CI+ |
|-----------------------------|-------------|------------|------------|
| Northern California (5,799) | 137.2 | 133.6 | 140.8 |
| Del Norte/ Humboldt (547) | 133.8 | 122.8 | 145.7 |
| Butte (849) | 133.5 | 124.3 | 143.3 |
| Lake (280) | 139.6 | 122.8 | 158.8 |
| Mendocino (320) | 130.0 | 116.0 | 145.4 |
| Napa (517) | 139.9 | 127.9 | 152.9 |
| Shasta (739) | 151.5 | 140.7 | 163.0 |
| Sonoma (1,754) | 141.6 | 135.0 | 148.4 |
| Colusa/ Glenn/ Tehama (373) | 128.4 | 115.4 | 142.6 |
| Lassen/ Modoc/ Plumas (183) | 109.2 | 93.7 | 127.0 |
| Siskiyou/ Trinity (237) | 132.7 | 116.0 | 151.7 |
| SF Bay Area (20,341) | 135.4 | 133.5 | 137.3 |
| Monterey Bay Area (2,138) | 135.2 | 129.5 | 141.0 |

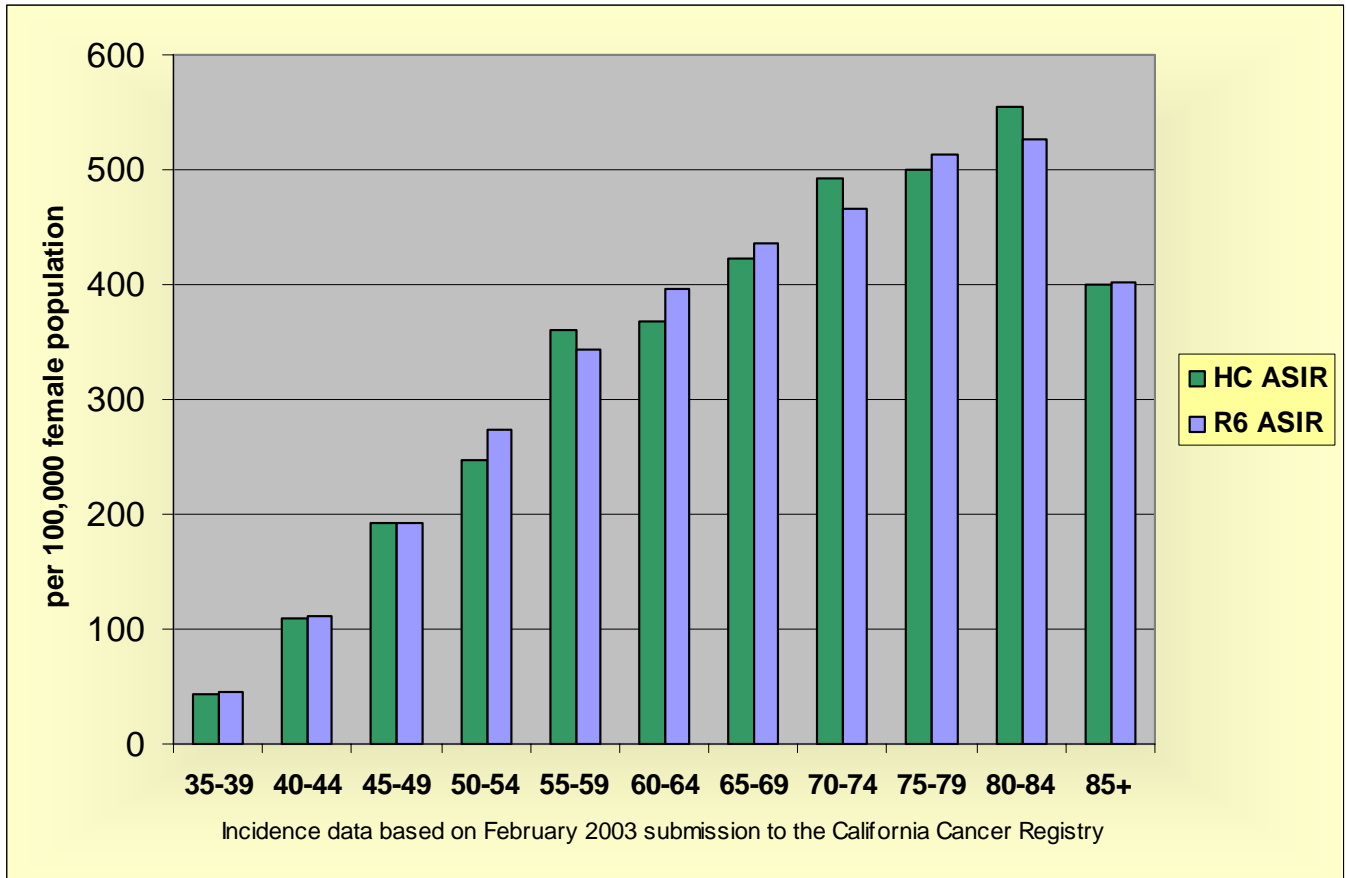
Campleman SL, Dryden M, Bauer KR. Cancer in Northern California, 1988-2000. Cancer Registry of Northern California, Chico, CA . Dec 2002.

