ONCOLOGISTS DISPUTE FINDINGS OF GAO STUDY ON BREAKTHROUGH CANCER TREATMENTS

Oncologists are taking exception to a recent report by the General Accounting Office (GAO) which concludes that a high percentage of eligible cancer patients are not receiving state-of-the-art chemotherapy treatment.

The report, entitled "Cancer Treatment 1975-1985: The Use of Breakthrough Treatments for Seven Types of Cancer," which was initiated at the request of Rep. Henry Waxman (D-CA), states that it can't be sure why state-of-the-art treatments were not being widely applied in 1985, because, "the obstacles to a more widespread application [may] lie with physicians or patients or both or neither."

Nevertheless, GAO claims that its findings are "especially troubling," because the breakthrough treatments it studied were available by 1982, proven to increase survival in large randomized clinical trials, and relevant for an identifiable group of cancer patients. These criteria were applied to patient data contained in the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) database.

The NCI also defined patient subgroups that should receive treatment for the GAO, (for example, adjuvant chemotherapy for breast cancer was "judged to be most relevant" for premenopausal women who had tumors of less than five centimeters at the time of diagnosis; metastasis to regional lymph nodes, but not to distant organs; and tumors that were classified as adenocarcinoma or duct adenocarcinoma).

Despite the GAO's adoption of NCI-defined patient subgroups, oncologists are questioning the accuracy of the selection of "eligible" patients from the SEER data. They point out that physicians' treatment decisions take into account many factors that would fall outside of the eligibility criteria GAO used, such as coexisting medical conditions, general poor health, advanced physiologic/chronologic age, and patient treatment compliance.

Oncologists such B. J. Kennedy, M.D., Professor of Medicine and Masonic Professor of Oncology, University of Minnesota Medical Center, Minneapolis, are also critical of what they see as the GAO's "typical, negative approach to progress in cancer treatment." The GAO's treatment conclusions about seven types of cancer and comments on those conclusions by Kennedy are as follows:

Oncologists are critical of what they see as GAO's "typical, negative approach to progress in cancer treatment."

GAO on breast cancer: More than one-third (36.9 percent) of eligible premenopausal women with breast cancer were not receiving adjuvant chemotherapy as late as 1985.

Kennedy: "Adjuvant therapy for breast cancer was not regarded nationally as standard therapy until after the 1980 NCI consensus meeting in Washington, DC." However, "the GAO study incorporates patients treated between 1975 and 1985." To conclude that patients weren't receiving adequate treatment is a "total misuse of statistics," Kennedy says. "In fact, the study shows that 2 out of 3 patients were receiving adjuvant therapy, which is a good result for successful treatments that evolved during a research era."

GAO on colon cancer: The number of colon cancer patients who did not receive adjuvant chemotherapy increased from 89 to 94 percent between 1981 and 1985.

Kennedy: The results of a number of adjuvant chemotherapy studies, including a study in the *New England Journal of Medicine* (March 22, 1984), conducted by the Gastrointestinal Tumor Study Group "did not support the use of adjuvant chemotherapy for patients who are at high-risk for recurrent colon cancer," Kennedy says. "The fact that 90 percent of patients didn't receive this treatment in an era when most data said it wasn't effective therapy is very appropriate." The 1984 report urged a study with an untreated control group, Kennedy notes. In the first issue of the new *Journal of the National Cancer Institute* (Mar. 2, 1988), the National Surgical Adjuvant Bowel Project (NSABP), demonstrated the value of adjuvant chemotherapy. "There certainly is a lack of consensus in colon cancer," Kennedy says.

GAO on rectal cancer Sixty percent of patients who might have benefited from adjuvant radiation therapy for rectum cancer were not receiving such therapy in 1985.

