

**The Quality of Cancer Care:  
Does the Literature Support the Rhetoric?**

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## EXECUTIVE SUMMARY

A review of the medical literature since 1988 in most areas does not address quality of cancer care to any substantial extent. In general, the organization of U.S. cancer care is so diffuse and diverse that providers have not had to provide accountability for specific process or outcomes at their centers.

- Are their indicators of superior cancer care comparable to those in cardiovascular disease?

No. Management of coronary artery disease, hypertension, congestive heart failure, and atrial fibrillation are many times more prevalent than the most frequent cancers. These four conditions also involve a higher relative percent of all cardiovascular disease than does the four most common cancers. Further, short-term outcomes that are simple and inexpensive to measure, such as 30-day mortality, do not apply to most cancers. Therefore, it is not surprising that insurers and the federal government have initially targeted cardiac diseases. Oncology care is not a prominent element of managed care benchmarking indicators. Only breast cancer is of growing interest and no prospective data are yet reported. The SEER and National Cancer Database registries do not detail process of care indicators or evaluate known variables (hospital type, physician specialty or volume) often associated with better outcomes. Cancer disease management programs have been slow to develop. Quality gaps for all conditions were found in retrospective assessments in their process of care.

- Does it matter which type of hospital provides your surgical cancer care?

No. The type of hospital is not or less important than case volume. Strong evidence for a volume-outcome benefit was found for most cancers with high-risk surgery. At least 25% of hospitals should not be doing these procedures. For several of these cancers (pancreas, esophagus, and lung) the majority of new patients are diagnosed at a stage where resection is not beneficial. In the U.S., there is no evidence for or against a benefit with specialty interest or academic cancer center care for breast, colon or prostate cancer.

- Does it matter who and where you get your care if you have a curable cancer?

Yes, but this is only documented in a limited set of circumstances. Consistent strong evidence from U.S. and Europe that specialty centers have better survival and process of care for testicular and ovarian cancer. This was also true in a large but old study of Hodgkin's disease. No assessments of leukemia (without bone marrow transplantation), melanoma or sarcoma were found.

- For cancers that with a low long-term survival or from first detection of metastatic disease does it matter where or who provides care?

Probably not but we do not know! A dramatic lack of data addressing this question was found. The literature shows that age is the best predictor of active treatment independent of site of care.

- What effect does managed care have cancer care?

Little. No difference to better outcomes were found (n=4) at staff model HMOs for breast and colorectal cancer. Studies of other managed care structures have not been done or reported.

- Is evidence of superior care at a specialized cancer center?

Inconsistent. Many but not all studies have shown an advantage in care and no studies found a disadvantage from care at specialized centers. The interactions between volume and cancer-institutional focus on outcomes need to be addressed. The benefit from single-site multi-disciplinary clinics has face-validity but has not been systematically contrasted to other arrangements.

## CHARGE

This report is our response to the charge from the National Cancer Advisory Board to address the following questions:

1. What evidence is there of cancer care quality problems in the health services literature?

Is there evidence that practices of known effectiveness are being underutilized, practices of known ineffectiveness are being overutilized, and services of equivocal effectiveness being utilized in accordance with provider rather than patient preferences?

2. What evidence is there that aspects of the health care delivery system affect the quality of cancer care?

Quality indicators to be considered include those related to morbidity, mortality, and patient satisfaction. Intermediate indicators of quality care to be considered might include adherence to standard cancer care protocols/guidelines or utilization of services known to be associated with desirable outcomes. Does a review of the health services literature provide evidence, for example, that characteristics of providers, facilities, or delivery systems affect the quality of cancer care?

3. A number of cancer-related quality indicators are being monitored throughout the health system. What evidence is there that these indicators are valid and meaningful measures of quality cancer care?

In addition, we will comment upon the potential roles of organizations actively involved in the measurement and monitoring of cancer care, those factors identified that can be modified within the current decentralized multiplicity structure of U.S. health care.

## QUALITY CONCEPTS

The Institute of Medicine has been extensively involved in the setting the national agenda related to defining and evaluating “quality” in medical care. Given the breadth of the topic, we will only superficially skim the surface of the topic’s terrain necessary for our subsequent evaluation.

Numerous sources can be referenced for how quality of care should be defined. For our task, we find the one prepared by the IOM related to Medicare to be succinct and readily pertinent:

“Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired outcome and are consistent with current professional knowledge.”<sup>1</sup>

Within these area, four additional topics are commonly distinguished: 1) **Quality Measurement:** the science of evaluating quality, 2) **Quality Assessment:** testing those methods in a variety of

settings, populations, and conditions, 3) **Quality Improvement**: designing and testing provider-centered, patient-centered, or systems-centered interventions for improving quality and 4) **Decision support**: providing information about quality to help patients, providers, and purchasers make more informed decisions.

In this report, we focus the quality assessment. We indirectly will reference the “how” or measurement components relevant to cancer. The models of excellence and the practice guideline paper primarily address the quality improvement issue. The literature related to decision support techniques will not be addressed.

The classic three components of quality of care, first stressed by Donabedian, are **structure, process and outcome**.<sup>12</sup> This taxonomy can be applied to health care from a variety of perspectives which may or may not be all in alignment: the individual patient, the physician, the purchaser of health care benefits (employer), the organization paying for the health care benefits (insurer or government), or hospital. In general, this report uses the patient perspective. Specific attributes of quality care for an individual or by a system include:

- Technical quality of care

This will be the primary area addressed focusing on the appropriateness of the services, the skill in which they are performed, and selectively the outcome of patients

- Emphasis of health promotion and disease prevention

This will not be addressed. The reason is that the availability and use of primary cancer preventive or early detection efforts are predominantly or exclusively issues that are dependent on **primary care structure and not readily within the control of cancer providers**.

- Extent of informed participation of patients

Although there is an extensive literature related to quality of life in cancer and the accuracy of agreement in alternations between patients and providers, there is a modest literature addressing informed participation. The surveys or videotaping of patients are needed. This concern as been the impetus for selected indicators described later.

- Scientific foundation or evidence base supporting a specific practice

This will be addressed in the Clinical Practice Guidelines section.

- Efficient use of financial resources.

Beyond the scope of these commissioned papers.

Brooks has described five methods by which quality can be assessed on the basis of process data, outcome data or both.<sup>14</sup> The least satisfactory are **implicit reviews** usually of the medical record

or secondary data (insurance claim or registry) where no prior standards or agreement about good or better care exists. Preferred are evaluations using **explicit process criteria**, i.e. did a breast cancer patient have an estrogen receptor assay performed and its results acknowledged in the record, and the result expressed as the proportion that were met. This later step requires setting targets or benchmarks. As will be discussed, few examples were found where targets for specific process components or outcomes were assessed. The optimal assessment is to show an association or relationship between achieving the targets or ordinal descriptions (poor, fair, good) and subsequent outcome.

In general, physicians define quality of care in terms of process not outcome. For example, despite the best possible care “bad things can happen to good people” and some patients do well despite the lack or noncompliance with care. Nevertheless, in this report for many cancers a higher volume-better outcome effect will be described. What the specific processes that lead to superior outcomes at specific hospitals or physician specialties have not been deciphered. The standard logic is: structure will influence process, process will influence outcome, and therefore structure will influence outcome. The ability to routinely find meaningful differences in outcomes between health plans or hospitals for specific conditions is limited by current techniques to account for differences in case-mix, that is identification and weighting of socioeconomic and comorbidity factors. In this review, attempts to identify differences between organizational structures (hospitals, health plans, and physicians) in patient co-morbidity for a specific condition were unusual. In addition, the socioeconomic factors were either not measured or minimally explored by inference generally using census tract not patient specific data.

The development of clinical practice guidelines has been the first, largest, and most expensive activities related to quality. The source (government, insurers and professional societies) of the guidelines and the extent to which the guidelines are evidence based varies. These guidelines are usually generated from an external group to reduce the variation (either up or down) of care. Most guidelines provide the foundation for the explicit quality assessment of care but they rarely set benchmarks for care or anticipated changes in outcomes if they are followed.

The dominant force behind the current movement to “report cards” related to quality of care has been driven by large corporate purchasers of health care benefits under various managed care or HMOs. HMOs come in four basic categories of contracting: staff model, group, independent practice associations (IPAs), or network. In most of the country, the group and IPA models have the largest membership. In group model HMOs, the contract is between one or more group of practices while in IPAs or individual independent practice association, contracts are between many individual physicians and providers. Staff model HMOs where HMOs directly employ physicians and may directly own their own hospitals currently represent only about 15% of all HMO care. In the report, where HMOs have been the variable of interest, staff models were predominantly studied.

## CURRENT EFFORTS TO DEFINE CANCER CARE QUALITY INDICATORS

Managed care plans of all types have entrusted the selection of benchmark criteria to a quasi-independent trade group, the National Committee for Quality Assurance (NCQA). The HEDIS (Health Plan Employer Data and Information) 3.0 version is included as an attachment. It is the first NCQA effort to begin measuring process and outcomes of care that move beyond tracking predominantly preventive care insurance claims. In 1998, Medicare began requiring managed care plans to submit 1997 data. The health plans are required to begin reporting on some factors and to begin collecting a “test set.” These factors are categorized as indicators of effectiveness of care, access to care, satisfaction, health plan stability, use of selected services, costs of care, informed choices, and health plan description information. The effectiveness of care section addresses 40 actions or clinical situations and 8 of which relate to cancer. Of these four are not directly within the control of cancer provider (cervical, breast and colorectal cancer screening and breast cancer stage at presentation), two relate to the referral process (follow-up post abnormal pap or mammogram), and two directly relate to breast cancer therapy (function and satisfaction post treatment). Benchmarks for most metrics including these breast cancer treatments ones have not been set.

Although, the assessment components themselves do not clarify the factors accounting for a potential deficiency, the effort to measure them often indirectly leads to an organizational reappraisal of their practice. Whether actual behavior changes is discussed by the other report.

Over the last decade, The Joint Commission on the Accreditation of Health Care Organizations quality programs has been migrating from quality assurance to quality improvement. In a report from 1990, the JCAHO had 19 oncology care indicators in the initial development testing.<sup>63</sup> These have been reduced to only nine indicators (listed in the Appendix B). These indicators deal with breast, colon, and lung cancer and focus exclusively on the initial diagnosis and therapy.

What are most notable are the indicators that were dropped from the 1990 draft list to the current active or final listing. Reasons for dropping them on unknown. Potential reasons include serial assessments of the record (#1), evaluating old vs. new cases (#2), out-patient therapy (#3,4,5,7,8), requiring to define complications (#6), and detailed review of medical records for medical actions (vs. administrative claims) (#1, 2,6,8) or knowledge of disease stage (#1,2,3). Conversely for each of these reasons, these eight indicators would be valuable.

1. Rehospitalization within 6 months of initial therapy excluding chemotherapy or metastatic disease
2. Systematic assessment for pain in all patients hospitalized with metastatic disease
3. Adjuvant therapy for stage II breast cancer
4. BCS without radiotherapy
5. Referral to support or rehabilitation groups for primary breast cancer
6. Mediastinoscopy or transthoracic needle biopsy complication rate
7. Referral and consultation by a radiation oncologist if primary rectal cancer

## 8. Enterostomy care and management following for colorectal cancer.

The nine currently used indicators may require a review of the individual medical record but not direct patient interview. The “ORNX” accreditation program allows institutions to select among 60 performance measures. Such a multiple choice type program may rarely include oncology indicators given the current focus, frequency, and ease of measurement of many of cardiovascular quality indicators.

A point by point review of this nine indicators leads us to conclude that failure to meet these indicators more likely reflect unacceptable **deficiencies** in care rather than quality care. For example, having staging information documented in the chart and evidence that the managing physician is aware of a patient stage is by first principles a sound indicator. In addition, it is in agreement with the requirements of American College of Surgeon program for Cancer certification. The measurement and documentation of estrogen receptor status for primary breast cancer again is a minimal threshold. The ratio of patients undergoing a thoracotomy with complete resection is an effective indicator of preoperative staging but a target benchmark is not given or suggested. For colorectal cancer, a preoperative examination of the entire colon is an appropriate indicator for surgical quality. The frequency of emergent cases is probably less than 5% in the U.S.

The lack of interest in cancer treatment issues reflects the purchaser’s primary interest in prevention and cardiovascular disease. Medicare and individual states have focused their quality of care energies of vascular disease: coronary artery bypass graft, management of acute myocardial infarctions, congestive heart failure, and stroke. Benchmarking studies and variation in hospital mortality for each of these has been published. The first oncology focus of Medicare will be breast cancer.

The Foundation for Accountability (FACCT) has developed outcome measure sets for several conditions one of which is breast cancer. The eight quality indicators were defined principally by Dr. Patti Ganz of UCLA/Rand (listed in Appendix C) The Health Care Financing Administration is considering requiring its managed care plans to submit data on performance measures for breast cancer, depression and diabetes. HCFA has also contracted with RAND to review, assess and evaluate the feasibility, reliability, and validity of performance measures for these conditions. Dr. Katherine Kahn is leading the breast cancer component evaluation of their potential use. The FACCT assessment is dominated by factors related to a woman’s cancer care choices, satisfaction and experiences with the disease. 5-year disease free survival is the sole outcome of interest. Health plans will need to identify and survey these women in order to comply

Many managed care companies have embraced efforts to manage specific high-cost, high-volume diseases using a “disease management” approach. Diabetes, asthma, and congestive heart failure are the most frequent. For each of these conditions, improved process and outcomes have been or expected to be achieved due to the mixing of practice guidelines, expanding the access (home visits and intense telephone follow-up) to non-physician health care providers, and the physician expertise.

After an initial burst of interest, oncology programs have been slow in their growth for a variety of reasons. One prominent limitation is that cancer is not one disease but hundreds of conditions. Another is the diversity of types of physicians and forms of treatment involved in providing cancer care. Unfortunately, the majority of patients with several common cancers (e.g., lung, ovarian, pancreas) present with metastatic disease. Therefore the model of disease management of preventing complications or progression is not applicable. Disease management programs are perceived to be a direct threat to physician incomes. This is especially true for medical and radiation oncologist. Given that chemotherapy is the largest non-procedural commodity sold in the U.S. and that most current guidelines restrict, rather than expand, the indications for chemotherapy, it is no surprise such programs are unwelcome.

## **IDENTIFICATION AND DESCRIPTION OF INFORMATION SOURCES**

Our review of the published literature related to the broad area of quality of cancer care is primarily based on published medical literature that is cited in Medline. We did not search the popular press, health insurance trade publications, medical “throw-away”, or administrative datasets.

The details of the search terms that we utilized are listed in the following table. We limited our assessment to reports published since 1988. Two prominent categories of papers were excluded (section B): reports related to screening or early detection efforts and surveys of physician attitudes or practices based on hypothetical patients described in written or video vignettes. Surveys of cancer patients who were currently or previously under treatment or reports using survey requests for specific individual patients were included.

Each of the medline search terms (section A) was used with the individual cancer terms (section C). In addition, the bibliography of each paper was reviewed for other citations that were subsequently reviewed. For selected papers, a Science Citation Index search of subsequent citations was tracked looking for more recent reports.

In a non-systematic manner, a variety of Internet sites of patient advocacy or information sources for individual cancers were pursued. The quality activities of the JCAHO, NCQA, FACCT related to cancer were abstracted from their Internet sites. The CONQUEST (Computerized Needs-Oriented Quality Measurement Evaluation System) version 1.1 maintained by the Agency for Health Care Policy and Research, the reports of the General Accounting Office, and the statements related to “quality” from the National Cancer Institute and the American Society of Clinical Oncology were reviewed and selectively abstracted.

These reports were subsequently categorized (see Section D) and are all listed in the Appendix. Major categories were type of cancer, outcome vs. process, methodology, year, unit of analysis, and variables. In addition, we assigned arbitrary impact scores (\*\* highest, \* high). Not all of these papers are discussed in the subsequent text.

## REGISTRIES: A NECESSARY RESOURCE FOR ADDRESSING CANCER QUALITY

The two overlapping data sources that provide a national perspective on the incidence, survival and, with varying completeness, treatment on cancer are the Surveillance, Epidemiology and End Results (SEER) program and the National Cancer Database (NCDB), a joint venture of the American College of Surgeons and the American Cancer Society. The SEER registry covers nine different regions or states of the United States and reports on about 14% of the population. The NCDB is a voluntary reporting system over 1,700 hospitals. Appendix E lists the characteristics of the NCDB hospitals from 1994.

These two sources have been compared for their completeness and representativeness of the United States population for breast, colon, lung and prostate cancer.<sup>70</sup> Both are hospital based. In 1992, patient age, race, and gender minimally differed between them. SEER provides more detail and patients of Hispanic, Asian, or American Indian heritage. Details about cancer characteristics and types of surgical treatment were generally very similar usually differing by less than one percent for most common treatments. We concur with the conclusion that the NCDB describes patient and disease treatment characteristics and patterns that differed only marginally from those described in the SEER data from the same year. This is important since the NCDB currently collects details between 50-60% of all cancers in the U.S. Therefore, it is approaching the population-based characteristics already present in the SEER data.

In this report, we extensively rely upon reports using these sources as an integral part of their quality assessments. Generally, the registries provide the clinical stage information to allow “apples to apples” comparisons. Selectively, we highlight where the opportunity currently exists but has not been exploited to assess variation in care associated with variables already in these respective databases. In general, we believe the opportunities are especially rich for NCDB. As Herman Menck, the director of NCDB, recently stated:

With its maturation, the NCDB now is a tool for quality assurance. The size of the database allows for the creation of "norms" of care, which are the means of resource utilization, therapy options, or survival outcomes. These norms can be applied by the local cancer program to determine whether the level of cancer care offered meets these norms. This is important because guidelines are currently offered by the National Institutes of Health (as consensus conferences) and organizations such as the ACS, the American Society for Clinical Oncology, and others that recommend how care is to be offered by physicians and surgeons to patients.<sup>68</sup>

To foreshadow one of our results, we could find only one example (adjuvant chemotherapy for stage III colon cancer) where the NCDB has looked at quality of care in its database. Currently, the NCDB has not explored cancer care organizational factors associated with superior care in general or for greater frequency of this single example.