Average 5-Year Annual Breast Cancer Rates (Female)
with 95% Confidence Intervals
1996-2000
(Age-Adjusted Incidence Rates/100,000 Female Population)



I evaluated whether breast cancer incidence in HC was significantly different than in the other registry counties, and included SF and the Monterey Bay areas as well. As the 95% CI intervals overlap, there was no significant difference; HC incidence is no different than the other Northern California counties.

Malignant female Breast Cancer age-specific incidence rates by age at diagnosis, Humboldt/Del Norte vs. Region 6 counties, 1996-2000



I next asked for age specific rates from the Cancer Registry, to estimate differences with the Region 6 rates. There was no apparent difference by age group, in the incidence of breast cancer between the 2 populations.

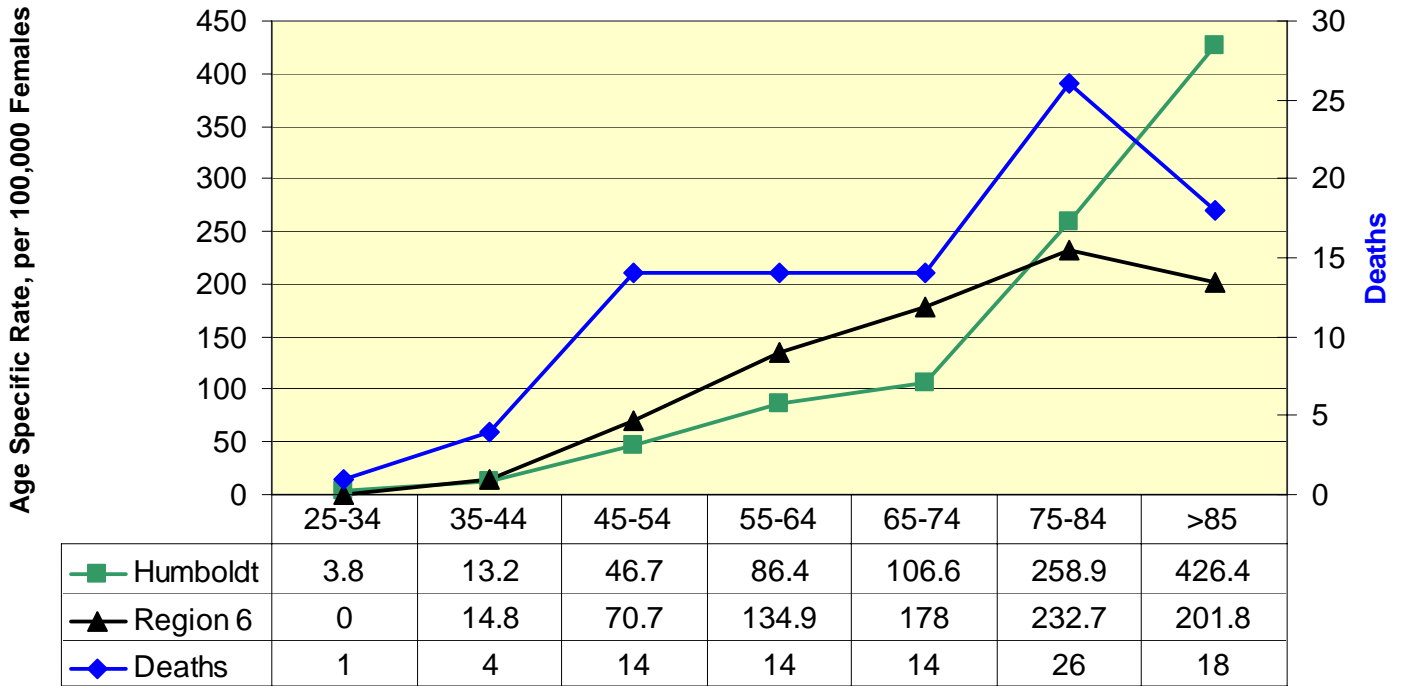
Ranked Causes of Mortality, Humboldt County 1999-2001