Kennedy: This type of cancer occurs "more and more in older persons," Kennedy says. Moreover, "recent studies that have attempted to verify the value of radiation therapy have been difficult to get going," he explains, because of the patients' age and such variables as the cost of treatment and the distance that older patients must travel to receive it. Moreover, Kennedy refers to the NSABP project on rectal cancer (*J. of the NCI*, Mar. 2, 1988), which shows adjuvant chemotherapy to be of value in treating young males. However, "radiotherapy did not prolong disease-free survival or overall survival," Kennedy says. "It only reduced local—regional recurrences."

GAO on testicular cancer: Fifty percent of eligible patients with nonseminoma testis cancer were not receiving chemotherapy in 1985.

Kennedy: "A major flaw in the GAO study is its inclusion of all nonseminoma testicular cancer patients in its evaluation. Their inclusion of stage I and stage II patients distorts

the interpretation of the data," Kennedy says, because it is not "standard practice" to treat those patients with chemotherapy. Nevertheless, Kennedy estimates that the "GAO data probably comprises 50 percent of stage I patients." There is "no rational conclusion but that the GAO looked at the data [under this category] improperly," he says.

GAO on small-cell lung cancer: Twenty-five percent of small-cell lung cancer patients were not receiving treatment in 1985.

Kennedy: Because of the higher age group of small-cell lung cancer patients and other medical conditions, such as cardiovascular disease, which enter into treatment decisions, "75 percent of patients receiving adjuvant therapy is a good percentage," Kennedy says.

GAO on non-Hodkins lymphoma: The number of eligible, untreated non-Hodgkin's lymphoma patients declined 10 percent from 1979 to 1985, but one-fifth of eligible patients remained untreated.

Kennedy: If 80 percent of patients with diffuse, intermediate or high-grade lymphomas are receiving therapy, "in other words, 4 out of 5 patients," that's a good result, Kennedy contends. Moreover, these types of lymphomas "can be managed on an outpatient basis, and you find that more and more of the patients who are being hospitalized are only those who are very ill, which again raises other treatment factors, such as overall health, age, and the patient's treatment wishes."

GAO on Hodgkin's disease: At least 18 percent of eligible patients with advanced Hodgkin's disease did not receive chemotherapy in any year following 1977.

Kennedy: Once again, Kennedy says, the GAO study doesn't mention "age, noncompliance, and other medical conditions." Nevertheless, he points out that if 80 percent of patients were being given chemotherapy by 1985, "we are doing well. Even if medical care was absolutely free, 100 percent of the population would not take advantage of it." Another disadvantage of the GAO report, according to Kennedy, is that "it does not include conclusions of the most recent reports."

Perhaps the most important caveat raised with regard to the GAO study is the historical under-reporting of chemotherapy treatment (as high as 25 percent of all patients) in hospital tumor registry data, because of limited follow-up of the therapy patients receive as outpatients or in physicians' offices. This is a data collection problem that NCI itself is investigating and which has prompted it to examine such options as pursuing active follow-up on every patient or even ceasing to collect any SEER data on chemotherapy treatment. And, it is a problem that is expected to grow worse as the number of alternate delivery systems, such as ambulatory surgery clinics, which do not have the same reporting requirements as hospitals, increase in number. In short, Kennedy says, "if we are to have adequate data on neoplasms, we need a better system than one that depends only on hospital records. ■

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studies. Are they the ones who recognize the value of such involvement as a means of providing quality care? Are those who prefer to develop their own studies, or insist that only they know the right answers for their patients, providing state-of-the-art care? How many understand that 408 patients with small-cell carcinoma of the lung who are studied on a single protocol are more likely to provide helpful answers than the same number of patients managed on 16 different routines? (See Dr. Rodger Winn's article in the same issue.)

When the reasons for success and failure are more fully understood, both graduate and post graduate medical education will be impacted, as well as clinical trials and, indirectly, cancer care. Only then will the legacy of the CCOPs be appreciated and a more complete report card be possible.—*R. W. Frelick, M.D., Wilmington, DE.* ■