## OVERVIEW REPORTS OF VARIATION AND QUALITY IN THE U.S.

Since there is no single agency focused on the quality of cancer (or any medical) care, a variety of investigators and funding sources have done assessments in the U.S. In this introductory section, only studies that considered more than one cancer are discussed.

### ***SEER Survival***

Due to well documented geographic variation in breast conserving surgery and radical prostatectomy, Farrow evaluated the SEER registry database for potential differences in survival for nine common cancers using the geographic location of the nine individual registries as the unit of evaluation for cancers diagnosed in 1983-1991.<sup>21</sup> Five-year survival was assessed after stratifying for patient age (ten year intervals beginning at 55 years, gender, stage (local, regional, distant or unstaged), and race. In the left column of the table, the relative risk of death across the nine SEER sites adjusted for sex, age and stage, in the middle when the comparisons were limited to younger patients with local disease who had a surgical therapy and at the far right the overall age unadjusted five year survivals.

### **5-year Survival Comparisons across the 9 SEER sites 1983-1991**

Cancer Site	Relative Risk of Death Across SEER sites All patients adjusted for sex, age, and stage	Relative Risk of Death Local Disease, age <70, and adjusted for surgical treatment	Range of 5-year Survivals Across SEER sites For All non-Hispanic Whites (unadjusted for stage)
Stomach	0.89-1.21	0.69-1.32	10.0-14.9
Colon	0.90-1.10	0.87-1.15	47.1-51.7
Rectum	0.91-1.09	0.76-1.17	47.0-52.4
Lung	0.93-1.12	0.74-1.19	10.9-16.1
Breast	0.82-1.11	0.64-1.34	71.1-79.9
Uterus	0.81-1.21	0.84-1.26	73.2-83.2
Ovary	0.91-1.08	0.82-1.16	34.1-39.2
Prostate	0.84-1.12	0.70-1.20	51.9-64.0
Bladder	0.91-1.15	0.84-1.16	58.4-64.2

For all cancers other than ovary and bladder, one or more regions were found whose survival rates significantly differed from the overall mean survival. These differences persisted and were even more pronounced when the analysis was limited to patients age less than 70 with local stage surgically treated disease. This suggests but does not confirm that the effect and extent of patient co-morbidity across regions is not the primary source of these differences.

The authors drew ambiguous conclusions from these results. On the one hand they comment “the observed variation between geographic areas, although statistically significant, were relatively modest from the standpoint of the practicing physician” and the other hand “this analysis suggests that survival after the diagnosis of cancer varies substantially across the United States.” In

addition, they noted that the variation was not due to differences in the percentage of cases presenting with stage III or IV disease. For five (rectal, lung, breast, uterus, bladder) of the nine cancers, 5-year survivals were higher in Hawaii than in any other regions.

The impact of this paper, based on the modest number of Science Citation Index citations, has been only modest. It highlights the need for further investigation into exploring social-economic, cultural, health care organizational and provider factors explaining these differences. For example, from the lowest to highest SEER locations the five-year relative death rates with limited disease (the middle column of the table) are over 100% and 70% different for breast and prostate cancer, respectively!

### **General Accounting Office**

In 1987 at the request of Representative Henry Waxman, the General Accounting Office (GAO) initiated an analysis that focused on the number of American cancer patients who were clinically eligible to receive state-of-the-art treatments but did not receive it.<sup>26</sup>

In the report, the GAO examined the usage patterns of seven specific "breakthrough" cancer treatment between 1975 and 1985: adjuvant chemotherapy for breast cancer, adjuvant chemotherapy for colon cancer, adjuvant radiation therapy for rectum cancer, chemotherapy for small-cell lung cancer, chemotherapy for testicular cancer, chemotherapy for Hodgkin's disease; and chemotherapy for non-Hodgkin's lymphoma. The selection of these treatments was done in consultation with the NCI. Using SEER data for these years, the GAO performed a relatively easy abstraction of the SEER database and examined the percentage of those patients who **did not** receive the treatments in question and graphically showed the annual temporal trends. For this report, the SEER treatment data fields of "given" and "planned" were combined as "given." The below table lists the findings from the most recent year evaluated (1985). It shows considerable variation in usage of these innovative therapies. The use of radiation therapy for rectum cancer was increasing, while the use of chemotherapy for colon cancer decreasing.

### **Selected Results from 1987 General Accounting Report**

Innovative Therapy	In 1985, Percent Treated of all Eligible Patients per SEER
Adjuvant chemotherapy for breast cancer (pre-menopausal node positive)	63%
Adjuvant chemotherapy for node positive colon cancer	6%
Adjuvant radiation therapy for rectum cancer	40%
Chemotherapy for limited small-cell lung cancer	75%
Chemotherapy for non-seminoma testicular cancer	50%
Chemotherapy for stage IIIB or IV Hodgkin's disease	90%
Chemotherapy for diffuse intermediate or high grade non-Hodgkin's lymphoma	80%*

\*(10% drop from 1979 to 1985)

The GAO concluded that these results were particularly troubling “in that all these treatments have been proven to extend patients’ survival in controlled experiments, many of which were concluded 10 or more years ago.” No details or analysis attempting to identify specific features of the health care system that did better or worse at providing state of the art care. In our opinion, this report can be primarily viewed as commentary about the slow rate of diffusion of innovation of cancer care during this interval; which predated ready electronic access to Medline and other electronic media of all types including the Internet.

### ***Community Oncology Programs***

The Clinical Hospital Oncology Programs and subsequently the Community Clinical Oncology Program (CCOP) were initiated in early 1980s to expand the access to state of the art cancer care. A more extensive discussion of these programs is included in the clinical practice guideline manuscript. Two reports from these programs are noteworthy because they evaluated more than one cancer and compared participating and non-participating physicians. Unfortunately, no descriptions of care of patients newly presenting with metastatic disease were either done or reported.

Ford evaluated the effect within community hospital oncology program of the use of clinical practice guidelines at seventeen sites from 1982 to 1984.<sup>25</sup> Data were abstracted from newly diagnosed breast (n=1,922), rectal (n=592), and small cell lung (n=388) cancer patients. The “gold standard” was that all breast and lung cancer patients would have clinical staging before definitive therapy, and all but lymph node negative breast cancer patients have a radiation therapy consultation. Using a chart audit approach, they found documentation of **any clinical staging** ranged from 3% to 90%, and only 33% of all charts had clinical stage noted before definitive therapy. For breast cancer women with positive lymph nodes, 73% had a medical oncology consultation. For rectal cancer patients, only 27% had a radiation therapy consultation. For the small-cell lung cancer patients, 67% had clinical staging but only 50% had a radiation therapy consultation.

Kaluzny has reported subsequent comparison of care between oncologists who participated in the community cancer trial network versus other oncologists in 1987-1990.<sup>52</sup> The evaluation focused exclusively on adjuvant therapies. Unfortunately, basic details such as the number of physician involved and patient records reviewed are not listed in this publication. (Only available in the final report to the NCI) Patients of CCOP physicians more likely to receive adjuvant treatments for breast, colon and rectal cancers. Only for breast cancer were specific differences listed: for node negative, estrogen receptor negative breast cancer in women age <49: in 1983, 27% vs. in 1989, 74% were given chemotherapy; and node negative breast cancer women age >50, in 1983 14% vs. in 1989, 63% received some form of adjuvant therapy. Women treated not treated by CCOP physicians were less likely to receive these therapies (percentages not given).

Given the size of the CCOP program (13 years in over 30 states, 250 hospitals and 100 group practices) it was disappointing to find so little peer-reviewed published reports directly or indirectly addressing changes in community practice patterns from the program. A more extensive

commentary of these programs is included in the clinical practice guideline manuscript.

## BREAST CANCER

Given its high incidence and the associated extent of patient advocacy, breast cancer has generated the most controversy about quality of its care. In the U.S., these discussions and research have primarily focused on the evaluation of factors associated with breast conserving surgery (BCS) compared to mastectomy.

### **Outcome--United States**

Excluding studies of uninsured woman, since 1988 only two U.S. studies were found addressing health system or specialty associated factors with breast cancer survival. Lee-Feldstein evaluated a cohort of 5,892 non-Hispanic white women diagnosed in 1984-90 in Orange County, California who were treated at four categories of hospital (small community, average census <200; large community, average census > 200; HMO' average census not reported, or teaching, average census not reported).<sup>59</sup> Orange County is a SEER cancer registry site, which contributed stage-specific information. A major limitation on this report is that about 15% of patients axillary nodal status was unknown and information about the use and type of adjuvant therapy was not reported probably since it was not available.

The impact of patient insurance or comorbidity was **not included** in the variables analyzed. The use of BCS compared to mastectomy markedly varied between hospital type: 40-70% at teaching hospitals depending on the year but only about 25% at community hospitals. The multivariate results are shown below.

### **Multi-variant Survival in White Women from Orange County, California Diagnosed in 1984-90**

	N, Local	RR of Death, 95% C.I., local	N, regional	RR of Death, 95% C.I., Regional
Primary Therapy				
BCS	282	2.34 (1.55-3.55)	94	1.92 (1.13-3.27)
BCS+XRT	665	1.00	237	1.00
Total mastectomy	2799	1.45 (1.06-1.99)	1798	1.44 (1.00-2.06)
Hospital type				
Small	2273	1.00	1327	1.00
Large	889	0.74 (0.59-0.91)	464	0.74 (0.60-0.91)
HMO	380	1.63 (1.16-2.30)	200	0.94 (0.66-1.34)
Teaching	204	0.96 (0.54-1.68)	155	0.78 (0.52-1.16)
Axillary nodes				
0	3160	1.00	105	1.20
1-3	22	2.06	957	1.00
>4	12	1.88	848	1.99
Unknown	552	2.21	236	2.87

On first appearance, this study would suggest that care was associated with better survival at larger hospitals and worse survival at HMOs. However, the study did not control for insurance

type, comorbidity or any indicator of social-economic status. Therefore, making such conclusions are weakened especially in light of the finding of a 45% increased risk of death between patients having a total mastectomy compared to BCS after controlling for axillary nodal involvement. Such differences are contrary to the numerous other clinical trial and population studies suggesting no differences between the types of surgery after controlling for axillary nodal involvement. It is more likely these women had substantial unmeasured co-morbidity, incomplete staging, unexplained contradictions, or social-economic barriers and attitudes towards adjuvant therapy. In addition, it is not reported if the distribution of women with unknown axillary node varied with type of hospital type. This paper generated a series of letters related to its results including skepticism of the completeness of ascertainment given the survival rates.

Potosky recently reported a comparison of elderly woman cared for in the Seattle and San Francisco areas that were treated either under traditional fee for service Medicare vs. a group model (Kaiser Permanente) or staff model HMO (Group Health).<sup>90</sup> Almost 11,000 new breast cancer cases from 1985-92 were identified by SEER registry data. SEER data provided the clinical characteristics and using these patient identifiers were subsequently linked to Medicare claims using a method described in other sections.

The stage distribution at initial diagnosis was much more favorable in the HMOs. Almost half of the HMOs had stage I disease compared to 43% and 37% of FFS patients in Seattle and San Francisco. Comorbidity scores were higher for FFS compared to HMO cases in both locations.

The table below shows the key results after adjusting for stage, age, race and comorbidity. Five year and 10-year survival were markedly better in the HMOs in overall survival especially in San Francisco with relative 30% greater survival. The survival benefit in San Francisco was noted for all age categories (65-69,70-74,75+) and AJCC stages I, II and unstaged. In Seattle, for each subgroup of age or stage categories HMO care was never worse than FFS. The process variables related to the use of BCS with or without radiation therapy showed markedly higher use in the HMOs. No data on the use of adjuvant therapies especially for stage II disease were reported. Given the size of the survival benefit, these findings are being flaunted in support of HMO care.

### **Outcome and Process Risk Ratios Comparing HMO vs. FFS for Elderly Woman with Breast Cancer by Location**

Endpoint	S.F-Oakland	Seattle-Puget Sound
Outcome		
10-year Overall Survival*	0.70 (0.62-0.79)	0.86 (0.72-1.03)
10-year Breast Cancer* survival	0.71 (0.59-0.87)	1.01 (0.77-1.76)
Process		
BCS	1.55 (1.35-1.77)	3.39 (2.76-4.17)
XRT post BCS	2.49 (1.95-3.19)	4.62 (3.20-6.66)

Reference group is fee for service care. Outcomes ratio less than one indicates greater survival and process ratios greater than indicate more frequent desired care.

\*Adjusted for age, race, census tract education and income, comorbidity and stage.

## **Process--United States**

### *Breast Conserving Surgery*

The literature is too extensive to be easily summarized related to the factors and temporal trends associated with the use of breast conserving surgery (BCS) versus total mastectomy for early stage breast cancer. The original NSABP studies, the subsequent independent audit of the clinical trials, an international Meta-analysis and an evaluation of the national sample reported to NCDB have each found no difference between the two therapies in overall survival.<sup>2,23,109</sup> The importance of this observation cannot be overemphasized: differences in the use of BCS reflect a mixture of clinical indications, provider and patient characteristics which commonly affect quality of life but not survival.

The same factors known to be associated with the greater use of BCS have been relatively consistently been found across studies. These factors also generally persist in studies limited to Medicare eligible (age >65) women compared to studies of all ages. The factors associated with greater use of BCS are:<sup>21,58,76 5</sup>

- 1) Patient socio-demographics: younger age, greater education and income (by census tract),
- 2) Clinical characteristics: smaller lesions (tumor size) and axillary node negative
- 3) Hospital characteristics: urban, teaching affiliation, larger size, on-site radiation therapy
- 4) Geographic location: more in the Northeast versus South.

Especially in the elderly, the dominant factor associated with mastectomy is age and to a lesser extent comorbidity. In only one study after controlling for other factors was race modestly associated with under-use of BCS.<sup>5</sup> For other factors that may influence the use of BCS, little data from the U.S. could be found: 1) a surgeon's workload (breast cancer or cancer specific) 2) surgeon's specialty interest 3) type of insurance and 4) concurrent use and extent of axillary node dissection.

Of these only insurance has had any evaluation. As previously noted, BCS was much more frequently performed in the California and Seattle area group or staff-model HMOs. The effect of IPA or network HMOs has not been studied. The only study contrasting traditional fee for service private insurance with public insurance was done by Young who compared the frequency in southeastern Pennsylvania prior to it having substantial HMO-type of insurance across all age groups.<sup>111</sup> She found that in 1986-1990 of eligible women to have BCS about 37% of all women and about 50% of woman age <60 had this type of surgery. What was surprising was that no differences were seen between younger BCBS insured and Medicare woman, about 80% in each group, received XRT. Only about 45% of Medicaid insured had XRT. Since no controlling or adjustment for socioeconomic factors was attempted, the source of the differences can only be speculated. Results limited to 1990 are shown below.

### **Breast Conserving Surgery and Radiation Use in SE Pennsylvania in 1990**

BCS	XRT post BCS
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BCBS	51.1%	79.9%
Medicaid	43.6%	60.0%
Medicare	36.9%	80.6%

Guadagnoli evaluated the use of BCS across a cross-section of woman in Minnesota and Massachusetts from 1993 to 1995.<sup>36</sup> In general, the process indicators of care were all substantially improved compared to those found in assessments from mid to late 1980s. This study was expensive since it used an individualized chart review for clinical eligibility and patient interviews. The authors suggest that the much higher rates of BCS reflect either a change in practice or an under-estimating of BCS in the prior studies since clinical stage was not available may have falsely raised the denominator of these reports. It is unclear from the manuscript, if the factors correlated were hypothesis driven or exploratory.

About 1600 women were interviewed. 27% in Minnesota and 15% in Massachusetts who underwent mastectomy and who were eligible for BCS reported that **their surgeon did not discuss** BCS with them. Of women offered both treatments and choosing mastectomy, 81-83% did so based on the fear that removal of the lump only would not “get it all.” For women who underwent BCS, 83-85% the primary reason was that their surgeon recommended it.

### BCS in Two States for Stage I and II Breast Cancer, 1993-1995

	Massachusetts	Minnesota
Overall BCS rate	64%	38%
Eligible for BCS	74%	48%
XRT post BCS	84%	86%
BCS if age 65-79	68%	45%
	Odds Ratio and 95% C.I. for BCS	Odds Ratio and 95% C.I. for BCS
HMO member	1.4 (0.9-1.9)	0.9 (0.7-1.4)
Male surgeon	0.6 (0.3-1.0)	0.6 (0.4-1.1)
Board certified surgeon	1.1 (0.7-1.8)	1.6 (0.8-3.3)
American College Surgeon’s approved Cancer program	1.6 (0.9-3.0)	1.5 (0.9-2.3)
Teaching hospital	2.4 (1.3-4.6)	1.5 (0.7-3.1)

### Staging and Adjuvant therapies

Use and type of adjuvant therapy does make a difference in survival, in contrast to which type of surgery is performed. Both SEER and NCDB have tracked the temporal trends to increased use of adjuvant therapies. However, these reports rarely look at physician or delivery system indicators associated with their use. In addition, detailed process of care evaluation related to the reporting of estrogen receptor status, the use, extent, and complications of axillary node dissection, and the duration of hormonal and type of chemotherapy are not discernable.