| 1999 | Cause of Death | # of Deaths | % of all deaths |
|-------------|---|-------------|-----------------|
| 1 | All other forms of chronic ischemic heart disease | 105 | 9.06% |
| 2 | Of trachea, bronchus and lung | 61 | 5.26% |
| 3 | Acute myocardial infarction | 57 | 4.92% |
| 4 | Other chronic obstructive pulmonary disease | 52 | 4.49% |
| 5 | Stroke, not specified as hemorrhage or infarction | 40 | 3.45% |
| 6 | Alzheimer's disease | 33 | 2.85% |
| 7 | Congestive heart failure | 32 | 2.76% |
| 8 | Diabetes mellitus | 30 | 2.59% |
| 9 | Bacterial pneumonia | 27 | 2.33% |
| 10 | Colon cancer | 25 | 2.16% |
| 11 | Atherosclerotic cardiovascular disease, so described | 25 | 2.16% |
| 12 | Breast Cancer | 24 | 2.07% |
| 2000 | | | |
| 1 | All other forms of chronic ischemic heart disease | 88 | 7.32% |
| 2 | Of trachea, bronchus and lung | 68 | 5.66% |
| 3 | Other chronic obstructive pulmonary disease | 61 | 5.07% |
| 4 | Acute myocardial infarction | 55 | 4.58% |
| 5 | Stroke, not specified as hemorrhage or infarction | 40 | 3.33% |
| 6 | Diabetes mellitus | 36 | 3.00% |
| 7 | Congestive heart failure | 36 | 3.00% |
| 8 | Breast Cancer | 33 | 2.75% |
| 9 | Other cerebrovascular diseases and their sequelae | 31 | 2.58% |
| 10 | Of other and unspecified sites | 27 | 2.25% |
| 2001 | | | |
| 1 | All other forms of chronic ischemic heart disease | 102 | 7.88% |
| 2 | Other chronic obstructive pulmonary disease | 88 | 6.80% |
| 3 | Acute myocardial infarction | 80 | 6.18% |
| 4 | Of trachea, bronchus and lung | 79 | 6.11% |
| 5 | Diabetes mellitus | 45 | 3.48% |
| 6 | Stroke, not specified as hemorrhage or infarction | 35 | 2.70% |
| 7 | Breast Cancer | 34 | 2.63% |
| 8 | Congestive heart failure | 34 | 2.63% |
| 9 | Accidental poisoning by and exposure to drugs and other bio | 28 | 2.16% |
| 10 | Alzheimer's disease | 27 | 2.09% |

Death from breast cancer occurred with increasing frequency over the data years under investigation, rising into the top-ten causes of death in 2000 – but is it significantly higher in HC than elsewhere?

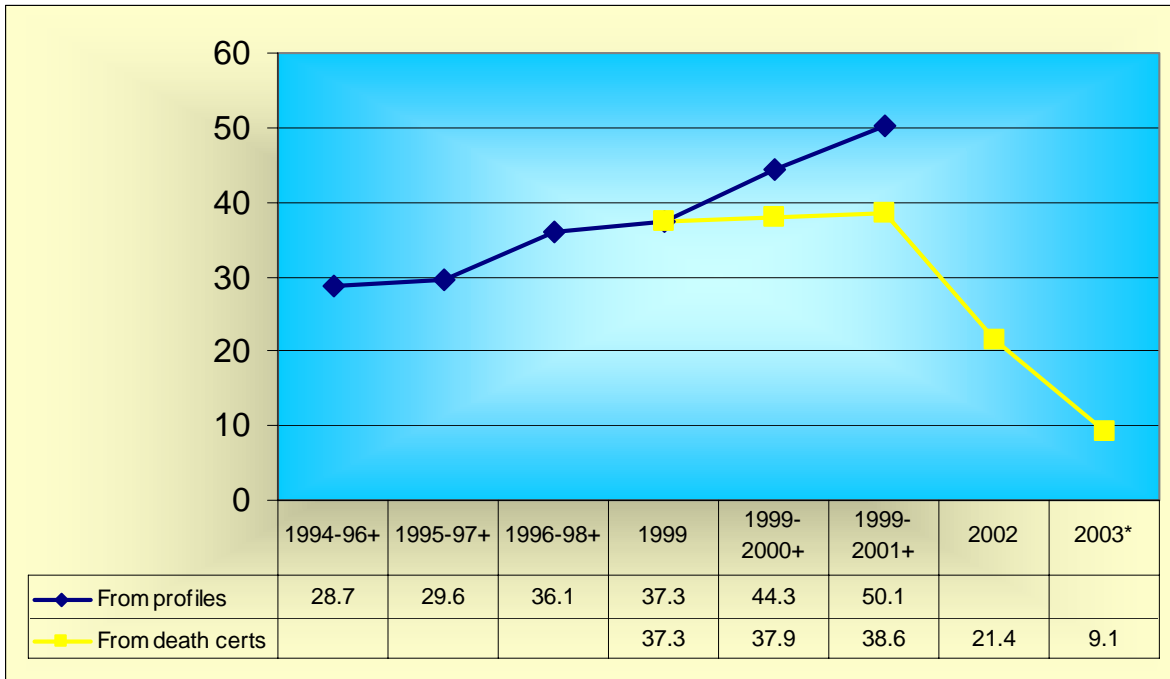
Hypothesis:
Breast cancer deaths in
Humboldt County occur at the
same rates as the Northern
California counties in Region 6.

