

## Health Services and Outcomes Research/National Comprehensive Cancer Network Outcomes Databases

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Historically, oncology research has focused on particular tumor types or drug classes, and success has been determined by endpoints such as reduction in mortality or response rate. However, the aging of the American population, improvements in medical technology and increases in health care costs have prompted interest in studies of alternative endpoints such as cost and quality of life.

Health Services research is a multi-disciplinary field that studies issues of access to care, costs of care, and consequences of health care for both individuals and populations. This is particularly important in oncology, with its significant trade offs between costs (both physical side effects and economic) and benefits therapy. The economic burden of cancer in the United States is substantial; the American Cancer Society estimated in 2004 that the total cost of cancer care was \$189.8 billion, with \$69.4 in direct medical costs, \$16.9 billion in indirect medical costs and \$103.5 billion in indirect mortality costs (lost productivity due to premature death). With the rapid advances in drug development, imaging modalities and other interventions for cancer patients, it is imperative that physicians, policy makers and insurers understand these issues to ensure access to high quality care for all patients.

The Health Services/Outcomes Research Section of the Population Science Division is actively examining these complex issues in cancer care.

### **National Comprehensive Cancer Network (NCCN) Outcomes Research Projects**

The NCCN Outcomes Research Projects in breast cancer, non-Hodgkin's lymphoma and colorectal cancer are multi-institutional databases that collect detailed information regarding the diagnosis, treatment and outcomes of patients treated at NCCN centers. These projects provide important quality improvement information to individual centers including their concordance with NCCN treatment guidelines. They have also served as a rich database for understand patterns of care and practice variation across the country. The databases are modified regularly to incorporate guideline changes and new technology.

**Breast cancer.** Wong, Sherman,<sup>a</sup> Bookman

The NCCN outcomes database project in breast

cancer was initiated on July 1, 1997. There are over 20,000 patients enrolled in 11 NCCN institutions and three community sites. Two additional sites joined in 2005. Recent projects have included studies of practice variations of taxane, the emergence of sentinel node biopsies, and the use of radiation as a component of breast conservation therapy.

**Non-Hodgkin's lymphoma.** Millenson, Sherman<sup>a</sup>

The NCCN outcomes database for non-Hodgkin's Lymphoma began in July 2000. There are currently over 1,500 patients enrolled across five centers with two centers joining in 2005. Recent projects have included the impact of age on treatment for diffuse large B cell lymphoma, and the impact of pathology review of therapy for NHL.

## **Colorectal cancer.** Engstrom, Wong, McGinn

The colorectal cancer database is the newest of the NCCN outcomes projects. It was initiated in September 2005 and will include patients enrolled in eight NCCN centers. It will include extensive patient-reported co-morbidity data.

### **Cost effectiveness analysis.**

Cost effectiveness analysis (CEA) is a method of economic evaluation that measures costs related to alternative interventions for a single common outcome. For example, it can be used to study different therapeutic options for a particular disease (e.g., dialysis vs. kidney transplantation for end stage renal disease) or public health interventions (e.g., annual fecal occult blood testing vs. colonoscopy every 10 years). Given the rising cost of health care and budget constraints many experts argue that CEA should be incorporated into decision making regarding insurance coverage.

### **Modeling the cost effectiveness of treatment options for patients with colorectal cancer.**

Wong, Beck, in collaboration with Meropol<sup>§</sup>

The introduction of four new drugs (irinotecan, oxaliplatin, cetuximab and bevacizumab) in the last decade has increased median overall survival of patients with metastatic colorectal cancer from 12 to 22 months. These new agents are given in the palliative setting with modest response rates, but are much more costly than 5-fluorouracil (5FU) and leucovorin (LV). Furthermore, since these agents are being added sequentially to, rather than replacing pre-existing regimens, the costs of newer regimens are increasing substantially. To the best of our knowledge there has not been a comprehensive cost effectiveness analysis of these new treatment regimens for metastatic colorectal cancer.

We have developed a model to measure the incremental cost effectiveness of treatment options for metastatic colorectal cancer. This model will measure the added costs and changes to life expectancy associated with

newly developed combination chemotherapy regimens, compared to 5FU/LV alone and best supportive care.

### **Cost effectiveness of amifostine for prevention of radiation induced xerostomia.** Sherman,<sup>a</sup> in collaboration with Snyder-Dougherty,<sup>§</sup> Nicolaou,<sup>§</sup> Feigenberg,<sup>§</sup> Lango,<sup>§</sup> R. Cohen,<sup>§</sup> Horwitz,<sup>§</sup> Langer,<sup>§</sup> Ridge<sup>§</sup>

Treatment of squamous cell cancers of the head and neck can be associated with severe short and long-term morbidity. Although studies have found that most short-term toxicities return to baseline, xerostomia (dry mouth) continues to be a long-term issue for survivors of head and neck cancer. Amifostine is used in the prevention of xerostomia, but is costly and burdensome to administer. Randomized studies have shown minimal, but significant benefits of treating chronic xerostomia.

We recently completed a decision analysis model of the cost-effectiveness of using amifostine in the prevention of chronic xerostomia. This project included the measurement of health utility of different grades of xerostomia. We presented our results at the 2005 ASCO meeting.

### **SEER (Survival, Epidemiology and End Results) Database of the National Cancer Institute survival analysis of SEER/Medicare data using propensity score methods.** Wong, in collaboration with Hudes,<sup>§</sup> Armstrong,<sup>b</sup> Mitra<sup>c</sup>

Prostate cancer is the most common cancer in American men with over 230,000 diagnosed in 2005. Up to 95% of will seek active treatment with surgery, radiotherapy and/or hormonal therapy, yet there is little randomized data comparing active therapy to observation for localized disease.

We are using the linked SEER-Medicare databases the effect for treatment with radiation or surgery on survival for men with low or intermediate risk prostate cancer. We are using propensity scores to adjust for the known confounders that may impact treatment choice such as demographics and co-morbidities.

## Publications

Buchholz, T.A., Theriault, R., Niland, J., Hughes, M.E., Ottesen, R., Edge, S.B., Bookman, M.A., Weeks, J.C. The use of radiation as a component of breast conservation therapy in National Comprehensive Cancer Network Centers. *J. Clin. Oncol.* (in press).

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*The Foxdragons at the Dragon Boat Festival*