Results from three 1980s U.S. assessments of data are shown below. Hand studied the patterns of care using Illinois cancer registry data and focused on defining hospital characteristics associated with performance defined as greater frequency of actions.<sup>38</sup> This report did not include a breakdown by patient age or how often tumor size was reported. He found that late stage (IIB-IV) was associated with urban (primarily Chicago) location, percent of poorly insured patients, and low breast cancer case volume. A second comparison source is abstracted from the NCDB 1992 report which included no stratification by hospital or location.<sup>82</sup> The third is a report from our group of an assessment of linked Virginia Cancer Registry and Medicare claims.<sup>44</sup> This study was similar to others in that age was the most consistent factor in staging and axillary node involvement predictive of adjuvant therapy. However the absolute rate of adjuvant therapy in the elderly in these years was low. Changes in the relative frequency for these process indicators have all show improvement in the 1990s (see next section)

### **Quality Process Deficiencies in Initial Breast Cancer Care in the 1980s**

Variable (stage)	Illinois All Ages, 1988	Virginia Age >65, 1985-89	NCDB All ages, 1988
No tumor size (I and II)	not reported	24%	23%
No estrogen receptors	11%	not reported	not reported
No lymph node dissection	9%	24%	18%
Adjuvant therapy (II)	56%	44%	49%
XRT post BCS	52%	46%	not reported
Metastatic Disease at presentation	5%	8%	5%

#### *1990s Staging and Pathology Reporting*

Breast cancer has routinely been the most completely staged on the common cancers. The temporal trend to more complete AJCC staging, that is required for American College of Surgeon cancer center certification, is also seen for breast cancer (see Appendix E). In 1994, breast cancer had the highest rate of AJCC staging at 94% of all common cancers.<sup>24</sup> Predictors of adjuvant therapy (stage, tumor size, nodes, age, and type of primary therapy) by type of hospital or geographic region have not been reported by the NCDB: for example; the type and frequency of adjuvant therapy for node positive women by hospital size.

The use of bone scans and imaging for liver metastases has been shown to have a low yield in clinical stage I and II disease in numerous studies. However, these are commonly done as standard of initial evaluation and often in subsequent follow-up care. For example, our group evaluated a variety of processes of care component including staging in 936 commercially insured women under the age 65. We noted 42% of women in Virginia in 1989-91 had peri-operative bone scans with stage I or II breast cancer.<sup>43</sup> No studies associating physician characteristics with this over use were found.

The College of American Pathologists has prepared an extensive series of recommendations on the processing and reporting of cancer associated surgical pathology specimens. In few areas has the actual practice been audited and/or compared to the published guidelines. For breast cancer

the guidelines were published in 1995 and 1997.<sup>3,40</sup> A separate initiative of the College of American Pathology is its “Q-Probe” quality improvement program. A recent report evaluated the reporting of 7,300-breast biopsy (not just cancer) specimens done in 1995 at 434 laboratories.<sup>75</sup> Although no benchmarks have been established, we concur with the authors that the content adequacy is poor especially in light of clinician expectations. They found that the use of a checklist was associated with more complete reporting (also true for other cancers). In a separate single center report, Hammond described how her hospital reduced from 15% to less than 1% over 5 years, the frequency of inadequate pathology reports using a checklist.<sup>37</sup>

### **1995 Q-Probe Audit of Pathology Reports of Breast Biopsies**

Action	Performed and Documented
Specimens received without fixative	83%
Specimen radiograph	83%
Tissue marked	82%
Blocks (Lesion/Specimen)	3/6
Documentation of mammographic abnormality and microscopy	62%
Tumor size/grade/extent intraductal component if malignant	77%/83%/76%
Estrogen/Progesterone receptor studies	75%

### *Adjuvant Therapy*

Johnson evaluated temporal trends for adjuvant therapy from 1983 to 1989 to evaluate the effect of the 1988 NIH clinical alert regarding treatment of node-negative disease.<sup>50</sup> Patient level information was abstracted from random samples of records at Community clinical oncology program sites (CCOP) and non-CCOP sites. Both office-based and hospital records were reviewed. Unfortunately, no stratification by CCOP/non-CCOP of the patient characteristics, consultation frequency or treatment patterns is reported. The patients were about 49% age less than 50, about 65% tumor size less than 30 mm, about 20% ER status unknown, and 28% of node negative and 54% of node positive patients known to see a medical oncologist.

The study showed a clear temporal effect of increased use of adjuvant therapies greatest in the node negative group. By the end of 1989, about 50% of node negative and 85-90% of node positive women received an adjuvant treatment. Women seen by a medical oncologist with node negative disease were about twice as likely to be treated. Any effect of an oncologist focusing on breast cancer was not addressed.

A second report from Guadagnoli restricted to Minnesota women addressed the use of adjuvant therapy.<sup>35</sup> Of the 746 post-menopausal (age >50) women evaluated 13% did not undergo axillary node dissection. Not having an axillary node dissection was associated with age >85, comorbidity and HMO insurance. Facts concerning the use and type of adjuvant therapy were obtained by interview for over 70% and the remainder by tumor registry, record review or surgeon. 62% of all node-negative and 92% of node-positive woman received an adjuvant therapy. The use of hormonal therapy increased with age and the likelihood of receiving

chemotherapy declined with age. These results from one state are contrary to the other reports that older women are under-treated.

### *Dose, Duration, and Adherence to Schedule*

Outside of clinical trials, no reports were found that addresses the patterns of use of individual chemotherapeutic combinations: the specific agents, their dosage or number of cycles outside of clinical trials. This is also true for the dose and duration of tamoxifen the primary hormonal therapy. We know that pharmaceutical marketing groups routinely track these trends for “market penetration”, sales projections and pricing.

Only one study for any cancer (excluding clinical trials) addressed adherence to combination chemotherapy. The maxim “more is better” can be traced to the Bonadonna report from 1981 showing that 85% of intended dose was necessary to achieve maximal benefit.<sup>13</sup> In addition, in this trial setting over half the patients did not receive full dosing for factors other than toxicity. Schleifer audited the care of 107 women with breast cancer in 1988-89 by 29 oncologists at 3 university-affiliated practices.<sup>98</sup> Adjuvant therapy over six months was retrospectively reviewed and patients were prospectively interviewed. 52% of patients had at least one unjustified dose reduction. The total dose intensity of the woman who had dose reductions was not reported. Older woman and treatment in a “clinic” vs. academic or private practice were associated with non-adherence to the treatment schedule.

### *Radiation therapy*

The American College of Radiology supported by the National Cancer Institute contracts conducts ongoing Patterns of Care Studies for a variety of cancers. In these reports individual charts are audited at **voluntary participating** radiation therapy centers center who **submit** patient names to be reviewed. If these selected patients could be biased or truly representative group of all patients at a given center cannot be readily determined from the reports. The two reports since published since 1988 address actual radiation care for breast cancer: a process survey in 1983 and treatment planning in 1989.<sup>57,102</sup> The centers were randomly selected from five strata: a) RTOG full member or comprehensive cancer center; b) centers having two or more residents but not meeting definition a, c) centers with >600 new patients per year but not meeting definition a or b; d) centers with 200-600 new patients and e) <200 new patients per year. All centers had to have a full time chief. The reports states the sample was statistically representative of the national averages.

In the 1983 study, each center submitted five to ten names (based on size) to be audited and a total of 191 patients were reported. A wide variation in the technical delivery of the radiation field and doses were used but no systematic difference across radiation therapy sites was found. The investigators developed a weighted sum process score, which averaged 85% across all sites. The one glaring quality gap was that 53% of axillary node negative woman, who did not need axillary radiation, received it.

The 1989 treatment planning study evaluated 449 patients found a generally consistent approach and no meaningful differences between academic, hospital, and freestanding facilities except for the rate of patient immobilization usually with an arm board. Factors evaluated included immobilization techniques, dose distribution and boost techniques, beam modification and avoiding lung volume.

### *Multiple Components of Initial Care*

Hillner evaluate multiple dimensions of initial breast cancer care that he stratified by evaluation, treatment, staging, adjuvant therapy, referral and follow-up of 983 women with early breast cancer under the age of 65 insured by the Virginia Blues.<sup>43</sup> He proposed a 12-point scorecard and expert opinion targets for each point. (Appendix F) He found that in cases diagnosed between 1989-1991 evidence of over and under use of procedures and referrals to other providers. A reassuring finding was that claims for at least one cycle of chemotherapy were found for 83% of pre-menopausal, node positive women.

Numerous surveys have addressed physician surveillance attitudes but few studies have audited actual practice. Hillner in the above study found that in the first three years after definitive surgery, only 81% of women had a mammogram; 76% in the first 18 months and 66% in the second 18 months. The use of diagnostic imaging varied minimally with time. Within 36 months, 34% of women had a bone scan and 21% a CT scan. For each of the 18-month periods, approximately 24% of women had one or more bone scans and 14% had a CT scan of some type. During the same period, Simon tracked for three years 222 women treated and followed at one university hospital.<sup>100</sup> In the first year, patients treated with radiation or followed by medical oncology had the most frequent visits and intensity of testing. Wide variation in practice unexplained by patient and/or provider characteristics was noted.

### *Inflammatory and Metastatic Breast Cancer*

In contrast, to the previously discussed extensive literature, no studies were found related to physician, hospital or health system predictors of evaluation and treatment for stage III or IV breast cancer. In particular no reports addressing predictors of type of first-line, second-line, or stopping rules for metastatic disease were found. Benner, as part of an attempt at developing a practice guideline for second-line chemotherapy in metastatic disease, surveyed Maryland oncologists and found marked variation in their attitudes.<sup>9</sup>

### ***The Rest of the World***

#### *Britain*

Numerous studies for Britain have audited the process and outcome of woman with breast cancer. These studies have used the surgeon and the individual hospital as the evaluation unit for variation. These results have lead to an extensive review and restructuring of cancer services in the United Kingdom.<sup>99,103</sup>

Sainsbury evaluated breast cancer care between 1979-1988 in Yorkshire (population 3.6 million).<sup>94</sup> He evaluated the five-year survival between districts in the region and the individual surgeon. The analysis consisted of 12,861 cases treated by surgery with “curative intent.” Patients were stratified by decade of age, affluence/social deprivation by census track, axillary nodes (yes, no) and histologic grade. He found there was no difference in survival between patients treated by consultants seeing <10 and 10-29 cases per year but if the consultants saw >30 cases per year the adjusted risk of death at 5-years was 0.85 (0.77-0.93). About 50% of patients were seen by high volume (>30 cases) surgeons. After controlling for case-mix and clinical variables, variation among the consultants accounted for about an absolute 8% difference in survival. This benefit was principally due to the greater use of chemotherapy. Financial deprivation (by census track) adjusted for clinical stage was associated with a poorer survival (relative risk 1.16, C.I. 1.10-1.22)

Gilles performed a similar assessment in western Scotland of breast cancer care in women that were diagnosed between 1980-1988.<sup>27</sup> Surgeons were characterized as “specialists” if they were involved in a dedicated breast clinic, organized and facilitated clinical trials, and kept separate records of patients limited to breast cancer. Such specialists provided about 25% of the care to the 3,786 cases. He found an absolute benefit in survival difference between groups at 5 years of 9%, at 10 years of 8%, and an adjusted relative risk of death of 0.84 (C.I. 0.75-0.94). The benefit was seen for all clinical and social indicators considered of which selected are shown below.

### **5-year Survivals for Specialty Surgeon in Scotland 1980-1988**

	Specialist Surgeon	Non-Specialist Surgeon
Node negative	81%	77%
Node positive	58%	47%
<i>Age</i>		
<50	72%	64%
51-64	68%	57%
65-74	59%	54%
<i>Social indicators</i>		
Affluent	72%	64%
Intermediate	66%	58%
Deprived	65%	54%

A smaller English study by Basnett compared survival of 999 women with breast cancer treated initially between 1982-1986 at two districts, one an urban teaching hospital and the other a rural non-teaching one, which both had radiation and chemotherapy capabilities.<sup>6</sup> Numerous differences in process of care were seen. After adjusting for age and stage the adjusted risk of relapse or death were worse (1.45 and 1.74, respectively) for the non-teaching hospitals. No multiple variable regression analysis reported to explore reasons for these differences. Chemotherapy was used in only 5-8% of women in both settings but more often at teaching hospitals. Processes of care studies of axillary node dissection and adjuvant therapy in Britain are listed in the database.

### *Canada*

In breast cancer, Canadian investigators have looked at the diffusion of recommendations for the breast conservation and adjuvant therapies within and between provinces. The future of cancer patterns of care research is practically bright in Ontario. The Institute for Clinical Evaluative Sciences in Toronto has not completed but has started a detailed small area analyses of the entire province of Ontario including stratification by hospital provider type (regional cancer center vs. community) or physician characteristics for all cancers. (Neill Iscoe, personal communication).

Goel compared the patterns of BCS and post-BCS radiation therapy in 1991 between Ontario and British Columbia in women with node-negative primary breast cancer.<sup>31</sup> In both provinces, factors seen in American studies associated with greater use of BCS were confirmed: lower patient age, smaller tumor size, and surgery at a teaching hospital. Similar findings for greater radiation use in both provinces of younger age and larger tumors were seen. However, as shown below, more women in British Columbia were referred and subsequently had radiation therapy. The authors speculate that the presence of practice guidelines in 1991 in British Columbia could account for the difference.

### **Breast Conserving Surgery and Radiation Use in 2 Canadian Provinces in 1991**

Characteristic	British Columbia, n=942	Ontario, n=938
BCS, total cases	43.8%	67.6%
If BCS, Pt seen by radiation oncologist	96.4%	82.3%
If BCS, radiation used	91.5%	75.6%

In a benchmark study that was the first and possibly the only of its kind currently available, Olivotto showed that adjuvant treatments outside the clinical trial setting has a benefit comparable to that seen on-trial.<sup>79</sup> He compared the temporal five-year disease specific survival in cases diagnosed in 1974 and 1984 with the province wide guidelines for using adjuvant chemotherapy and hormonal therapy. A 32% reduction in breast cancer death for pre-menopausal women and a 20% reduction in post-menopausal women were found. These reductions were about the same size as observed in the 1992 meta-analysis from randomized trials.

Olivotto audited of all node negative cases from 1991 in British Columbia and found high compliance with the provinces guidelines for adjuvant chemotherapy or hormonal therapy.<sup>78</sup> Overall compliance with adjuvant therapy guidelines was 97% for radiotherapy, 96% for chemotherapy, and 89% for tamoxifen. An oncology specialist was consulted by 94% of patients with an indication for adjuvant treatment and by 58% of those without an indication. Although infrequent, noncompliance among patients with an indication for treatment was related to non-referral to an oncology specialist.

Goel and colleagues have also looked at the temporal trends for tamoxifen use in Ontario between 1985 and 1992 in woman over age 65 by tracking the Ontario Drug benefit electronic database.<sup>83</sup> Using the county as the unit of analysis, a province wide increase in use and a persistent but decreased absolute variation between counties was seen. Sources of the county to county variation were not explored.

## *Australia*

Hill evaluated all 856 cases diagnosed during six months of 1990 in the Victoria province by sending a patient specific questionnaire to each surgeon.<sup>41</sup> 176 surgeons responded. Surgeons treating over 20 patients per year operated on 36% of all cases. High volume surgeons were likely to do BCS, enter patients on clinical trials, but less likely to consult a medical oncologist. 33% of all cases were seen by a medical oncologist, 20% were given chemotherapy that was given by a medical oncologist 83% of the time. 40% of cases received hormonal therapy, which did not vary with surgeon volume.

## **Notable Gaps**

Our review found few U.S. assessments related to potential system factors associated with better outcomes. Specific factors such as a surgeon's volume and the use of BCS and referral for adjuvant therapy, the effect of a hospital's volume on breast cancer survival, and the effect of managed care, other than closed panel HMOs, on patient survival, use of reconstruction surgery, and radiation therapy. Variation in process of care indicators such as delays in getting to a see a physician or specialist, clinical process indicators in the peri-operative, adjuvant, or follow-up care are major concerns of patients, advocacy groups and clinicians. If real problems exist or perception and the legacy of the high-dose therapy wars cloud judgement is unclear. In contrast, the British have focused on system factors associated with their national health system that show disturbing variation and have been the impetus for a national reorganization of cancer care.

## **COLORECTAL CANCER**

Colorectal cancer incidence has been relatively stable for many years. Measurable improvements in overall and stage specific survival over the 20-30 years have occurred throughout the Western world. Reasons include improvements in surgical technique especially in reducing peri-operative mortality, the addition of adjuvant chemotherapy, and are unlikely to be confounded by any significant stage migration.

### ***Outcomes-U.S. and Canada***

Jarhult has reviewed the literature of studies of colorectal survival in cases diagnosed before 1993 that addressed the effect of hospital or surgeon volume on colorectal cancer survival.<sup>48</sup> He found an inconsistent volume effect. Two U.S. studies were included: a study from 1972 did find an associated with the number of resections at a hospital and another from 1977 did not find a volume effect for either hospital or surgeon. Since 1988, no U.S. studies were identified.

An important recent report from Canada addressed care between 1983-1990 at five Edmonton hospitals of 683 patients treated by 52 surgeons for rectal cancer.<sup>89</sup> Five surgeons had specific fellowship training in colorectal surgery. After adjusting for known clinical factors, the multivariate analysis showed that local recurrence and disease specific survival were both adversely affected by being cared for by a non-specialty trained surgeon or low-volume surgeon

(less than an 3 cases per year on average). Local recurrence is an especially strong indicator of surgical technique and a much more disastrous (essentially untreatable) event than local recurrence in breast cancer. The hazard rates for local recurrence were 2.5 and disease free survival of 1.4-1.5 if not specialty trained or a low-volume surgeon.

### ***Process-United States***

Retchin assessed the effect of being insured by an HMO in two different studies related to care for colorectal cancer in the elderly. The first study from 1983-86 of 506 patients found no differences in stage at presentation, treatment or follow-up between HMO and fee for service care.<sup>91</sup> A more detailed study from 1989 of 813 patients cared for at a national cross-section of 19 geographically dispersed HMOs with large Medicare membership was compared to FFS.<sup>92</sup> No difference in stage at presentation or in hospitality mortality (unadjusted 3.4% vs. 4.7%) was found. FFS patients had greater co-morbidity. HMOs had about a 3-day shorter length of hospitalization. HMO patients were less likely to be discharged to a nursing home (6% vs. 12%). No studies of the non-elderly or comparison of types of HMO organization (IPA vs. group vs. staff) were found.