Age Specific Mortality Rates, 1999-2001, from DHS data files



This chart shows the state mortality data, which is based on death certificates reported to the state by the counties. I pulled death certificates for breast cancer for all three years. Using the death certificates, I abstracted detailed data, beginning with the crude mortality rates...

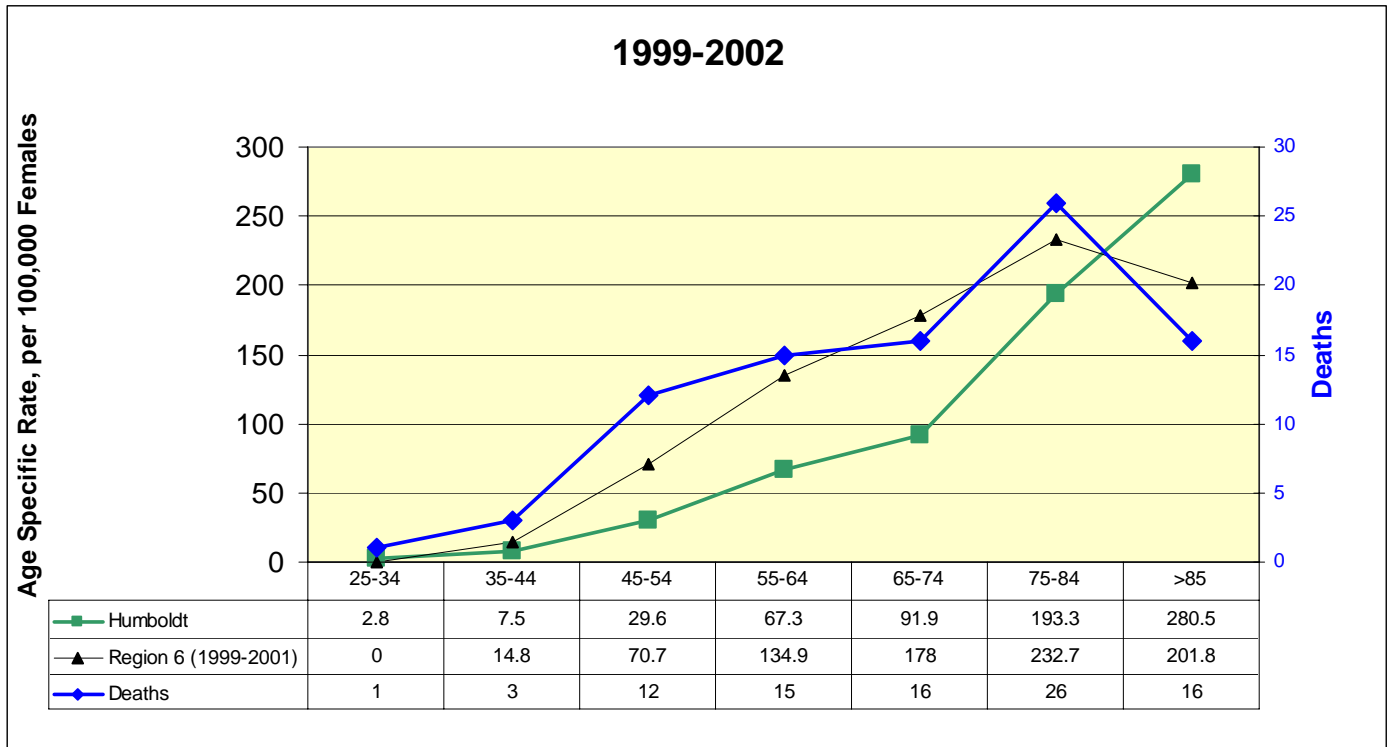
Crude Mortality Rates 1994-2003



...which I compared to the state master files, as well as previous years' rates, as reported in the County Health Profiles. What I found was that the numbers since 1999 don't match up, as can be seen here. I chose to be very conservative and classified deaths from breast cancer only if it was the immediate cause of death--and the numbers were much lower than are reported in the state's master files. Additionally, the rates for 2002 and 2003 have fallen. I inquired and have been awaiting response from the vital statistics section at DHS to determine what criteria they use to code deaths from breast cancer.

Given the different counts, I recalculated the age-strata rates...

Age Specific Mortality Rates, 1999-2002 from death certificates



...which don't paint as bleak a picture as before. Using this method, the county rates are much lower than the Region 6 rates (note the amended rates for Humboldt and the adjusted scale on the left of the chart above). Even the greater rate for the over-85 age group is not as profoundly higher as was shown in the DHS chart (page 22).