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A Comprehensive Clinical Research Program

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The Ochsner Cancer Institute has learned one simple truth: communication is the key to success. By encouraging close interaction among its physicians and trial coordinators, and through impeccable organization, the New Orleans-based institute is able to maintain a wide variety of protocols.

Ochsner conducts many of its own protocols through the Ochsner Cancer Study Group, but

most of its studies come from the Community Clinical Oncology Program. Research bases providing protocols to the Ochsner CCOP include the North Central Cancer Treatment Group (NCCTG), the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Eastern Cooperative Oncology Group (ECOG), the Pediatric Oncology Group, and the M.D. Anderson CCOP.

The Ochsner Foundation serves

as the fiscal and administrative agent for the CCOP, which is a consortium of Ochsner Clinics in New Orleans and Baton Rouge, with components in Houma, Louisiana, and in Jackson, Hattiesburg, Gulfport, and Biloxi, Mississippi.

Ochsner's primary focus is the study of breast cancer, lung cancer, G.I. malignancies, new drug investigation, and supportive care issues, particularly antiemetic and quality of life studies. The institute is

The Ochsner Clinic consists of 200 board-certified specialists in all areas of medical practice. Since its founding in the 1940s, the Ochsner medical institutions have had a strong interest in cancer care. In September 1981, the Ochsner Cancer Institute was formed to coordinate multidisciplinary cancer

care, clinical research, education programs, and cancer control efforts. The Alton Ochsner Medical Foundation is the fiscal and administrative agent for a CCOP consortium of the Ochsner Clinic of New Orleans, the Ochsner Clinic of Baton Rouge, and a component in Houma,

Louisiana, as well as components in Mississippi.

VITAL STATISTICS

- Total institution bed size: 550
- Dedicated cancer unit beds: 30
- New cancer patients seen each year: 1,250
- Annual number of patients on NCI-approved protocols: 200
- Annual number of other external protocols: 120
- Managed care penetration in the state: 7.3 percent

SOCIAL SUPPORT SERVICES

- Two social workers provide counseling, discharge planning and placement, and specialty referrals on an inpatient and outpatient basis.
- A monthly support group helps patients and their families and friends cope with the financial burdens of cancer treatment. Expert guest speakers discuss relaxation methods and provide information on individual cancers.
- The institute works closely with community groups in providing outside resources for patients.
- The Oncology Nursing Council meets weekly to coordinate patient care, discuss continuity of care and problem-solving, and to plan special projects.



usually involved in about 100 studies at a time; current studies include the NSABP Tamoxifen trial, the Proscar Prostate Cancer Prevention Trial, and the Cis Retinoic Acid Lung Cancer Prevention Trial. In addition, the institute was recently approved for an NCI grant to study the barriers that exist to minorities for cancer care and involvement in cancer clinical trials.

OPEN COMMUNICATION

With so many studies going at once, the institute has taken the necessary precautions against competing and overlapping protocols, according to Richard J. Gralla, M.D., Ochsner's cancer program administrator. These precautions consist of an internal communication system whereby physicians and trial coordinators are regularly notified of the patient population within each trial. A priority list of protocols can be updated monthly. Although this system ensures that the protocols do not overlap, according to Gralla, Ochsner recognizes the complementary aspects of each of its studies.

"We feel that these all cross-reference each other," he said. "We would hope that they would be sufficiently of interest...to then take back to the CCOP."

Communication is the cornerstone of individual patient care for those entered on clinical trials. Staff work to ensure that information is shared with the members of the health care team, according to Nursing Administrator Marilyn M. Bateman, R.N. "At Ochsner," she said, "we have full cooperation among all medical specialties involved in protocol therapy.

We're trying to have a very global outlook and meet the needs of patients that cross disciplines."

The institute also places heavy emphasis on high-quality data management. Most of the institute's data managers are oncology certified nurses, who assume a great deal of responsibility, essentially serving as a primary care giver.

"These nurses are independent thinkers who are well qualified and accustomed to organizing the cancer patient's care," said Bateman. "We are involved with the patient's care as it progresses. We collect data as we go along rather than waiting until after treatment is rendered. The nurses are well versed in oncology and work collaboratively with the oncologists to assure that patients participating in clinical trials receive the best available care."

QUALITY OF LIFE

Measuring the quality of life in cancer patients is also one of Ochsner's challenges. Although there are several reliable instruments that measure the quality of life, getting unbiased results is difficult because some patients die before a study is completed or they transfer to another trial. To overcome this obstacle, Ochsner focuses its analysis of quality of life on the first 100 days of a study. Through this method, Ochsner researchers hope to obtain more reliable results that will reflect upon all patients, not just those who stay in the study over a long period of time.

The Lung Cancer Symptom Scale is one instrument the institute is studying to determine whether 1) the scale measures what it is

intended to, 2) the results are reproducible, and 3) the scale is acceptable to both patients and staff.

In all its studies, Ochsner places emphasis on pharmaceutical Phase I and Phase II trials rather than on postmarketing studies, which are conducted after a decision has already been made to purchase a particular drug. Currently, the institute is involved in a Phase I trial combination of Taxotere (docetaxel) and cisplatin in-hopes of finding the optimal dose of each agent. The institute is also conducting Navelbine (vinorelbine) studies, both as a single agent and in combination with mitomycin and cisplatin. In these studies, they hope to improve on dose intensity while lessening side effects. The results will be used in the treatment of breast, lung, and colon cancer.

In addition, the Ochsner Cancer Institute has conducted studies with several 5-HT₃ antagonist antiemetics, such as granisetron, dolasetron, and RG12915, and it is conducting cost-effectiveness surveys as preparation for what Gralla believes will be a negative fallout from health care reform.

"We believe that the Clinton Health Plan has not come out as firmly as one would like in terms of supporting clinical research," he said. "As I recall, it leaves it up to various alliances. I worry about that since research is the future in the treatment of cancer. Health care reform as we currently are seeing could have a major impact—we hope for the better, but more likely negative—on clinical research." ■