For rectal and sigmoid cancers, the ongoing Patterns of Care Study addressed radiation treatment planning and delivery in two separate reports. The first study focused on treatment planning.<sup>55</sup> A representative cross-section of academic, hospital based and free standing centers were invited to participate. 21/24 academic, 24/26 hospital based, and 24/26 free-standing facilities agreed and subsequently 408 randomly chosen patients were audited. Consensus guidelines for care developed in 1992 were applied retrospectively to the audit of care in 1989-90. A major strength of the study is that most results are shown graphically comparing the results of the three treatment categories but only a few had statistically comparisons. Unfortunately, as for most guidelines, numeric benchmarks for individual components were not given. 11 different steps were evaluated. Numerous differences were seen between types of center with academic centers generally being closer to the process ideal. Which steps were most critical to optimal care are not obvious from the report.

Minsky reported on rectal cancer care in 1992-94 on a national sample of 507 patients from 57 hospitals.<sup>71</sup> Each case had detailed chart review. By definition, all patients had received radiation therefore the patients are not representative of all rectal cancer (the GAO found in 1985 only 40% of rectal cancer patients received radiation). The radiation therapy details used “modern techniques: 74% to an iso-dose line; 77% 10-MV or greater photons, 80% prone, 88% had all fields treated each session and 64% had the abdomino-perineal resection scar treated. However less than 60% of patients had technical actions done to avoid small bowel injury. A medical oncologist saw 84% of all patients and subsequent 80% received chemotherapy for a median of nine weeks.

The National Cancer Database has regularly described the U.S. care trends but has not carefully stratified care looking for variation. The most recent report reviewed general care patterns from 1985 to 1993 with detailed comments on care in 1993.<sup>49</sup> In 1993, 91% of patients were AJCC staged. Since 1985, no notable changes in relative distribution in stage (of stage patients) were

found. This suggests that secondary prevention efforts are not yet making an impact on the disease. 46% of patients with stage III disease nationally received adjuvant chemotherapy following surgery. Factors such as patient age, income, geographic region, and type of hospital were not evaluated but are available in the database. The non-randomized data in the NCDB shows a 3-5% absolute survival benefit for adjuvant chemotherapy in stage III disease for patients diagnosed in 1985-1988 consistent with the size of the benefit observed in randomized trials. Other broad issues of general trends in colorectal care were: 1) stage specific survival was worse in the elderly, 2) no differences or a better stage specific survival for blacks compared to whites, 3) a steady improvement to greater than 90% of patients having TNM staging, and 4) increasing prognostic importance of tumor grade.

Although the NCDB reports that 90+% of patients have AJCC staging, major deficiencies in the quality of pathology reports when audited have been found. The College of American Pathologist's Q-probe (see section breast section for additional comments) program in 1991 evaluated practices in 532 institutions of 15,940 surgical pathology reports of resected primary colorectal cancer.<sup>112</sup> 12 factors were assessed for deficiencies and are reported in the table. The results are rather deceptively presented and obscure potentially meaningful differences since the majority of erring hospitals were in the 1-49% category. For example, separating hospitals with a 5% vs. 45% failure cannot be distinguished.

### 1991 Q-Probe Audit of Colorectal Cancer Surgical Pathology by Hospital

Descriptor	% Of Cases Where Descriptor is "Not Reported"				Total Hospitals reporting
	0%	1%- 49%	50%- 94%	95%-100%	
Size	360	26	0	0	386
Site	424	33	1	0	458
Configuration	375	41	0	0	416
Histologic type	513	1	1	0	515
Grade	318	83	11	2	414
Gross Depth	213	200	8	0	421
Histologic depth	442	13	0	0	455
Gross margin	148	236	22	6	412
Histologic margin	176	185	59	4	424
Total lymph nodes	252	118	8	3	381
Involved nodes	295	94	2	0	391
Blocks designated	286	103	69	23	481

The one single factor associated with increased likelihood of communicating more complete information content was the use of a standardized report form or checklist. Unfortunately, this report did not explore any potential associations between report completeness and subsequent physician actions. No consistent benefit in more complete reporting was found with being a teaching institution, size, or having a residency program. In 1997, the American College of Pathologists updated its guidelines or practice protocol for colorectal cancer including a checklist.<sup>18</sup> No studies were found addressing overuse of pathology prognostic factors; e.g. ploidy, p53, or various gene abnormalities.

## **Britain**

An early report by McArdle from 1974-1979 in Scotland found a four-fold variation in survival and surgical complications based on a surgeon's specialty volume and interest in colorectal disease or surgical oncology.<sup>64</sup> However, subsequent British studies have not confirmed this effect. Kingston evaluated care by 12 surgeons interested in colorectal cancer but outside academia to university care for 578 patients and found not benefit from university care.<sup>54</sup> Mella performed a one-year audit of 3221 patients diagnosed in 1992-3 in Wales and Scotland. The 30-day mortality was 7.6%. No surgeon volume effect (using either 10 or 30 cases per year as a dichotomous variable) or specialty interest effect was noted on 30-day mortality.<sup>66</sup>

Bull audited the quality of surgical pathology for almost every colorectal cancer cases in Wales from 1993 from 17 laboratories.<sup>15</sup> He found reporting gaps similar but more extensive than those found in the U.S. audit. Major gaps were particularly noted in the reporting completeness of resection and number of lymph nodes involved. 75% of colon cancer cancers had Duke's staging reporting and 95% whether, but not number, of lymph nodes were involved. 78% reports for colon and 47% of rectal cancer meet their minimal standards.

## **Australia**

An Australian report was the only study found of actual surveillance (compared to questionnaire) post-primary surgical therapy.<sup>65</sup> Of 1139 cases diagnosed in 1987, in the first two years after treatment 38% of rectal and 47% of colon cancers did not have either a sigmoidoscopy or colonoscopy and 65% never had a CEA assay.

## **Notable Gaps**

Although, colorectal cancer has been a major area where hospital and case-volume survival have been studied; there is a notable lack of studies addressing practice variation in pre-operative evaluation, adjuvant chemotherapy in stage III disease, and actual (vs. survey) patterns of follow-up care. Given the frequency of quality gaps in the 1991 American audit of surgical pathology reports, a high priority should be for the Q-PROBE to revisit this issue using the 1997 national guidelines of the American College of Pathology. In addition, the effect of managed care, if present, on limiting specimen evaluation and quality of care could possibly be detected.

## **CANCERS ASSOCIATED WITH HIGH RISK SURGERY**

The quality of cancer care might be superior at specialty vs. smaller community centers in the evaluation and treatment of cancers where the primary therapy is a high-risk surgical intervention. Cancers fitting this category are non-small cell lung cancer, pancreas, esophagus, and gastric cancer. However, the support for this premise is variable with the predominance of studies limited to pancreas surgery. The unit of analysis has been principally the hospital with little evaluation of the effect of specific surgeon volume and no data on the effect of the payer system (HMO).

## Non-Small Cell Lung Cancer (NSCLC)

Despite being the leading cause of death in the U.S., there are minimal data evaluating the quality of care for NSCLC. Only two studies could be found related to surgical care and none related to potential quality or process variation in radiation therapy or palliative care. There are numerous survey reports of physician attitudes concerning the optimal form of care predominantly for patients presenting with advance disease. These studies are not discussed since actual care was not described.

### Outcomes—United States

There has been no recent change in the dictum that surgical resection represents the preferred treatment for operative NSCLC. Due to the lack of an effective screening technique and despite improved imaging techniques about one-third of all NSCLC patients have a surgical procedure as part of their initial care. The expected peri-operative or 30 day mortality varies with the extent of the primary surgery (pneumonectomy (~6%) > lobectomy (>3%) > segmental resection (1%)<sup>28</sup>. These absolute mortality risks are known to vary with patient characteristics (age, stage of disease, and co-morbidity). These mortality estimates are typical of those reported by university centers. However, Whittle found much higher rates in an evaluation of a national sampling of Medicare claims from the early 1980s. He found a 17% 30-day mortality after pneumonectomy.<sup>108</sup>

Since 1988, only two studies were found that address patient and provider characteristics associated with in-hospital mortality for NSCLC. Romano and Marks assessed hospital discharge abstracts from 12,439 adults in the state of California who underwent pulmonary resections in 1983 to 1986.<sup>93</sup> The in-hospital mortality was 3.8% after wedge resection, 3.7% after segmental resection, and 11.6% after pneumonectomy. The mean age was 62 for pneumonectomy and 65 for lesser procedures. 499 hospitals were stratified into high, low and non-teaching depending on the number of residency programs at a facility. Hospital volume was defined by the total number of lung resections for lung cancer per year and broken into quartiles. A multi-variant regression model that included demographic data and clinical co-morbidity (COPD, coronary artery disease, and diabetes) found no difference in the risk of post-operative death associated with teaching status. A consistent lower operative mortality at higher volume centers was seen. The effect of individual surgeon volume was not addressed.

### California Post-Operative Mortality with Lung Cancer Surgery 1983-86

Hospital Volume (#/Year)	Lesser Resections			Pneumonectomy		
	Patients	Adjusted Mortality (%)	Adjusted Odds Ratio	Patients	Adjusted Mortality (%)	Adjusted Odds Ratio
<9	2,588	5.2	1.0	365	13.6	1.0
9-16	2,945	4.1	0.7	374	11.4	0.8
17-24	2,553	3.5	0.6	377	11.7	0.8
>24	2,822	3.4	0.6	413	9.7	0.6

Begg has recently performed an assessment restricted to the elderly that used linked Medicare-SEER databases of care between 1984-1993 that used 30-day mortality as its endpoint and hospital volume as its primary variable of interest. <sup>7</sup> **NOTE THE AUTHORS SERVED AS PEER-REVIEWERS FOR THIS WORK. IT HAS NOT YET BEEN PUBLISHED.** The linkage allowed identification of precise details of the surgical procedures, co-morbidity, and stage information. The analysis addressed a variety of surgical procedures: pneumonectomy, pancreatectomy, and esophagectomy for esophageal cancer, hepatic resection, and pelvic exenteration. These were chosen since these procedures “involve pre-operative judgement, diagnostic accuracy, meticulous surgical technique, and demanding post-operative care.” In addition, this study was a rare example of having a pre-study hypothesis although the size of anticipated differences was not given.

The first major finding was that “curative surgery” is rarely performed for these cancers in the elderly. The table below shows that of all incident cases of these cancers over the 10-year period, the number of procedures within two months of diagnosis (excluding hepatic resection) ranged from about one to seven percent.

### **Medicare-SEER 1984-1993 Patient Selection Statistics**

Procedure	Primary Diagnosis	Incident Cases	Procedures	%
Pancreatectomy	Pancreas	19,205	742	3.9
Esophagectomy	Esophagus	6,782	503	7.4
Pneumonectomy	Lung-Bronchus	103,425	1,375	1.3
Hepatic Resection	Colon-Rectum	126,395	801	0.6
Pelvic Exenteration	Various	185,305	1,592	0.9

Yet, within that small set of patients undergoing surgery, a distinct trend of decreasing mortality with increasing volume was seen for all conditions except for pneumonectomy. A detailed assessment looking at the distribution of co-morbidity and hospital volume showed no difference in the relative co-morbidity across hospitals. In other words, there was no evidence that high (or low) centers operated on a lower risk set of patients.

### **30-day mortality and hospital volume for high risk cancer surgery in Medicare-SEER 1984-1993**

Procedure	30-day mortality (%)		
	1-5 cases	6-10 cases	11+ cases
Pancreatectomy	12.9	7.7	5.8
Esophagectomy	17.3	3.9	3.4
Pneumonectomy	13.8	14.1	10.7
Hepatic resection	5.4	3.5	1.7
Pelvic Exenteration	3.7	3.2	1.5

*Process-United States*

No studies were identified that addressed factors associated with the variation in NSCLC process of care. Such variation is commonly seen but not yet sufficiently explained.

We have performed assessments of two different cohorts in Virginia. Smith described the patterns of care in Medicare patients in Virginia diagnosed in 1985-1989. Younger age was the dominant predictor for active therapy and surgical therapy for loco-regional disease and active vs. no therapy if distant disease were present at initial diagnosis.<sup>101</sup> A separate analysis looked at Virginia Blue Cross Blue Shield enrollees (either primary insured or Medigap coverage) diagnosed in 1989-1991. This cohort probably is a relatively homogenous one related to economic factors. Within any stage of disease using age as a dichotomous category (age less than or greater than 65) substantial variation was seen.<sup>42</sup> The source of this variation needs further investigation.

### Initial NSCLC Care in Virginia in 1989-1991

Initial Treatment Category	Total		Local		Regional		Distant	
	Age <64 %	Age ≥65 %						
	(n=336)	(n=1132)	(n=71)	(n=331)	(n=105)	(n=331)	(n=160)	(n=468)
Surgery only	23.6	21.2	74.6 <sup>†</sup>	50.4 <sup>†</sup>	23.1	18.8	1.3	3.1
Surgery plus*	13.1	7.8	5.6	4.1	28.8 <sup>†</sup>	13.8 <sup>†</sup>	5.6	6.1
Radiation	40.0	39.4	7.0	25.8	31.7	41.9	60.0	47.0
Radiation+Chemo	6.9	1.2	1.4	0.6	3.8	0.6	11.3	2.0
Chemotherapy	4.2	1.6	0.0	0.0	2.9	1.1	6.9	2.9
None	12.2	28.9	11.3	19.1	8.7	23.9	15.0 <sup>†</sup>	38.9 <sup>†</sup>
Any Surgery	36.7 <sup>†</sup>	28.0 <sup>†</sup>	80.2 <sup>†</sup>	54.8 <sup>†</sup>	51.9 <sup>†</sup>	32.0 <sup>†</sup>	6.9	9.1
Any Radiation	59.1 <sup>†</sup>	47.9 <sup>†</sup>	14.0	30.5	65.4	56.0	76.2 <sup>†</sup>	54.9 <sup>†</sup>
Any Chemotherapy	11.9 <sup>†</sup>	3.3 <sup>†</sup>	1.4	0.8	8.6	2.0	18.8 <sup>†</sup>	5.1 <sup>†</sup>

Unstaged patients were excluded.

\* Surgery plus defined as surgery plus radiation, chemotherapy, or radiation and chemotherapy

<sup>†</sup> Differences between cohorts were statistically different at  $p < 0.00005$ .

Only two reports of variation in process of care were found. As part of the early reports from the National Comprehensive Cancer Network, Walsh retrospectively reviewed the patterns of pre-operative evaluation at one center, MD Anderson, of 107 patients from 1995-96.<sup>107</sup> 50% of patients had an excess number of pre-operative scans compared to the NCCN guidelines. More encouraging was that the optimal use or withholding of mediastinoscopy occurred in 97 of 107 patients. Virgo and colleagues have done a series of studies, predominantly surveys, about the patterns and costs of follow-up cancer care. In their only study that actually audited the post-surgical treatment of lung cancer was done at a single center in the 1980s and found substantial variation in testing and visits but no difference in survival if greater intensity of follow-up.<sup>106</sup>

### Notable Gaps

No studies were found addressing differences and the effects associated with the types of physician providers, hospitals, or geographic regions. We specifically could not find studies addressing referral patterns to medical or radiation oncologist based on the characteristics of the primary physician, patterns of staging especially for stage III disease, the types and quantity of radiation therapy, the use of first or second-line chemotherapy, or the effectiveness in end stage symptom control.

There is a common yet unsubstantiated impression that patients presenting with more advanced disease are not routinely referred to cancer specialists early in their course due to nihilistic attitudes of their primary care physicians or pulmonologists. If this is true is this pattern changing with the growth of managed care? Given that about 50% of patients present with metastatic disease, identifying examples of effective organizational structure of care to provide effective palliation (either home-based, hospice, or hospital based) is needed. We could find no examples of case studies of single centers describing the effectiveness of their multi-disciplinary practice, compliance with internal guidelines, or any external audits of pre-determined areas of process of care factors that have construct validity for quality in NSCLC. In addition, details about the actual patterns and medical audit of quality of radiotherapy or chemotherapy (vs. survey of attitudes) are not available.

### **Pancreas**

There has been numerous studies showing a consistent trend that hospital case volume is predictor for better outcome in pancreas surgery. These sets of studies are the single most compelling collection supporting the hospital case volume hypothesis due to the size and diversity of study designs utilized.

#### *Outcomes—United States*

Using the approach pioneered by Romano for NSCLC, Glasgow evaluated the effect of hospital volume by studying all California hospital discharge summaries from 1990 to 1994 for major pancreatic resections.<sup>29</sup> Of the 298 reporting hospitals, 88% treated 2 or less patients per year. The table below shows the relationship between hospital volume during the five-year interval on length of stay, charges, and mortality (death before hospital discharge). Higher volume centers had better profiles in all-important areas excluding costs at one category of centers.

#### **California Hospital Pancreatectomy Volume and Outcomes 1990-94**

Hospital Volume, No.	Number of Hospitals	Length of Hospital Stay, days	Total Charges, \$	Patients Discharged to Home, %	Crude Mortality, %	Risk-Adjusted Mortality Rate, %
1 to 5	210	22.7	87,857	74.3	14.1	14.1
6 to 10	53	22.7	76,593	80.0	10.4	9.6
11 to 20	20	22.9	78,003	81.8	8.9	8.7
21 to 30	9	20.2	70,959	92.1	5.7	6.9
31 to 50	4	23.9	111,497	87.1	8.2	8.3

> 50	2	20.5	71,585	95.1	3.5	3.5
Mean		22.3	83,479	82.1	9.9	9.9

Using a similar method, Lieberman evaluated hospital discharge abstracts form for 1972 patients having a pancreatic resection in New York State between 1984-91.<sup>60</sup> About 25% of cases were done at hospitals averaging about one cases per year or less and about 75% of cases averaged less than seven cases per year. Conversely, two-thirds of the hospitals doing pancreatectomy were low volume facilities. The table below clearly shows the same higher volume better survival relationship. In addition, he evaluated the effect of the physician volume. The logistic regression model found that after adjusting for hospital volume, comorbidity, clinical variables, and time trends that **physician volume was not a predictor** (power of analysis not stated)

### **Volume Outcome Effect for Pancreatectomy in N.Y. state, 1984-91**

Hospital Volume, over 7 years, N.	Number of Hospitals	% of total patients	Length of Hospital Stay, days	Standardized Mortality
<10	124	24	35	18.9
10-50	57	54	32	11.8
51-80	1	3	22	12.9
>81	2	19	27	5.5

Taking a total disease view, Janes used the NCDB to evaluate the national patterns of care for pancreatic cancer in 1983-85 of 8,917 and 1990 on 8,025 cases from 978 hospitals (25% teaching institutions).<sup>47</sup> This study was supplemental to the core NCDB activities and entailed a 160 element abstraction of patient records. About 15-17% of cases had cancer directed surgery. Unadjusted operative mortality was 7.7% at hospitals where less than 5 patients were seen per year and 4.2% operative mortality if 20 or more patients per year were diagnosed.

