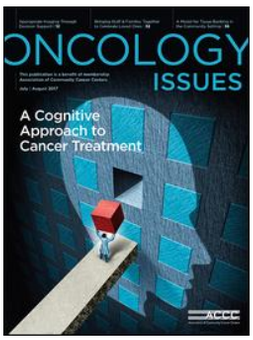


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# Letters to the Editor

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## When Is Off-Label Drug Use Appropriate?

I would like to comment on the article regarding the off-label debate by Lee Mortenson, D.P.A., which appeared in the Summer 1992 issue of *Oncology Issues.* As Medical Director for the Medicare carrier in Arkansas, I'm asked to respond to oncologists' requests for coverage for off-label uses of chemotherapeutic agents. It is my belief that Medicare should cover off-label uses of chemotherapy drugs, and the use of the compendia has been helpful to me in determining what drugs to cover.

I found Dr. Mortenson's article to be instructive and unbiased. However, I do have one problem. Oncologists frequently complain because we do not cover some aspect of chemotherapy that they feel should be covered. But I have yet to hear an oncologist say, perhaps we should not cover chemotherapeutic drugs when there has been no scientific evidence that the use of those drugs has been effective in any significant number of patients.

I practiced pulmonary and critical care medicine for 26 years and administered chemotherapy myself when the number of practicing oncologists was so small that they limited themselves to the treatment of malignancies that had a high response rate. But as the number of oncologists have proliferated, I have not yet found a cancer patient who cannot find some oncologist to treat his malignancy even when the data regarding effectiveness is lacking.

I recognize that occasionally a patient responds to chemotherapy when, "by the books," the patient would not be expected to respond. Is this justification for treating everyone? I have seen a 110 year-old woman with cancer of the esophagus treated with chemotherapy. Does that justify an insurance carrier refusing to pay for off-label drug therapy?

I'm disappointed in the lack of leadership by the Oncology Society in helping oncologists make some judgments about the appropriateness of therapy. I don't have a problem with drugs being used for the treatment of malignancy, even when the data suggests that the treatment will not be effective, if it is done in a controlled situation and not on a totally open basis where no data is accumulated to ultimately tell us whether it is effective. The way the system works today, physicians give chemotherapy (such as in squamous cell lung cancer) when there is no data (in large studies) to indicate that it prolongs life, using the justification that "this is done in the hope that this will be the one person who will respond to the therapy." But it is done in an uncontrolled manner, and those same physicians will continue to use the therapy forever until some new drug comes along.

*—James S. Adamson, M.D., Medical Director, Government Programs Services, Medicare, Little Rock, AR.*

**James L. Wade, III, M.D., Decatur (IL) Memorial Hospital and Chair of ACCC's Government Relations Committee, responds:**

Dr. Adamson has clearly outlined the two sides of an issue that faces health care reimbursement providers across the land. The first is not to do harm; that is, not to deny a patient appropriate therapy just because a drug is off-label. The second side of this issue is whether or not the agency that reimburses for treatment should also be the agency that determines the appropriateness of treatment—a very difficult question and one which clearly impacts the doctor-patient relationship.

As a medical oncologist and principal investigator of the Central Illinois Community Clinical Oncology Program, almost all of my practice is comprised of community-based oncology. Approximately 20 percent of my patients participate in NCI-approved clinical trials. Every day patients ask for the best treatment, while other patients do not desire any treatment.

I agree that the example of the 110-year-old woman receiving chemotherapy for squamous cell carcinoma seems bizarre. If her family, however, had called the PDQ database at the National Cancer Institute (NCI) and received a print-out on the best treatment for unresectable squamous cell carcinoma of the esophagus, they would have learned that the survival rates are significantly better when chemotherapy is combined with radiation treatment. This then puts the physician in a paradox between providing what he thinks may be appropriate treatment while, at the same time, the medical literature, public agencies, and the NCI may be recommending a more aggressive approach.

I can only answer Dr. Adamson's concern by saying that we need to trust the physicians we train. At the same time, however, ongoing peer review, in the form of cancer committees, is an excellent mechanism for ensuring that the right patient gets the right treatment.

I know of no other field of medicine where the management of patients is reviewed so thoroughly and vigorously as oncology. Almost all of the hospitals in the United States have a cancer committee mechanism of some form in which the case of the 110-year-old woman would come under review and be open to discussion among the physicians at the hospital and in the community. This is probably our best defense against over- or under-treatment.

As far as patients with metastatic squamous cell carcinoma of the lung are concerned, I agree completely with Dr. Adamson that the role of chemotherapy is limited. However, a recent Canadian trial comparing platinum-based chemotherapy to no treatment did demonstrate a statistically significant improvement in survival and, in fact, the Canadians' analysis concluded that the additional cost per month of improved survival compared reasonably well with other aggressive medical therapies that are routinely accepted (i.e., dialysis).

Our best hope for the next century is the elimination of risk factors, such as tobacco smoking, and the widespread use of chemo prevention, both of which will help to dramatically lower the cancer incidence rate.