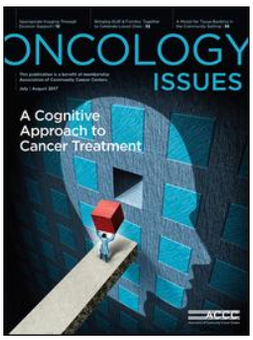

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Lee E. Mortenson & James L. Wade III

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FROM THE EDITOR

The Demise of Clinical Trials?

By Lee E. Mortenson, D.P.A. and James L. Wade, III, M.D.

Michigan Blue Cross and Blue Shield has once again led the nation in denying oncology patients their rightful benefits. In a mailing to their 4,000 subscribers, the Michigan Blues told them last week they would no longer pay for any (NOTE: ANY) of the costs associated with a patient on a clinical trial! That's the doctor's costs, the tests, the other drugs, the facility costs, EVERYTHING.

Research and development is the lifeblood of the American health care industry, especially oncology. Patient care has improved because of clinical research, but with half a million cancer deaths a year, our state-of-the-art remains unacceptable. Improved survival, better quality of life, and lower costs can only be achieved through clinical research. The network of NCI-approved trials in the United States provides the tools we need for tomorrow's better care.

Clinical research is already paying off. Research that was done in the 1970s has resulted in a 10 percent decrease in the mortality of breast cancer in women under the age of 50. Based on improved results to date, we anticipate continued increases in breast cancer survival in all groups of women. Colon cancer patients who have lymph node involvement at the time of their initial surgery now have new hope; the risk of dying within five years has dropped by one third. Future advances that avoid the burden of treating patients with metastatic disease will translate into lower patient care costs.

In some instances we may not be able to improve survival, but we can discover equivalent treatments with less toxicity and lower costs. This spring, the Southwest Oncology Group (SWOG) published the results of a study comparing carboplatin, a drug that can be given in a physician's office, to cisplatin, which is administered in a hospital, for patients with advanced cancer of the ovary. Sixty percent of the patients accrued on this trial were treated in community hospitals. The results demonstrate that the use of carboplatin, which was, at the time, an investigational drug, provided equivalent anti-tumor effect but with markedly lower side effects. This moved the treatment of ovarian cancer patients from the hospital to the private office at an enormous cost savings to third-party payers. If insurers had not paid for the clinical costs of this trial, which was completed in the late 1980s, patients with ovarian cancer would still be receiving cisplatin in the hospital setting.

Recently SWOG summarized the results of a non-Hodgkin's lymphoma study in which more than 1,100 patients with advanced, aggressive disease received one of four different types of chemotherapy. The results show that CHOP chemotherapy (cytoxan, adriamycin, vincristine, and prednisone) is equivalent in disease-free survival, and survival, to more expensive and aggressive treatments. The difference in cost between the most expensive treatment in the trial and CHOP may result in a savings of 60 percent or more. The study also found that the major side effects that often require hospitalization are one-fifth as common with CHOP than the other regimens. This trial could not have been done without reimbursement from third-party payers.

Now we can be passive about this or forthright. We believe the time for passivity is past and we must take decisive action. There are two approaches: we can legislate or we can work out wording with the Blues and the Health Insurance Association of America (HIAA). But, this cannot go on too long. Clinical trials and prevention trials are the core of the oncology community. They hold the hope of the American people and we should let the public know that what the Michigan Blues are proposing is a cut in their current benefits and in their hope for the future.