Gordon looked at the effects of regionalization of care by comparing the hospital mortality, length of stay, and costs between care at Johns Hopkins in 1988-1993 compared to the rest of the state of Maryland (38 hospitals) using hospital discharge data.<sup>33</sup> The results were striking: in-hospital mortality 2.2% vs. 13.5% (a relative risk of 6.1 (C.I. 2.9-12.7), mean length of stay (23 vs. 27 days) and mean total charges were 20% greater outside Johns Hopkins. A follow-up study by Gordon attributes 61% of the decline in the Maryland in-hospital mortality for pancreas surgery (17.2% to 4.9%) between 1984 and 1995 to the increase in share of discharges at the high-volume provider, Johns Hopkins.<sup>32</sup>

### **Esophagus**

Begg's assessment was the only one found related to patterns of esophageal cancer care.

### **Gastric**

Since 1988, there has been only one major study of the effect of hospital type and gastrectomy reported. Valen assessed 1165 patients who were entered into a prospective, national

observational study in Norway from 1982-1984 representing over half of the countries cases during these years.<sup>105</sup> There were significant differences in patient characteristics between hospital categories (local, county, and university). The number of hospitals per category is not listed. Patients at local hospitals were older, had poorer performance status, and underwent less extensive surgery. Due to the extent of pre-treatment clinical differences, the authors felt detail multi-variable regression analysis was inappropriate. No similar studies from North America were found.

## HIGHLY CURABLE CANCERS

### *Testicular Cancer*

Only three outcomes or process of care studies were found for testicular cancer but each of these was well done and has major implications.

#### *Outcomes—United States*

Only one indirect outcome comparison study has been reported in the US. Feuer retrospectively compared survival between care for metastatic testicular cancer at the Memorial-Sloan Kettering Center (n=133) with cases identified from five SEER registries (n=172) in 1978-1984.<sup>22</sup> Although 89% of the SEER cases received chemotherapy and 95% of these used Cisplatin regimens, the 3-year survival was markedly better at MSKCC. For the minimally/moderate extent of disease patients the benefit was most striking (94% vs. 73%) than the advanced cases (52% vs. 40%). The authors speculate that the differences could have been due to many factors including chemotherapy regimen, dose-intensity, salvage therapies or institutional factors.

#### *Outcome--Britain*

Two studies from Scotland addressed the patterns of referral and outcomes. Clarke found between 1983-1990 that 92% of testicular cancer was referred to specialty centers. The subsequent care at these specialty centers broadly varied.<sup>16</sup> Harding performed a population-based audit of management of 440 men diagnosed in 1977-1989 with non-seminomatous germ cell tumors (NSGCT) in western Scotland.<sup>39</sup> All but 11 patients were treated at tertiary referral centers; 235 were treated at a single unit (unit 1) and 194 at four other units (2-5). 99 men (20%) had died at the time of the report.

Independent prognostic factors for NSGCT survival were extent of tumor at diagnosis, 5-year period of diagnosis (from 1975-79 to 1985-89), and treatment unit (unit 1 vs. units 2-5). Unit 1 had the best survival rates, had treated the most patients overall (53%) and the majority (70%) with the worst prognosis (poor-prognosis metastatic disease). 97% at unit 1 vs. 61% at units 2-5 received care on the nationally agreed protocol treatment. After adjusting for known prognostic factors and limiting the analysis to those treated on protocol, the relative risk of death outside of unit 1 was 2.8 (confidence interval 1.5-5.2). We concur with the authors that “these findings

suggest that centralization of treatment for NSGCT improve outcome; the benefit seems to be additional to any advantage resulting from protocol treatment."

Aass noted a similar trend though not as dramatic. She studied patients treated at 14 Swedish or Norwegian centers between 1981-86 who entered a clinical trial.<sup>4</sup> The multi-variant analysis of 193 patients found that if care had been given at the lead institution, which provided 46% of cases, the chance of dying after controlling for known prognostic factors was reduced 28%.

### ***Lymphoma—Non-Hodgkin or Hodgkin's***

Since chemotherapy and/or radiation therapy are the primary treatments for lymphoma, this condition was anticipated to be the best opportunity to find practice variation and quality differences in non-surgical cancer care. However, after extensive literature searching, no studies since 1988 were found for either category of lymphoma. This is especially disappointing in light of the report by Davis contrasting survival between 3,607 Hodgkin's disease (HD) patients registered by SEER (community care) and 2,278 HD patients treated at one of 21 comprehensive cancer (university or referral) centers diagnosed in 1977-1982.<sup>19</sup> Modest differences in the patient age, histologic pattern and frequency of stage II disease between locations were seen and were adjusted for in the multi-variant model comparison. The morality rate among SEER patients was higher (relative risk 1.5; 95% confidence intervals 1.3-1.7) than those treated at comprehensive centers. The survival difference was consistently seen for all stages, histologic types, and patient age.

The most recent report from the NCDB for HD was released in 1992. It did not include any stratification by site of care. The GAO report attributes that 20% of HD cases between 1975-1985 did not received state of the art care.

The Patterns of Care Study of the American College of Radiology compared care in 1973 to 1983 for stage I-II HD of patients only receiving radiation therapy.<sup>45</sup> They audited 78 patients in 1983 at 13 centers. They found that almost all patients (92-94%) were treated using a linear accelerator, had individual shaped blocks, and clear portal margins. The five-year disease free and overall survivals increased by an absolute 9-12% between 1973 and 1983.

The NCDB recently described its data on 91,300 cases of non-Hodgkin's lymphoma.<sup>30</sup> No patterns of care stratified by location, type of hospital, etc were reported.

### ***Melanoma***

The absolute and relative growth in the rates of melanoma is a major cancer public health concern in the United States. The 1990 NCDB database of about 5,000 new cases was the only source of patterns of care identified.<sup>104</sup> Only 2% of cases were treated at NCI designated cancer centers. About 75% of patients were treated by "appropriate" wide local excisions based on the extent of tumor penetrations through the skin. 13% of patients had lymph node removal. The NCNB does not report any details on who performed the surgery or about the quality of the pathology reporting.

The overall picture of melanoma may be biased since it is likely to be the most under-reported cancer due to its being identified usually at an ambulatory, often non-hospital based, surgery. Between 1977-94 in Iowa the proportion of melanoma diagnosed at independent pathology laboratories increased to 25% of all cases. They estimated a 10-17% underreporting of cases.<sup>69</sup> Others suggest that over 50% of U.S. cases are not reported and the true incidence is 80,000 cases per year.<sup>95</sup>

In addition, no population-based data could be found evaluating who is involved in the initial management of melanoma. That is the relative breakdown of primary care, dermatology, and various surgical subspecialties. A 1992 survey attributes that 68% of dermatologists do excisional biopsies and 28% are comfortable doing “definitive surgery.”<sup>96,97</sup> No reports address associations between who (dermatologist, general surgeon, or surgical oncologist) and where (university, hospital or contract pathology laboratory) of melanoma care is provided. No work from the American College of Pathology related to standards for melanoma pathology was found. Assessments of linked cancer registries and insurance claims are notably missing. A variety of organizations have published guidelines but no reports of compliance are known. Given the known effectiveness of adjuvant interferon-alpha as adjuvant therapy for node-positive disease, this is an opportunity to address the diffusion of information to patients and providers similar to 10 years ago for node-negative breast cancer.

### **Sarcoma**

Recently, the NCDB described its data on national patterns of care in 1988 (n=3,500) and 1993 (n=4252).<sup>88</sup> The mean age was 53 to 56 years. The NCDB noted an increase in limb-sparing surgical procedures but not an increase in concurrent radiation therapy with surgery. No evaluation for predictors of outcomes or process based on hospital characteristics; region, patient age or if this uncommon cancer has shown any trend to regionalization of its care.

### **Acute Leukemia**

The volume-outcome relationship was evaluated for leukemia in one study from the International Bone Marrow transplant registry.<sup>46</sup> 1,313 transplants of HLA identical sibling bone marrow transplants for early leukemia (acute leukemia in first remission or CML in first chronic phase) using transplant center volume as the unit of analysis between 1983-1988. 24% of centers performed five or fewer allogeneic transplants per and five (6%) performed more than 40 per year. After adjustment for differences in patient and disease characteristics, the relative risks of treatment-related mortality (1.53,  $p < .01$ ) and treatment failure (1.38,  $P < .04$ ) were higher among patients who received transplants at centers doing five or fewer transplants per year than among those at larger centers. This lead to an absolute 10% difference in two-year survival (65% vs. 55%) at the high volume centers. No differences in centers performing more than 5 transplant per year (up to 40 or more per year) were found. The registry has not reported any volume outcome evaluations for other conditions. No studies of volume-outcome or other quality of care indicators excluding transplantation for leukemia were found.

A variety of accrediting organizations worldwide exists related to setting standards for certification in allograft or autograft transplantation. For example, the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) has used 10 combined transplants as the minimal number per year. Any effect on compliance with accreditation factors, the growth in number of centers or outcomes by size for auto-transplants is yet to be explored.

## **Ovarian Cancer**

### *Outcomes—United States*

Ovarian cancer has been the focus of a modest number of assessments in the U.S. and Britain primarily on the effect of the type of surgeon who provides the initial care.

Nguyen and colleagues as part of the U.S. National Survey of Ovarian Carcinoma performed the most prominent outcome study.<sup>77</sup> Detailed data was requested from 25 consecutive patients from 1,230 hospitals with cancer programs across the U.S. from calendar years 1983 and 1988. 904 hospitals provided data on 5,156 patients from 1983 and 7,160 patients from 1988. About 96% of patients had exploratory surgery as their initial management. The specialty of the physician's breakdown was about 20% general surgeons, 20% gynecologic oncologists, and 45% general gynecologists. In general, gynecologists saw patients with less advanced disease at presentation. About half of gynecologists patients compared to two-thirds of gyne-oncologists or general surgeon patients were found to have stage III or IV disease.

The most prominent finding was that the surgical staging, completeness of surgical debulking and median survival all varied with specialty. Staging and debulking were assessed for 1983 and 1988 while survival was limited to the 1983 cohort. The biopsy rates were highest among the gyne-oncologists but were less than ideal (~35% in stage I to IIIB disease). Optimal tumor debulking was done in about 45% by each of the gynecology groups versus 25% by the general surgeons. As shown in the table, stage stratified median survival varied statistically and by clinical meaningful amounts by specialty.

### **Ovarian Cancer Survival by Physician's Specialty Diagnosed in 1983**

Stage	Patients, n	Five-year survival (%)			Median Survival (mo.)		
		GYO	OBG	GS	GYO	OBG	GS
I	1377	88.6 ± 2.5	89.6 ± 1.1	87.8 ± 2.1	96+	96+	96+
II	448	62.6 ± 5.9	60.9 ± 3.1	47.4 ± 5.5	84+	96+	61.7
III	1355	25.2 ± 2.6	29.2 ± 1.9	16.8 ± 2.0	26.4	29.1	20.7
IV	1080	10.4 ± 2.6	16.8 ± 1.8	10.9 ± 1.6	18.0	19.2	14.3

A limitation of this study is the lack of details about post-operative management specifically chemotherapy especially platinum-based regimens. However, we believe that the authors correctly used the assumption that the primary surgeon also was in charges of the patient's

postoperative care, including chemotherapy and referral to a medical oncologist, and that the ultimate survival outcome depended on the total management by the primary surgeon.

### *Process—United States*

Munoz and colleagues from the National Cancer Institute assessed in detail the process of ovarian cancer in 785 women in 1991 selected from SEER sites.<sup>74</sup> Only about 10% of women with presumptive stage I and II compared to 71% with stage III and 53% with stage IV disease received recommended staging and treatment. The absence of lymphadenectomy and histologic tumor grade were the primary deficiencies in stage I and II disease. The principal deficiency in stage III and IV was withholding of platinum-based chemotherapy in older women. The only provider variable assessed was if care was provided at a hospital with a residency program. The odds ratio for receiving appropriate care was 1.9, or an almost a doubling, if care was given at a resident-based hospital. No data about provider specialty, university affiliation, hospital size, or patient insurance were assessed.

The NCDB has not reported any systemic assessment of various hospitals or provider factors of ovarian cancer care or made any comment about appropriateness of care such as tumor debulking. In 1993, about 90% of patients were “staged” but details about surgical technique or lymphadenectomy was not given.<sup>85</sup> The national patterns of care are described but details on surgical technique or chemotherapy combinations were not provided. 85% of treated patients with stage III disease received treatment after surgery usually chemotherapy.

The NCDB has focused on the differences in care received by race.<sup>84</sup> They found that African-American women with advanced ovarian cancer were less often treated with combined surgery and chemotherapy and more often treated with chemotherapy only. For example, within the same hospital and stage, about 43% of whites compared to 33% of African-American women were treated with surgery and chemotherapy. As seen in other cancers among staged cases, African-American women were more often diagnosed with Stage IV disease.

More is not necessarily better. In the only identified direct comparison 61 Canadian and 68 American women with stage IV ovarian cancer at two tertiary care centers from 1987-89 were compared.<sup>61</sup> Primary cisplatin chemotherapy was given to 98% of Canadian and 93% of American women. The U.S. patients received a higher mean number of different chemotherapy regimens and total courses than the Canadians (3.0/12.6 vs. 2.4/8.8). Given the small numbers it was not surprising no differences in survival were found.

### *Outcomes--Britain*

In two British studies, the effect of surgical specialty and survival was strongly noted. Kehoe retrospectively assessed the survival of about 1200 patients in central England between 1985 and 1987.<sup>53</sup> General surgeons cared for patients with more advanced disease and poorer prognosis. However, a multi-variant model found that the 5-year relative risk of death if a general surgeon gave initial care was 1.34 compared to a gynecologist.

Woodman found similar results in 691 woman diagnosed in 1991-92 in the NorthWest region of Britain.<sup>110</sup> Surgeons compared to gynecologists had a risk adjusted risk of death over 50% greater (1.58) compared to gynecologists. More interestingly, case volume was not predictive of survival but referral to medical oncologist was strongly predictive (RR=0.54). Given the general low use of chemotherapy in Britain, it would be important to know the relative rates of chemotherapy in women with advance disease; but this is not reported. Junor reported one of the few studies addressing the benefits of multi-disciplinary clinical care.<sup>51</sup> In 1987, 533 cases of ovarian cancer were diagnosed and 479 records were available for audit in Scotland. 27% of cases were referred post-operatively to a combined clinic. After adjusting for clinical factors and the use of platinum chemotherapy (about 50% of patients less than 65 received chemotherapy), the relative risk of death was 0.73 (27% reduction) if patients received care at the multidisciplinary clinic.

### *Notable Gaps.*

We are surprised by the lack of studies addressing the effect of provider specialty in advanced disease: medical oncologists vs. gyne-oncologists related to the delivery of chemotherapy, pain control, patient satisfaction and survival. The patterns of use, specifically types of treatment, dose, schedule, and palliative care, all are unexplored.

Given the strong specialty effect and survival, the effect of academic centers (presumably all gyne-oncologists) vs. other hospitals should be addressed. The effect of patient insurance such as lack of access to specialists has not been explored. Studies like those in breast cancer have not addressed the different forms of managed vs. FFS care. The benefits of multi-disciplinary clinics, who (medical vs. gyne-oncologist) and where (large vs. community hospitals) care is provided have been minimally explored in the U.S.

The only strong conclusion warranted is that ovarian cancer should be exclusively cared for by gynecologists and probably gyne-oncologists.

## **PROSTATE CANCER**

It is generally known that the clinical patterns of care for prostate cancer have markedly changed over the last 15 years with an increase in the use of radical prostatectomy and radiation therapy. The rate of radical prostatectomy appears to have crested since 1992. In addition, the proportion of men diagnosed when age < 70 has increased to about 50% of all cases in 1993. Unfortunately, it is also well known that there is no consensus on the optimal form of therapy for men with early stage disease. Therefore, it is not surprising that there are few studies related to outcomes in this area especially since comparisons within a specific AJCC stage is generally not possible. (This occurs since patients treated with radiation do not have local lymph nodes removed and pathologically examined). In this section, case series of surgical or radiation therapies without comparisons are not discussed.

## United States

The effect of hospital and surgical volume on peri-operative mortality is just beginning to be addressed. Lu-Yao at the 1998 ASCO meeting presented the preliminary results of an analysis of 1991-94 Medicare claims of 101,604 men having radical prostatectomy that addressed 30-day mortality and complication rates related to hospital volume.<sup>{1339}</sup> A clear gradient effect of hospital volume by quartiles and outcomes adjusted for patient age was seen (below). Details of clinical co-morbidity and appropriateness were not discussed. He is currently evaluating the effect of urologist specific volume since many operate at more than one hospital (personal communication, May 1998)

### **Hospital Volume and Radical Prostatectomy Complications in Medicare 1991-94**

Odds Ratio compared to High Volume Hospitals

Hospital Volume	30 day mortality	Readmission rate	Surgical complication
Low	1.53	1.25	1.30
Medium Low	1.44	1.13	1.16
Medium High	1.41	1.08	1.08
High	1.00	1.00	1.00

A broad general quality of care concern is the appropriateness of radical prostatectomy particularly if most men are not believed to be curable at the time of their surgery. Lu-Yao in an earlier study of a link database of Medicare claims using three SEER registries evaluated men having radical prostatectomy between 1985 to 1991. They found that 14-17% of men needed additional prostate cancer therapy (radiation, orchiectomy, chemotherapy, and androgen-deprivation) within 6 months of their surgery and an additional 19-26% of men needed therapy between 6 and 60 months.<sup>62</sup> In other words, one in six or seven men who had surgery performed with curative intent subsequently had to have treatments for metastatic disease within six months strongly suggesting that these men were misstaged.

In the only cross-sectional study of men younger than 65, Optenberg evaluated 1059 men insured by the Department of Defense and whose clinical details were reported the DOD cancer registry. The 30-day surgical mortality was 0.28% and re-hospitalization rate was 3.1%.<sup>81</sup>

There is only one small study addressing the effect of insurance type. Greenwald reported a small study involving HMO-Medicare risk contracting from 1980-82 in the Seattle area.<sup>34</sup> He found that the HMO patients (n=141) after adjusting for clinical stage had less surgery, more radiation therapy, and after adjusting for stage, urban location, and age a better survival (relative risk for death 0.74, confidence interval 0.55-0.99) compared to fee-for-service patients (n=1129). We could find no similar studies addressing closed or open panel HMOs or the use of disease management programs other than surveys.

An important reassuring study addresses the greater incidence and mortality in African-American men due to prostate cancer.<sup>80</sup> A second study by Optenberg addressed this question using a population without any access to care barriers. He retrospectively assessed 1,606 active-duty, retired or dependent members of the US Department of Defense (DOD) using the DOD cancer

registry. They found that African-American men more frequently presented with metastatic disease but found no difference in their waiting time for care or stage adjusted therapy. They concluded that in an equal-access medical care system there are no stage-specific differences in treatment between black and white patients.

There were two prominent studies related to ageism and therapy. Bennett did a detailed chart review of 242 men at ten southern California hospitals from 1980-82.<sup>10</sup> Using a pre-defined branching criteria map for appropriate therapy he found that men older than 75 years had significantly less intensive staging, and less surgical or radiation therapy for their disease. Desch and colleagues assessed all elderly men in Virginia using a linked cancer registry and Medicare claims database from 1985-89. They found a temporal trend to more active therapy. Age was the most important and dominant predictor of therapy received before and after adjusting for comorbidity.<sup>20</sup>

### *Notable gaps*

There are numerous survey reports of provider attitudes about a variety of areas of screening, treatment and follow-up of prostate cancer including differences between countries. However, outside of assessments of Medicare data there is shocking little known about the actual patterns of care: men under age 65 (excluding the Department of Defense), the effects of patient specific social-economic factors (versus census-track inferences), or provider/hospital volume. In addition, patterns of actual care (versus surveys) for metastatic disease have not been explored. Anecdotal reports of changes to less expensive care in managed care patients, i.e. orchiectomy vs. LHRH agonists, has not been systematically confirmed.

## **GENERAL PROCESS ISSUES**

### ***Trends in Staging (AJCC/TNM)***

The American Joint Committee on Cancer (AJCC) staging procedures was initially published in 1977 and has been updated subsequently every 3-5 years. Since 1991, the Commission on Cancer has required AJCC staging of all non-pediatric cases with defined benchmarks for hospital certification as an 'approved' cancer program. In addition, a nation-wide training effort to educate hospitals and physicians in AJCC staging occurred in the early 1990s. The NCDB has serially looked at trends in staging at its reporting hospitals. The most recent national assessment in 1994 used a definition of "complete" staging if  $\geq 90\%$  of evaluable cases were AJCC staged.<sup>24</sup> A detailed breakdown of trends by specific cancer, time and region is listed in Appendix E. In 1994, 88% of all cases were staged and 61% of hospitals meet the complete staging definition. What was surprising is that the NCI-designated cancer centers had the lowest of all hospital categories in its percentage of staging. Regionally, the South Atlantic was the highest in the U.S.

### ***Radiotherapy***

In the U.S., radiotherapy has an extensive quality assurance-reporting program. Each center must report on errors in related to dosing or fields during treatment. In general as a consequence of the National Patterns of Care audit program, the approach and schedule for most common cancers is quite consistent. However, this program does not address issues of appropriateness, that is over-use and under-use.

Radiation therapy has been an area where concerns of physician self-referral exist. Mitchell studied in 1980 radiation therapy care in Florida since it had 44% of its facilities were free-standing (for profit).<sup>72</sup> She found the frequency and costs of radiation-therapy treatments at free-standing centers were 40 to 60 percent higher in Florida than in the rest of the United States for Medicare beneficiaries. As a control, there was no evidence at hospital-based facilities of under-use of radiation or any survival benefit among cancer patients in Florida.

In selected early sections, comments about the patterns of radiation therapy were included. At the simplest level, radiation may be given with curative or palliative intent. The primary palliative indication is pain control. The number of treatments (fractions) and dose per treatment for pain control differs markedly between the United States and Europe. In the U.S., long fractions are much more commonly used. This has been attributed to our fee-for-service incentives. A 1995 U.S. survey of current patterns of care for osseous metastases found that long fractions (10 or more) was used by 90% of respondents and was primarily associated with being in private practice or being trained before 1982.<sup>8</sup> No direct quality of symptom control studies have been done in the U.S. but numerous European studies have found equal levels of pain control. The quality of care consequences of the high fractions schedules are indirect; fewer patients per unit time can be seen at one facility leading to the need for more facilities, total expense, and possibly a lower frequency per professional of seeing other types of conditions. No studies of actual patterns of care of palliative XRT stratified by indication were found.

## **Chemotherapy**

The patterns and types of chemotherapy used in patients with any type of advance cancers outside clinical trials is extensively tracked by the marketing divisions of major pharmaceutical corporations. Not surprisingly, this propriety information never appears in the medical literature. Therefore, concerns about the quality of care issues and data (not surveys of attitudes) addressing the impression of overuse of chemotherapy by private practice American oncologist could not found. This is likely to be an overarching problem to quality improvement and cost containment in oncology. Medical oncologists are the only specialty physicians to sell a high-priced, high volume commodity from their practice. Kurowski reports that typically 40-60% of a medical oncologists' income is derived from revenue related to office-based drug administration.<sup>56</sup> Efforts to make chemotherapy a revenue-neutral decision for the medical oncologist have yet to be successful.

As noted in the breast cancer section, compliance, dose and type of chemotherapy may make a difference in adjuvant treatment of breast cancer. In a rare example of a value-added product provided by a pharmaceutical company, Amgen has developed a comparative database that tracks adjuvant chemotherapy across over (currently) 200 sites. The database reports dose intensity,

dose delay, dose reduction, drug combination, and at selective sites if febrile neutropenia develops. Amgen's agenda is clear, provide data to support filgrastim sales. Still this is the only example that we are aware where anonymous comparisons between physicians is willfully being conducted.

### ***Pain Management***

Suboptimal pain control has been a long-standing concern of the cancer community and was the focus of one of the first national clinical practice guidelines of the Agency for Health Care Policy and Research. Worldwide many centers have assessed pain management in their centers and referral patterns to their pain clinics. The single study most highlight worthy is the broad cross-sectional report from 1990-1991 by Cleeland of 1308 outpatients with metastatic cancer from 54 treatment locations affiliated with the Eastern Cooperative Oncology Group.<sup>17</sup> They rated the severity of their pain during the preceding week, as well as the degree of pain-related functional impairment and the degree of relief provided by analgesic drugs. Their physicians attributed the pain to various factors, described its treatment, and estimated the impact of pain on the patients' ability to function. They found 67% of the patients reporting having pain or need for daily analgesics, 36% pain that limited their ability to function, and 42% were given inadequate analgesics. Racial minorities (unadjusted for educational status) were three-fold more likely to have been untreated. A discrepancy between patient and physician in judging the severity of the patient's pain was predictive of inadequate pain management (odds ratio, 2.3).

### ***Multi-disciplinary Approach***

One area where a presumed benefit will occur is for the organization of cancer care to be shifted from diversified by location cancer care into a single site "multi-disciplinary" clinic. Most university hospitals and large community hospitals advertise their "integrated approach" for most common cancers. Our own center has a breast, chest, gastrointestinal, and brain cancer clinic. Our literature review found no U.S. pre/post comparisons for single centers or reports contrasting outcome or process variables between centers using or not using such approaches. As described in the ovarian section, a benefit was inferred from the multi-disciplinary approach at the university vs. community care in Scotland.<sup>51</sup>

### ***Defining hospital or organizational characteristics***

The National Cancer Policy Board suggested a variety of factors that could be associated with superior cancer care. For each of these factors, we found no or only an occasional study that included considered the factor. The liking reasons are that these factors are **too detailed to abstract**. For example, studies of hospital characteristics include at most three variables: size, resident or no residency, and type usually university, large community, and small community. Factors such as breadth of services and technology, nurse staff levels, multidisciplinary teams, type of internal quality programs, ACS or NCI designation were not included. Some of these characteristics are available in the American Hospital Association characterizations of hospitalizations. However, when available these characteristics describe an entire hospital not just its cancer program. Additional unexplored, specifically for oncology care, hospital and health

plan factors include any effect associated with having board certified physicians, the stage of managed care in the local marketplace or other indicators of competition. This does not mean that these factors do not have face validity or are not important to insurers in their selection of physicians or medical centers. For example, Aetna/U.S. Health care recently described that they “We use the following criteria in selecting facilities to be designated as transplant centers in our Medical Excellence Program: reputation of the facility and the transplant team; volume and outcomes of procedures; service issues (such as waiting time and ancillary support); quality management program; and willingness to participate with specialized or full service agreement at competitive rates.”<sup>73</sup>

An important concern of patients is if their insurer has impediments to prompt access to cancer specific evaluation and specialty care. The literature evaluation specifically did not consider barriers due to access to chemotherapy for off-label indications or clinical trials. With the prominent exception of high-dose chemotherapy for advanced breast cancer, no Medline references could be found systematic barriers to advanced care.<sup>86</sup> An example where we did detailed searching was the use of radiosurgery or “gamma knife” for brain cancer. What we did find was only a recent retrospective assessment that the intervention is “cost-effective” for single brain metastases.<sup>66</sup>

We do not suggest that barriers on a case by case basis do not exist. Most readers have experience with “health care rationing through inconvenience” techniques such as prolonged telephone holding, pre-authorization of services referred for review to higher levels of the organization, and lifted access to emergency care. However, a detailed dissection of the taxonomy by type of cancer, insurer, location, or type of treatment could be found. This is likely to be due to the pluralistic nature of the U.S. insurance landscape that makes comparisons difficult and generalizations will be primarily opinion. As Berwick noted such delays may lead to “patients who fear that they will be denied care are often thereby induced to demand it, if only to test for their own security.”<sup>11</sup> Another explanation is that the wrong data sources were considered. A state by state review of complaints and grievances to their insurance regulators for each insurer could reveal major problems. However, no such reporting is readily available like exists for comparing United States airlines or automobiles .

Another critical unexplored area is the effect on quality in a variety of forms associated with non-staff model HMOs. Specifically, since the physician and hospital providers are only contractors to the HMO, variation is likely to reflect the administrative hurdles or inducements of a specific HMO not the cognitive or technical skills of the providers.

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## APPENDICES

### Appendix A: HEDIS 3.0® Reporting and Testing Set

#### Cancer Care Indicators listed in bold

##### I. Effectiveness of Care

###### Reporting Set Measures

- \* Advising smokers to quit (in Member Satisfaction Survey)
- \* Beta blocker treatment after a heart attack
- \* The health of seniors
- \* Eye exams for people with diabetes
- \* Flu shots for older adults
- \* Cervical cancer screening
- \* Breast cancer screening
- \* Childhood immunization status
- \* Adolescent immunization status
- \* Treating children's ear infections
- \* Prenatal care in the first trimester
- \* Low birth-weight babies
- \* Check-ups after delivery
- \* Follow up after hospitalization for mental illness

###### Testing Set Measures

- \* Number of people in the plan who smoke
- \* Smokers who quit
- \* Flu shots for high-risk adults
- \* Cholesterol management of patients hospitalized after coronary artery disease
- \* Aspirin treatment after a heart attack
- \* Outpatient care of patients hospitalized for heart failure
- \* Controlling high blood pressure
- \* Prevention of stroke in people with atrial fibrillation
- \* Colorectal cancer screening
- \* **FOLLOW-UP AFTER AN ABNORMAL PAP SMEAR**
- \* **FOLLOW-UP AFTER AN ABNORMAL MAMMOGRAM**
- \* **STAGE AT WHICH BREAST CANCER WAS DETECTED**
- \* **ASSESSMENT OF HOW BREAST CANCER THERAPY AFFECTS THE PATIENT'S ABILITY TO FUNCTION**
- \* Continuity of care for substance abuse patients
- \* Substance counseling for adolescents
- \* Availability of medication management and psychotherapy for patients with schizophrenia
- \* Patient satisfaction with mental health care

- \* Family visits for children 12 years of age or younger
- \* Failure of substance abuse treatment
- \* Screening for chemical dependency
- \* Appropriate use of psychotherapeutic medications
- \* Continuation of depression treatment
- \* Monitoring diabetes patients
- \* Chlamydia screening
- \* Prescription of antibiotics for the prevention of HIV-related pneumonia
- \* Use of appropriate medications for people with asthma

##### II. Access/Availability of Care

###### Reporting Set Measures

- \* Availability of primary care providers
- \* Children's access to primary care providers
- \* Availability of mental health/chemical dependency providers (phased in)
- \* Annual dental visit
- \* Availability of dentists
- \* Adults' access to preventive/ambulatory health services
- \* Initiation of prenatal care (phased in)
- \* Availability of obstetrical/prenatal care providers (phased in)
- \* Low birth-weight deliveries at facilities for high-risk deliveries and neonates
- \* Availability of language interpretation services

###### Testing Set Measures

- \* Problems with obtaining care

##### III. Satisfaction with the Experience of Care

###### Reporting Set

- \* The Member Satisfaction Survey (numerous measures)
- \* Survey descriptive information

###### Testing Set

- \* Consumer Assessments of Health Plans Study (CAHPS)
- \* Disenrollment survey
- \* SATISFACTION WITH BREAST CANCER TREATMENT

#### IV. Health Plan Stability

##### Reporting Set

- \* Disenrollment
- \* Provider turnover
- \* Narrative information on rate trends, financial stability and insolvency protection
- \* Indicators of financial stability
- \* Years in business/total membership

#### V. Use of Services

##### Reporting Set

- \* Well-child visits in the first 15 months of life (phased in)
- \* Well-child visits in the third, fourth, fifth and sixth year of life (phased in)
- \* Adolescent well-care visit (phased in)
- \* Frequency of selected procedures
- \* Inpatient utilization -- non-acute care
- \* Inpatient utilization -- general hospital/acute care
- \* Ambulatory care
- \* Cesarean section and vaginal birth after cesarean rate (VBAC-rate)
- \* Discharge and average length of stay for females in maternity care
- \* Births and average length of stay, newborns
- \* Frequency of ongoing prenatal care
- \* Mental health utilization -- % members receiving inpatient day/night and ambulatory services
- \* Readmission for specified mental health disorders
- \* Chemical dependency utilization -- inpatient discharges and average length of stay
- \* Chemical dependency utilization -- percentage of members receiving inpatient, day/night care and ambulatory services
- \* Mental health utilization - inpatient discharges and average length of stay
- \* Readmission for chemical dependency
- \* Outpatient drug utilization

##### Testing Set

- \* Use of Behavioral Services

#### VI. Cost of Care

##### Reporting Set

- \* High-occurrence/high-cost DRGs
- \* Rate trends

##### Testing Set

- \* Health plan costs per member per month

#### VII. Informed Health Care Choices

##### Reporting Set

- \* Language translation services
- \* New member orientation/education

##### Testing Set

- \* Counseling women about hormone replacement therapy

#### VIII. Health Plan Descriptive Information

##### Reporting Set

- \* Board certification/residency completion
- \* Provider compensation
- \* Physicians under capitation
- \* Recredentialing
- \* Pediatric mental health network
- \* Chemical dependency services
- \* Arrangements with public health, educational and social service organizations
- \* Weeks of pregnancy at time of enrollment
- \* Family planning services
- \* Preventive care and health promotion
- \* Quality assessment and improvement
- \* Case management
- \* Utilization management
- \* Risk management
- \* Diversity of Medicaid membership
- \* Unduplicated Count of Medicaid members
- \* Enrollment by payer (member years/months)
- \* Total Enrollment

Note: plans are not required to report measures that are being phased in (shown in italics) for Reporting Year 1996, except for the Medicaid populations to which these measures originally applied. These measures will apply to all populations and will be required for reporting in Reporting Year 1997.

**Appendix B: Oncology Indicators of the Joint Commission on the Accreditation of Health Care Organizations**

	DATA	STAGING	BREAST CANCER	LUNG CANCER	COLON CANCER
Focus:	Availability of data for diagnosis and staging.	Use of staging by managing physicians.	Use of tests critical for prognosis and clinical management of female breast cancer.	Effectiveness of preoperative diagnosis and staging.	Comprehensiveness of diagnostic workup.
Numerator:	Patients undergoing resection for primary cancer of the lung, colon/rectum, or female breast for which a surgical pathology consultation report is present in the medical record.	Patients undergoing resection for primary cancer of the lung, colon/rectum, or female breast with stage of tumor designated by a managing physician.	Female patients with Stage I or greater primary breast cancer that, after initial biopsy or resection, have estrogen receptor analysis results in the medical record.	Patients with non-small cell primary lung cancer undergoing thoracotomy with complete surgical resection of tumor.	Patients undergoing resection for primary cancer of the colon/rectum whose preoperative evaluation, by a managing physician, included examination of the entire colon.
Denominator:	Patients undergoing resection for primary cancer of the lung, Colon/rectum, or female breast.	Patients undergoing Resection for primary cancer of the lung, colon/rectum, or female breast.	Female patients with Stage I or greater primary breast cancer undergoing initial biopsy or resection.	Patients with non-small cell primary lung cancer undergoing thoracotomy.	Patients undergoing resection for primary cancer of the colon/rectum.

### Appendix C: FACCT Breast Cancer Quality Indicators

Measure	Performance Value	Instrument/Data Source
Steps to Good Care		
Mammography	<u>Proportion</u> of women age 52-69 who have had a mammogram within a two-year period	Doctor's billing or claims records (NCQA's HEDIS 3.0 Breast Screening measure used)
Early stage detection	<u>Proportion</u> of patients whose breast cancer was detected at Stage 0 or Stage I	Patient records from cancer registry
Informed about radiation treatment options	<u>Proportion</u> of Stage I and Stage II patients who indicate that they had adequate information about their radiation treatment options before deciding about treatment	One question in patient satisfaction survey completed three to six months after diagnosis
Breast conserving surgery	<u>Proportion</u> of Stage I and Stage II patients who undergo breast conserving surgery	Patient records from cancer registry or claims records
Radiation therapy following breast conserving surgery	<u>Proportion</u> of breast conserving surgery patients who receive radiation treatment after breast conserving surgery	Patient records from cancer registry or claims records
Experience and Satisfaction		
Patient satisfaction with care	<u>Mean</u> score for patients' level of satisfaction with breast cancer care including the technical quality, interpersonal and communication skills of their cancer doctor, their involvement in treatment decisions and the timeliness of getting information and services	Thirty-two item patient satisfaction survey completed three to six months after diagnosis
Results		
Experience of disease	<u>Mean</u> score for patients on CARES-SF survey which assesses patients' quality of life and experience in living with breast cancer	Fifty-nine item CARES-SF patient survey completed 12 to 15 months after diagnosis
Five-year disease-free survival (cancer treatment center measure)	<u>Probability</u> of disease-free survival for a group of patients, Stages I-IV, who were diagnosed during prior five years	Patient records from cancer registry

**Appendix D: Medline Search Terms and Data Categories (1988 to 5/1998)***Terms Searched (A)*

Cancer Care Facilities  
 Disease Management  
 English  
 Epidemiology  
 Medical Audit  
 Outcome Assessment (Health Care)  
 Outcome and Process Assessment (Health Care)  
 Patient Compliance  
 Physician Practice Patterns  
 Quality Assurance  
 Quality Indicators, Health Care  
 Quality of Health Care  
 Registries  
 Standards  
 Surgical Pathology  
 Treatment Outcome  
 Utilization

*Exclusion Terms (B)*

Child  
 Letters  
 News  
 Mass Screening  
 Pediatric  
 Surveys  
     Written or telephone survey or questionnaires that assessed attitudes or care patterns.  
     Questionnaires that addressed care for a specific patient were characterized as “chart reviews.”

*Cancer Terms (C)*

Neoplasm (all)  
 Bone Marrow Transplantation  
 Breast Neoplasm  
 Colorectal Neoplasm  
 Leukemia  
 Lung Neoplasm  
 Lymphoma, Hodgkin and Non-Hodgkin

Ovarian Neoplasm  
 Melanoma  
 Prostate Neoplasm  
 Testicular Neoplasm  
 Radiation Therapy  
     Brachytherapy  
     Dose Fractionation  
     Radiotherapy  
     Radiotherapy, Dosage  
     Radiotherapy, Planning  
     Radiotherapy, High-Energy  
 Oncology, medical  
 Sarcoma  
 Transplantation, Autologous

*Categorizing the Literature (D)*

Cancer Type  
 Outcome or Process  
 Methodology  
     Chart Review  
     Claims (Insurance)  
     Editorial  
     Registry  
     Report review (pathology, radiology)  
     Survey  
 Country  
 Year  
 Size  
 Patient Age  
     All  
     Over 65 (Medicare only)  
 Unit of Analysis  
     Geographic Region  
     Hospital  
     Insurer  
     Patient  
     Physician  
 Variables (selected)  
     Survival  
     Physician  
     Surgery (type)  
     Adjuvant treatment  
     Clinical factors

Comorbidities

Complications

## Appendix E: Characteristics of National Cancer Database<sup>24,67</sup>

### National Cancer Database Hospitals: Number and Percentage of Hospitals by Geographic Region and Characteristics, 1994

	Northeast	Southeast	Midwest	South	Mountain	Pacific	Total %	Total no.
Hospitals (No.)	234	194	312	205	77	205		1227
Hospitals (%)	19	16	25	17	6	17	100	
Type of hospital								
NCI-recognized	3	3	1	1	3	2	2	22
Teaching	14	9	9	5	1	4	8	99
Large community	23	20	22	18	18	27	22	265
Med/small community	32	20	33	16	23	34	27	337
Government	8	15	12	19	26	9	13	163
Profit	0	8	2	9	8	7	5	61
Other approved	1	(0.5)	1	1	1	1	1	11
Nonapproved	19	25	20	31	20	16	22	269
Total	100	100	100	100	100	100	100	1227
Caseload	%	%	%	%	%	%	%	
<100 cases	3	7	6	15	19	7	8	102
100-299 cases	22	11	21	18	22	27	20	248
300-499 cases	24	17	24	22	22	21	22	267
500-999 cases	36	44	37	30	25	32	36	432
1000+ cases	15	21	12	15	12	13	14	178
Total	100	100	100	100	100	100	100	1227
Average	649	697	559	532	437	529	581	

## AJCC Staging Completeness at NCDB Hospitals by Primary Site and Year of Diagnosis: Percent of Cases Stage

	1990	1991	1992	1993	1994
All stageable cases					
No. of Cases	323,598	402,943	494,983	470,118	488,846
Percent Staged	78%	83%	81%	87%	88%
Ampulla of Vater	74%	73%	72%	77%	78%
Anal canal	71%	73%	76%	82%	83%
Bone	59%	61%	62%	68%	69%
Brain	60%	59%	62%	67%	72%
Breast <sup>a</sup>	88%	90%	88%	94%	94%
Cervix uteri <sup>a</sup>	83%	89%	87%	92%	93%
Colon and rectum <sup>a</sup>	83%	88%	85%	90%	90%
Corpus uteri	85%	87%	85%	92%	93%
Esophagus	66%	69%	66%	72%	74%
Eyelid melanoma	86%	67%	63%	75%	81%
Exocrine pancreas	68%	73%	72%	78%	79%
Extrahepatic bile ducts	58%	58%	55%	61%	59%
Gallbladder	79%	86%	82%	87%	85%
Hodgkin's disease	68%	72%	73%	79%	83%
Kidney	79%	87%	84%	90%	91%
Larynx	82%	89%	86%	93%	93%
Lip and oral cavity	76%	83%	82%	87%	88%
Liver	57%	56%	58%	63%	64%
Lung <sup>a</sup>	76%	83%	81%	87%	88%
Maxillary sinus	72%	75%	73%	82%	79%
Ovary	81%	85%	83%	89%	91%
Penis	78%	79%	79%	86%	84%
Pharynx	77%	81%	80%	86%	87%
Pleural mesothelioma	<sup>b</sup>	<sup>b</sup>	38%	69%	70%
Prostate <sup>a</sup>	75%	81%	81%	88%	89%
Renal pelvis and ureter	80%	84%	81%	88%	89%
Retinoblastoma	50%	33%	50%	40%	17%
Salivary glands	71%	74%	72%	77%	77%
Skin melanoma	76%	79%	79%	86%	88%
Skin carcinoma	60%	61%	58%	60%	59%
Small intestine	<sup>b</sup>	<sup>b</sup>	46%	64%	65%
Soft tissues	63%	63%	65%	72%	72%
Stomach	73%	73%	72%	76%	77%
Testis	66%	70%	75%	84%	86%
Thyroid gland	82%	85%	84%	91%	92%
Urethra	73%	71%	62%	70%	72%
Urinary bladder	77%	86%	84%	89%	90%
Uvea melanoma	65%	64%	61%	79%	76%
Vulva	77%	85%	83%	91%	92%

Vagina	69%	73%	75%	82%	85%
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### Recent Trends in Hospital Completeness of AJCC Staging in the NCDB

	1990	1991	1992	1993	1994
No. of hospitals with stageable cases	1199	1342	1385	1346	1170
Percent of hospitals with "complete" staging (> 90%)	49%	49%	52%	58%	61%
Percent of hospitals with "no" staging (< 5%)	6%	6%	7%	3%	3%

AJCC: American Joint Committee on Cancer.

### Trends in Staging Completeness by Type of Hospital: % of Hospitals with Complete Staging (> 90%) by Hospital Type and Year of Diagnosis, 1990-1994

	N. hospitals <sup>a</sup>	Year of diagnosis				
		1990	1991	1992	1993	1994
All hospital types <sup>b</sup>	1678	49%	49%	52%	58%	61%
NCI-Designated	26	25%	32%	26%	52%	50%
Government	247	42%	51%	56%	52%	61%
For-Profit	68	62%	41%	41%	46%	61%
Teaching Hospital	89	48%	45%	49%	61%	70%
Large Community	248	52%	50%	54%	61%	65%
Medium/Small Community	284	53%	55%	54%	62%	62%
Other Hospitals	716	49%	45%	51%	58%	56%

NCI: National Cancer Institute.

<sup>a</sup> Number of hospitals that submitted cases in any year. Percents are based on the number of hospitals that submitted cases for the specified year.

<sup>b</sup> NCI-Designated, Government, and For-Profit categories include hospitals with and without Commission on Cancer (COC) program approval. NCI-Designated hospitals likewise may be government or private, for profit or nonprofit. Teaching Hospital, Large Community, and Medium/Small Community hospital types are limited to hospitals with COC program approval that were not included in the first three categories.

### Regional Trends in Complete Staging (> 90%) by NCDB Reporting Hospitals

Region	1990	1992	1994
Northeast	52%	54%	61%
South Atlantic	50%	57%	71%
Midwest	48%	54%	62%
South	55%	56%	59%

Mountain	20%	40%	62%
Pacific	56%	44%	54%

## **Appendix F: Benchmarks in Oncology Disease Management**

### *SalickNet Cancer Outcomes Indicators*

#### MORBIDITY

Chemotherapy Related Deaths in Patients without acute Leukemia

Admissions and days/1,000

Neutropenic Fever

Dehydration

#### SURVIVAL

5-year survival Stage II Breast Cancer

5-year survival Stage III Colorectal Cancer (T2, N1, 2, MO) 3 Year, 5 Year

3-year survival Aggressive (Intermediate and High Grade) Lymphoma

2-year, 5year survivals stage I to IIIA Lung

#### Appropriateness

Admission and days/1000

Chemotherapy

Transfusion

Hospice Deaths

Adjuvant Therapy for Breast Cancer Stage II/III

Adjuvant Chemotherapy for Colorectal Cancer Stage III (Dukes C)

Radiation Therapy after Breast Conserving Surgery

#### SATISFICATION

Patient Satisfaction Survey

“FACCT” Scores: Breast, Colon, and Lung

Source: abstracted from Piro and Doctor <sup>87</sup>

*Accountable Oncology Clinical Performance Measures and Targets, 1997*

Clinical Issue	Target
Bone scan in stage I/II breast cancer	<10%
Breast reconstruction	>40%
Mammography surveillance within 18 mo. diagnosis	>80%
Adjuvant chemotherapy in stage II/III colon cancer	>75%
Colonoscopy 6-18 MO post surgery if no evidence of recurrence	>70%
Analog pain scale	>60%
Advanced directives with metastatic or terminal disease	>50%
Single daily dose antibiotics febrile neutropenia	>70%
Serotonin antagonist limited to high emetogenic drugs	>80%
G-CSF in stage IV disease	<10%
No second line chemotherapy for gastric, lung, colon off RCTs	<20%

Source: Chris Desch, 1998

### Hillner Proposed Report Card for Early Stage Breast Cancer

Target and Observed Care in 1989-1991 in Virginia BCBS women age <65<sup>43</sup>

Issue	Expert Target*	BCBS Cohort*
<b>Evaluation</b>		
An initial biopsy prior to total mastectomy †	>95%	92%
<b>Treatment</b>		
Undergo axillary node dissection	>90%	88% §
Breast conserving surgery for local disease	50%	33%
Local breast radiation following lumpectomy	>95%	86%
<b>Staging</b>		
Peri-operative (within 30 days) bone scan	<10%	34%
Peri-operative (within 30 days) abdominal CT scan	<10%	12%
<b>Adjuvant Chemotherapy</b>		
If pre-menopausal and > 1 axillary nodes (+), then receive chemotherapy.	>90%	83%
If post-menopausal and > 1 axillary nodes (+), then receive chemotherapy ‡	50%	52%
<b>Referral</b>		
At least one visit to a medical oncologist to discuss adjuvant therapy	>80%	56%
If a mastectomy, at least one visit to a plastic surgeon to discuss reconstructive surgery.	>60%	27%
<b>Follow-up</b>		
Mammography within the first 18 months post-operatively	>95%	79%
Bone or CT scans for suspicious symptoms per year	<15%	18-35%

\* BCBS cohort used local and regional summary staging.

† Biopsy could be aspiration cytology, core biopsy, or excisional biopsy prior to total mastectomy. A two-step surgical procedure is not implied.

§ Based on axillary nodes reported to registry of those patients with summary staging. 11% of women with breast cancer were excluded since no staging data was reported.

‡ Chemotherapy only. Use of hormonal therapy could not be assessed.

## **Appendix G: Imperatives for Quality Cancer Care: Access, Advocacy, Action, and Accountability**

### *Quality Cancer Care*

Source: (**Error! Bookmark not defined.**)

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Insurers are becoming health plans and providers; providers are becoming insurers; suppliers are becoming "disease state managers;" hospitals are going out of business; health care delivery mechanisms are "moving" to the Internet; and anyone is in the business of writing clinical pathways (a.k.a. practice guidelines). The rules of the game are changing faster than management structures and information systems can support, payers can understand or track, and regulators and legislators can control. Wall Street and venture capitalists are making a killing. Development of cancer care quality guidelines will occur in this very difficult "free-for-all" environment. --*Elan Rubinstein*

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### **Background**

In September 1995, the National Coalition for Cancer Survivorship (NCCS) surveyed health providers, government officials, professional and advocacy organizations, scientists, and others regarding a critical issue facing this nation's ten million cancer survivors: quality cancer care. The responses were illuminating as they portrayed a system in flux. The United States is moving away from a health care system where fee-for-service insurance plans predominate to one where market-based alternatives quickly are gaining favor among employers, consumers, and other purchasers of health care coverage. What this fundamental transition will mean for survivors and individuals with serious or life-threatening diseases and the people who care for them is an open question with important public policy implications.

This position paper summarizes the opinions of experts from a diversity of disciplines regarding the strengths and weaknesses of both fee-for-service and market-based approaches and the particular needs of cancer survivors. It incorporates input from invited participants at a Leadership Forum convened by NCCS during the First National Congress on Cancer Survivorship in Washington, DC, a working group on Quality Cancer Care comprised of Congress delegates, and a Speak Out where the working groups reported their findings to the assembled delegates.

### **Fee-For-Service**

#### **Strengths**

Not surprisingly, the respondents cited choice--of providers, treatments, and institutions--as the overwhelming strength of fee-for-service plans. The experts agreed that the initial selection of, and resulting satisfaction with, a particular health care provider can be influenced by factors as distinct as convenience, cost, expertise, and personal compatibility. Freedom of choice was seen as offering both strictly medical advantages--for example, the ability to seek second opinions from

specialists in cases of rare conditions--as well as psychological benefits, including the encouragement of strong doctor/patient relationships. As stated by one survivor:

"In the traditional fee-for-service system, the patient/survivor has choice; from this stems the opportunity for control and confidence. If the opportunity is seized, the patient motivates the physician and the medical team to their best performances, and, through them, the delivery system to its best performance. With control, the patient can insist on explanations and alternatives. This leads to confidence. Lacking either control or confidence, the patient in this system still has the choice of finding a new physician."

In addition to choice, the availability of state of the art cancer treatment, including long-term follow-up by specialists, was regarded as another significant strong point of the fee-for-service approach. Although fee-for-service plans may not have paid directly for research treatments, generous reimbursement for ancillary costs often supported major clinical research programs. This led to a network of oncologists and specialized centers conducting clinical trials involving promising new therapies. As a result, the United States is a leader in innovative diagnostic, imaging, and therapeutic technology.

Fee-for-service also allows providers maximum flexibility in utilizing these advancements, as they can individualize treatment plans in order to care for patients as they deem best. Flexibility, discretion, and creativity were terms associated with fee-for-service. As one expert stated: "(T)he fee-for-service system has many faults but does result in physicians being advocates for therapy and for patients. Alternative managed care systems may make physicians the rationed(s) of health care rather than the advocate(s) of health care."

### **Drawbacks**

As recognized in the foregoing statement, the fee-for-service approach does have significant faults. On a macro level, respondents pointed to financial incentives which can encourage over-utilization of services offering little or no improvement in either length or quality of life. The resulting inefficiencies have contributed to escalating health care costs that many regard as impossible to sustain in the future. Examples of situations where better use of our resources could be achieved included:

- Continuing aggressive care when support or palliative care would be more appropriate
- "Shopping" for third or fourth opinions
- Promoting expensive new care to patients before the efficacy of the particular procedure or treatment is clearly established through qualified clinical trials
- Allowing "me too" programs and services to proliferate in a manner that is not efficient or cost-effective given geographic location, population, or incidence
- Promoting clinical trials which are redundant or otherwise not designed to yield useful new data
- Practicing defensive medicine by using redundant or unnecessary treatments

A second fundamental problem of the current system is reflected in the more than 40 million Americans who do not have health insurance. With the fee-for-service system tied to employment, employees of small businesses, the unemployed, low-income individuals who do not qualify for Medicaid, undocumented workers, and other entire classes of people do not have ready access to the health care delivery system. Although respondents noted that most of these people can obtain health care, it is often fragmented and rendered at great expense. The result is cost shifting,

leading to higher costs, higher premiums, higher deductions, and higher co-payments for those who have insurance.

Once in the system, all participants--survivors, health care providers, and payers--face a labyrinth of codes, forms, bills, and other often duplicative records that exact huge administrative and psychological costs to process. Other weaknesses of the fee-for-service structure that directly impact survivors' qualities of care include: lack of coordinated services; failure to reimburse for preventive measures, supportive services, and long-term follow-up; and the absence of good quality control measures.

In addition, restrictive insurance practices--pre-existing condition clauses, life-time caps, and health-based eligibility standards--often act to deny people coverage when they need it the most. Cancer survivors in particular often experience difficulty in receiving state of the art care because many insurers refuse to cover the patient care costs associated with clinical trials and off-label or other "investigational" therapies.

Perhaps the crux of the problem with the fee-for-service system is that too many people do not have information about these limitations or do not comprehend their implications until it is too late. As one expert noted: "Beneficiaries may voluntarily choose reduced benefits in order to save monthly premium costs (goal: to maximize beneficiaries' short term gain). However, it is important to note that employers generally establish the health insurance options, associated premiums and cafeteria-style variables among which employees may select, and *that beneficiaries may not be fully aware of the risk they run in voluntarily choosing less expensive health insurance*. Finally, it is critical to note that health insurance choices by healthy individuals may differ from choices made by those afflicted by serious disease, but one may not select a 'better' insurance plan once being diagnosed. Buying health insurance is like gambling in that respect."

## **Market-Based Approaches**

### **Opportunities and potential drawbacks**

At the time of this survey, respondents agreed that the fee-for-service system had fundamental flaws; market-based plans may well address many of these shortcomings, especially with regard to prevention and early detection. However, it also is apparent that some aspects of the transition to market-based health care are troubling to the surveyed experts. Most of these concerns focused on our ability to remain in the forefront of cancer research and care and to continue to encourage technological innovation if decisions are driven primarily by short-term financial considerations.

A hallmark of most market-based plans is the gatekeeping role played by primary care physicians who are responsible for coordinating individuals' care and referring them to specialists. The surveyed experts were unanimous in stating that survivors must have continued timely access to specialists, and that they should not face high out-of-pocket expenses if they are forced to go outside of their plan to be treated by the needed specialist. Other important characteristics which the experts wanted to see in market-based plans were:

- Nondiscriminatory clauses based on preexisting conditions or genetic risk factors
- Guaranteed portability

- Expeditious and fair appeal mechanisms
- Inclusion of credentialed specialists in networks
- The ready availability of second opinions
- Coordinated care across the spectrum of survivorship

When specifically asked, most respondents felt that oncologists should be the primary managers of care for survivors with active malignancies and those in the early stages of remission. To support their position, they cited several factors:

- The complexities of treating cancer, a term which includes more than 100 different conditions
- Oncologists' specific knowledge of long-term and late effects, rehabilitative services, and pain management and hospice
- Survivors' increased risk for second malignancies and the importance of early detection and treatment

The respondents also acknowledged, however, that in many cases longer-term survivors can be followed successfully by a primary care physician, especially if (1) they have an annual evaluation by a specialist, (2) there was ongoing consultation between the primary care physician and the oncologist, and (3) there were adequate care guidelines for monitoring the physiologic long-term and late effects of cancer treatment. Education of primary care physicians, the development of guidelines, and more emphasis on extended follow-up were regarded as components that could improve survivors' quality of care under these circumstances.

In addition to continued access to specialists, respondents also were troubled about the commitment of market-based plans to support the cancer research system currently in place. They feared that we will be forced to seek increases in public funding for basic and clinical research at a time when neither the public nor Congress will support such expenditures. In fact, many felt that all health care plans, whether fee-for-service or market-based, should be required to cover clinical trials meeting specific standards.

Indeed, a refrain throughout the various opinions was that we cannot sacrifice long-term quality care for short-term cost savings. People lose confidence in systems that do not meet needs.

Instead, there was widespread support for a more balanced approach that attempts to define cancer care which is both cost-effective and of optimum quality:

- Reasonable guidelines and clinical care pathways must be developed to standardize care and to help eliminate unnecessary, and often costly, services and procedures.
- Outcomes data need to be collected so that valid quality measurements are available to guide providers' treatment recommendations.
- Survivors must have access to information like practice patterns and outcomes data in a concise and easily understood form so that they are able to reach truly informed decisions.

## **Measuring Quality Cancer Care**

### **Special considerations**

Although rudimentary attempts at assessing quality cancer care are underway, NCCS believes that several fundamental issues must be reflected in standards and guidelines if we are to design reliable measurements of care:

- Unlike many common diseases, "cancer" is many different diseases, some of which are not encountered frequently by any one provider.
- Cancer, particularly in the acute stage, often requires specialized care.
- Standards need to be developed that measure care across the spectrum of survivorship, from prevention and screening mechanisms through early diagnosis and treatment to long-term follow-up and palliative care.
- Variations in such important factors as geographic setting and socioeconomic status can dramatically impact the quality of available care.
- Cancer is unique because sometimes the best treatment available may only be found through a well-designed, patient-oriented clinical trial.
- Occasionally, state of the art cancer treatment offers only small benefits over established treatments, yet may be more costly.
- For cancer survivors, improvements in quality of life are significant end points that must be considered in addition to increased longevity.
- 

### **Suggested Strategies to Ensure Quality Cancer Care**

#### **Initiatives to overcome barriers: December 1995-April 1996**

At the conclusion of the First National Congress on Cancer Survivorship, NCCS indicated it would go forward and discuss the issues raised in the working draft of this position paper with others in the community who might share our interest in reaching broad agreement on the definition of "quality cancer care."

Between December, 1995, and April, 1996, NCCS leadership met with many experts in cancer research, cancer care, and health policy to discuss the position paper on quality cancer care. NCCS also has been invited to participate with oncology advisory boards and other cancer agencies which are exploring ways to deal with managed care organizations and private sector groups who are seeking to define quality care for their audiences. Over the last four months many groups used the working draft of the position paper as a point of information and discussion to examine ways their organizations and institutions could address the issues raised in the document.

In a direct response to the concerns articulated by NCCS, in December, 1995, Dr. Richard Klausner, the Director of the National Cancer Institute (NCI) appointed a working group to focus attention on the issues related to the psychological and biomedical consequences of a cancer diagnosis. The result has been Dr. Klausner's public announcement in April, 1996, of the formation of a new Office of Cancer Survivorship within the NCI, located within the Division of Cancer Treatment, Diagnosis and Centers in the Clinical Investigations Branch, Cancer Therapy and Evaluation Program. The purpose of this new office is to explore the research issues and

consequences of cancer survivorship. The office will interact with the entire spectrum of the NCI, including scientific disciplines ranging from those involved with genetics and clinical trials to behavioral research and quality of life. Survivorship issues for children and adults will be addressed, including long-term and late effects--the physiological and psychosocial aspects of cancer survival. The new office will take advantage of existing programs and develop new research initiatives.

Further development of the position paper on quality cancer care has taken place during the past several months, and overarching themes and issues have emerged. For example, in February, 1995, the Association of Community Cancer Centers (ACCC) sponsored a retreat entitled "Patient Advocacy Issues in a Changing Health Care Environment." During this meeting and at the annual ACCC President's Retreat immediately following, NCCS enumerated the criteria people with cancer should be looking for in health care plans. A version of these widely accepted criteria was published in the March/April, 1996, *Oncology Issues*. These criteria will be further refined as NCCS works with them in other settings, including the development of a "report card" for people with cancer. Briefly, these criteria are:

- The primacy of the doctor/patient relationship should be preserved.
- Health care plans should provide for appropriate and timely screening.
- Upon diagnosis of cancer, the patient should be referred immediately to a cancer care specialist.
- Cancer should be treated using a multidisciplinary approach.
- During active treatment, the gatekeeping function should be performed by an oncologist or other specialty physician.
- Children with cancer should be treated by pediatric oncology specialists.
- Where appropriate, and without additional financial burden, health care organizations should provide for treatment of people with cancer at specialized facilities.
- Health care plans should provide for enrollment of patients in clinical trials.
- Cancer patients in remission should be monitored periodically by cancer specialists--not only by primary care physicians--and have access to rehabilitative care when indicated.
- People with cancer should have access to a full range of supportive care services, including, but not limited to, psychosocial services, nutritional and vocational counseling, management of pain, nausea, fatigue, and other debilitating side effects of treatment.
- Systematic long-term follow-up care guidelines should be established for adult cancer survivors and incorporated into health care plans.
- People with cancer should receive referrals to hospice services in a variety of settings, including home health care.

NCCS has since used these criteria as a discussion document in several meetings about quality cancer care involving representatives from the American Cancer Society, the Cancer Leadership Council, the National Comprehensive Cancer Network, the Foundation for Accountability, the Alliance for Aging Research, and the American Society of Clinical Oncology. These opportunities for discussion among different groups over the last several months have enabled the cancer community to begin using a common, patient-centered language about quality cancer care.

## Strategic Imperatives to the Year 2000

If the cancer community is to succeed in getting its definition of quality cancer care into the marketplace and into the reporting mechanisms of health care plans where people with cancer can directly benefit, it must ensure that strategies and a plan for implementing those strategies are in place.

While all of us have a stake in the outcome, it will be important that those who have the most to gain and the most to lose--people who have been diagnosed with cancer--assume some responsibility for ensuring that the messages in these position papers are delivered to the appropriate agencies, organizations, and the public at large. NCCS believes that, in the future, an educated and enlightened public will take the lead in mapping a course for an accountable health care system. As managed care evolves, *individuals will demand the most value for their health care dollar.*

One of the few remaining impediments to an educated public is a divided cancer community. Little else can stand in the way if the cancer community works in concert--united in its resolve to move forward in an expedient manner with the following initiatives:

- Develop a communications plan to educate the public about the need for a system of health care that will ensure quality cancer care for all people
- Work with all sectors of the cancer community to define quality cancer care and to develop a systematic methodology for having health care plans, accrediting agencies, and other constituency groups utilize that definition
- Develop a communications plan to educate the public about the need for patient-oriented cancer research
- Encourage the development of practice guidelines that will elevate the standard of cancer care; provide better choices for decision-making by patients; and look at quality of life (as well as survival) as a desired endpoint
- Develop standards of measurement (qualitative as well as quantitative) that are universal in their recognition of capturing the patient experience across the spectrum of cancer care and that are not specific to any particular setting or system of health care
- Convene meetings among health care providers, voluntary agencies, researchers, industry, and the federal government, to encourage more collaboration and avoid duplication of effort
- Educate and periodically update policy makers, opinion leaders, and the media about the importance of receiving quality cancer care
- Work with the cancer community to develop a legislative agenda that can be used by grassroots organizations and national associations to ensure that public policies are favorable to accessing quality cancer care
- Design a patient "report card" around the quality cancer care issues that is easy to understand and applicable to all populations

## *Declaration of Principles*

National Cancer Institute: Imperatives for Quality Cancer Care (**Error! Bookmark not defined.**)

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### **Principle 1**

People with cancer have the right to a system of universal health care. This access should not be precluded because of preexisting conditions, genetic or other risk factors, or employment status.

### **Principle 2**

Quality cancer care should be available in a health care system whose standards and guidelines are developed in consideration of treating the whole person with cancer. Health care plans must regard the cancer patient as an autonomous individual who has the right to be involved in decisions about his or her care.

### **Principle 3**

Standards of cancer care should be driven by the quality of care, not only by the cost of care, and should include participation in clinical trials and quality of life considerations.

### **Principle 4**

All people diagnosed with cancer should have access to and coverage for services provided by a multidisciplinary team of care providers across the full continuum of care. Health care plans should be held accountable for timely referral to appropriate specialists when symptoms of cancer or its recurrence may be present.

### **Principle 5**

People with cancer should be provided a range of benefits by all health care plans that includes primary and secondary prevention, early detection, initial treatment, supportive therapies to manage pain, nausea, fatigue and infections, long-term follow-up, psychosocial services, palliative care, hospice care, and bereavement counseling.

### **Principle 6**

People with histories of cancer have the right to continued medical follow-up with basic standards of care that include the specific needs of long-term survivors.

### **Principle 7**

Long-term survivors should have access to specialized follow-up clinics that focus on health promotion, disease prevention, rehabilitation, and identification of physiologic and psychosocial problems. Communication with the primary care physician must be maintained.

### **Principle 8**

Systematic long-term follow-up should generate data that contribute to improvements in cancer therapies and decreases in morbidity.

### **Principle 9**

The responsibility for appropriate long-term medical care must be shared by cancer survivors, their families, the oncology team, and primary care providers.

**Principle 10**

The provision of psychosocial services must be safeguarded and promoted. Persons diagnosed with cancer should receive psychosocial assessments at critical junctures along the continuum of cancer care to determine availability of needed support and their ability to seek information and to advocate on their own behalf.

**Principle 11**

Psychosocial research is integral to comprehensive cancer care and, as such, psychosocial outcome measures should be included in all future clinical trials. The importance of this research and its application and transfer to oncology care plans should be recognized and encouraged.

**Principle 12**

Cancer survivors, health care providers and other key constituency groups must work together to increase public awareness; educate consumers, professionals, and public policy makers; develop guidelines and disseminate information; advocate for increased research funding; and articulate for and promote survivors' rights.

## **Appendix H: Access to Quality Cancer Care: Consensus Statement**

By the American Federation of Clinical Oncology Societies

QUALITY CANCER CARE can only be assured if patients with cancer are guaranteed medically appropriate and timely access to specialists and specialized treatment. Efforts to contain overall health care expenditures should not impede a patient's ability to receive necessary services. A patient's diagnosis, not fiscal constraints, should determine how and what care is provided.

Cancer care requires that the patient has access to a multidisciplinary team of cancer providers across the full continuum of care and coordination of services, including prevention, early detection, staging evaluation, initial and subsequent treatment, palliative care, supportive therapies, long-term follow-up, rehabilitation, psychosocial services, and hospice. Oncologic specialists are skilled in selecting treatment options and, in the case of terminal illnesses, are able to provide palliative care that improves quality of life.

The cancer community recognizes its role in assuring that specialty services result in cost-effective, high-quality care. Professional clinical oncology organizations, people with cancer, and payors are strongly encouraged to facilitate the collection, validation, and dissemination of outcomes data so that purchasers of health care can make informed choices about which plans offer access to quality specialty care that is cost effective.

Oncologic health care professionals are committed to working with patient advocates to optimize cancer care. Providing medically appropriate and expeditious access to cancer specialty care involves several aspects which are detailed below.

### **ELEMENTS OF QUALITY CANCER CARE**

- Primary care providers should be encouraged to refer patients for specialty care when they lack the experience and skills to provide necessary and appropriate care. Similarly, primary care providers and specialists must be permitted to refer patients to oncologic health care professionals or facilities outside the payor's network if medically necessary services are not available within the plan.
- All persons with cancer and their families must have access to appropriate and culturally sensitive information, be allowed to participate in decision-making, and have full informed consent.
- All persons should have timely access to high-quality cancer screening and other diagnostic tests. When tests fail to conclusively establish or negate a cancer diagnosis, patients must have direct access to a cancer specialist for further evaluation.

- Upon diagnosis of cancer, timely referral for treatment increases the opportunity for optimal outcomes, including in many cases improved rates of cure, longer survival, and quality of life. The interval between the time of diagnosis and initial treatment should be minimized.
- Determining the extent of disease at initial diagnosis and at relapse (i.e., staging) is essential.
- To achieve optimal outcome, most cancer care delivery should be planned and coordinated by a multidisciplinary team of oncologic health care professionals.
- Payors must provide ready access to pediatric oncologists, recognizing that childhood cancers are biologically distinct. Research has clearly demonstrated that the likelihood of successful outcome in children is enhanced when treatment is provided by pediatric cancer specialists.
- An oncologic specialist should be able to serve as the primary care physician when delivering active cancer therapy.
- Payors must provide access to and coverage of medically appropriate, state-of-the-art cancer treatment. Payors must cover, as a matter of policy, unlabeled indications of drugs and biologics used in anticancer chemotherapy regimens if the uses are listed in one of the compendia or are otherwise supported in the peer-reviewed medical literature. Payors must also provide timely and convenient access to high-quality radiation therapy planning and delivery equipment, as well as to other specialized radiotherapeutic procedures and equipment. Payors must provide access to surgical subspecialty care, including specialized techniques when medically indicated. Payors must further recognize that specialized oncology nursing care and oncology social work are an essential part of multidisciplinary cancer care.
- Treatment in a clinical trial is often a cancer patient's best option. Payors must provide patient access to and coverage of the patient care costs associated with participating in cancer clinical trials that have been approved by the National Institutes of Health (NIH), NIH cooperative groups and centers, the Food and Drug Administration, the Department of Defense, the Department of Veterans Affairs, or a qualified nongovernmental research entity identified in the guidelines issued by NIH for cancer center support grants.
- Psychosocial services are an important component of cancer care. These include support groups, counseling by oncology social workers and other trained psychosocial professionals, and medical interventions. People with cancer should receive access to such services, not limited by their previously existing conditions.

- Supportive care services and effective symptom management are essential to promoting the quality of life for people diagnosed with cancer. Patients must have access to these services and therapies as part of their comprehensive cancer care.
- Patients must have access to and coverage for hospice services.
- Comprehensive rehabilitation, including reconstruction, prosthetic devices, and durable and disposable medical devices, is critically important and must be covered by payors.
- Delayed and long-term complications of treatment, late relapse, and second malignancy are all well-recognized sequelae of cancer. Therefore, long-term follow-up is essential. Many patients who have been treated for a long period of time by a cancer specialist want to continue seeing the specialist even after the cancer is in remission or considered cured. In the interest of dealing with the sequelae of cancer treatment and to improve patient satisfaction, these arrangements should be permitted to continue.
- All obstacles to access and coverage based on pre-existing conditions, genetics, or other risk factors must be eliminated.

Berwick Aims of Health System Reform	Impression of Authors
Reducing inappropriate surgery, hospital admissions, and diagnostic tests	Salick guidelines focus on reducing admissions for chemotherapy and its complications
Reduce the use of unwanted medical procedures at the end of life	Report temporal trends of the percent of patients using hospice for the four most common cancers
Simplifying pharmaceutical use	Single centers should restrict their pharmacies to one agent with a class
Increasing active patient participation in therapeutic decision making	Expanded use of Informed Decision Making model for breast and prostate surgery
Decreasing waiting times in health care settings	Excluding clinical trials and off-label use, no waiting times for cancer treatments should routinely occur
Reducing inventory levels in health care organizations	Independently access if US. has an excess capacity of radiation oncology facilities Work with professional societies to reduce the number of surgeons doing cancer procedures

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Most threatening of all; too many centers doing  
cancer surgery

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